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A WHO guide to good manufacturing pratice (GMP) requirements

Part 3: Training

Immunization, Vaccines and Biologicals

World Health Organization

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Abbreviations and acronyms

BioCen	Centro Nacional de Biopreparados
CBER	Center for Biologics Evaluation and Research
CBT	computer-based training
CDL	Central Drugs Laboratory
cGMP	current good manufacturing practices
GLPs	good laboratory practices (for non-clinical studies)
GMP	good manufacturing practices
HVAC	heating, ventilation and air conditioning
ISD	instructional systems design
OJT	on-the-job training
QC	quality control
RODAC	replicate organism detection and counting
SOPs	standard operating procedures
USP	United States Pharmacopoeia
WFI	water for injection

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1. Introduction and purpose of this guide

Regulatory agencies around the world require that training on good manufacturing practices (GMP) be conducted on a regular basis for those who are involved in producing pharmaceutical and biological products. Documentation is also needed as evidence that the training occurred. More and more frequently, regulatory agencies and their inspectors are requesting evidence that the training was effective.

While regulatory agencies have these requirements and expectations, they give few specific details as to how the training is to be performed; they do not say how it should be done. To date, no guidance document on training for industry has been available from any regulatory agency or official (governmental, nongovernmental or industrial) organization. Unfortunately, this lack of guidance may cause some in industry to think that training is a simple process. However, for training to be an effective and efficient tool that contributes to performance, it must be done properly.

It is not unusual for someone, when first given the responsibility for training a drug or vaccine workforce, to realize the complexity of training; things that seemed obvious or unimportant from the outside now demand specific simple, clear answers.

Some of the frequent questions of new trainers or training managers include:

- What training is required for each area or each worker?
- How frequently should training be performed?
- How can I design an effective training programme or course?
- Who is responsible for training?
- Can all experts be trainers?
- How can the results of training be evaluated and assessed?
- How should training be documented?

This guide has been prepared to aid vaccine manufacturers in the planning, conducting and evaluation of training programmes required by good manufacturing practices of the World Health Organization (WHO). It is not meant to restrict in anyway the freedom that manufacturers have to provide training in the way they consider best for their staff.

It has been written to help both trainers and supervisors solve some of the problems they face involving training, such as how to make the training interesting to adult learners or how to effectively use a variety of instructional methods.

This guide can also benefit those whose work is related to training activities in a vaccine manufacturing facility. It can be used in either of two ways, as an information tool or as additional reading during a structured workshop for developing effective trainers.

The guide presents the GMP requirements on training from different regions and countries of the world, an overview of the training process, types of training and different groups requiring training, the instructional systems design (ISD) model, and some considerations to make training more effective. This guide also discusses what to include in a training procedure. Different evaluation and assessment methods are explained along with ways to plan and document training.

In addition to the examples found in the chapters, some documents contributed by vaccine manufacturers who cooperated in this project have been included as annexes. The guide also includes selected statements regarding training from different authors. These references and others relevant to training are listed in Annex 8.

As in most other disciplines and endeavours, there are different approaches that can be used to reach a particular goal. The models and examples presented here are based on the training, experiences (some of which were successful and others not), and work that the authors have done in training and in the pharmaceutical and vaccine industry. It is meant to be a guide; not a rigid formula that must always be followed.

This guide for training is Part 3 of *A WHO guide to good manufacturing practice (GMP) requirements*. Part 1 (WHO/VSQ/97.01) consists of a guide to standard operating procedures and master formulae (*1*) and Part 2 (WHO/VSQ/97.02) is a guide for validation (*2*).

It is clear that this guide is intended as a first step to approach this topic. Suggestions for specific ways in which this guide could be more useful to trainers, training coordinators, supervisors, quality assurance and human resources staff would be welcomed by the authors and WHO for its future editions. For this purpose a tear-out questionnaire has been included (see page 76).

2. The importance of training

There are business and quality reasons for training, as well as regulatory requirements and expectations. This chapter provides some examples on why training is so critically important.

2.1 Why training is important

Training is recognized in the preamble to the current good manufacturing practice regulations as a dynamic process that cannot be satisfied by a single training course to be given to an employee at the time of hire. Training should be a dynamic process, in respect to both, the training an employee receives during his or her career with a firm, and in terms of ensuring that training programmes and materials keep pace with job requirements and performance expectations (*3*).

Training is an investment in people that pays its dividends in a more skilled workforce, improved productivity, and higher levels of product and service quality.

That is a bold statement which can be supported with evidence from around the world.

First, consider the investment side of the equation. Two of the largest manufacturing firms that make pharmaceuticals and vaccines allocate 5–10% of their payroll budgets for training their personnel; the average number of training hours per employee ranges from 40 to 59 annually (*4*). More generally, an international survey showed that training expenditures as a percentage of payroll was the highest in Asia, with respondent firms investing 3.8% in training; the general average was 2.5% (*5*). Survey respondents from Middle East countries had the highest number of hours per year, 57, in training eligible employees; the average was 25.6 hours. The survey also showed that in each region, respondent firms planned substantial increases in training-related expenditures in the coming years: nearly all regions contemplated increases of a minimum of 20% over current expenditures.

Training does take time, resources, a qualified training staff and money. How much time, for example, should be invested in training? One answer is not applicable in all situations. The amount of time depends on several factors, as shown in Table 1.

Table 1: Amount of training required

More training is required when…	Less training is required when…
• The workforce is relatively new to the job	• The workforce is experienced
• There is a high, rapid employee turnover rate	• There is a low employee turnover rate
• New products are being added	• No new products are being added
• There are some/many worker performance issues	• There are few worker performance issues
• The technology, equipment, or process is new or changing	• The technology, equipment, or process is stable
• New personnel are added; the firm is expanding	• Few new personnel are added; the firm is staying the same size
• The facility operates 24 hours a day using multiple shifts	• The firm operates on one shift
• There are gaps between what a person can do when hired and what he is required to do.	• There is a close match between knowledge and skills of personnel and what is required of them

When new facilities are being commissioned with new technology and new personnel, it would not be surprising to see nearly all of the available time spent on training activities: becoming familiar with the equipment, learning the process, procedures, safety practices and systems. In firms with skilled, experienced personnel, training could be reduced to 3–5% of available time.

What are some of the benefits achieved by having well-trained, knowledgeable workers and professionals? Few vaccine and drug manufacturers have conducted thorough evaluation studies (see section 5, Assessment and evaluation) that prove the efficacy of training. Instead, the results are focused more on problems/solutions and are anecdotal and qualitative in nature.

Here are some examples of how training has had an impact on people and organizations.

- During a GMP training course on materials-handling personnel at a firm making biological products, contamination and product purity was discussed. This included the effects that temperature could have on the product. At one point, a materials handler spoke up, saying, "Now I understand why I have to limit the time the product is kept outside the cold room – if it is out too long, the temperature can affect its purity and potency."
- One firm found that people were washing their hands much more frequently after a training course in which people put their hands – one washed and the other unwashed – on culture media plates (Petri dishes). The dramatic difference that hand washing made became a motivating factor.
- After conducting training on record-keeping techniques, a firm showed that the number of "first-time-right" batch records greatly increased, shortening the Quality Assurance (QA) review time.
- Another firm provided extensive training to key technical, production and quality personnel on how to investigate problems (i.e. deviations) and write reports. After a period of two years, because the investigation teams knew how to determine root causes to problems and recommend and implement corrective actions, they had a significant reduction in recurring deviations.

Training can also be a way of avoiding waste and costs. One firm, making a sterile protein product, discovered the costs of not training an operator. During a quality control (QC) review of in-process documents, a QC representative found that the new operator had incorrectly performed a test used to confirm the integrity of a sterilizing filter. The product had already been passed through the filter and could not be recovered. That afternoon, the firm had to destroy one million dollars worth of product.

2.2 GMP requirements for training

The following presents parts of selected GMP texts related to what training should include from the point of view of the GMP requirements of different regions.

World Health Organization

Good manufacturing practices for pharmaceutical products: main principles (6)

9. Personnel

9.1 Principle

The establishment and maintenance of a satisfactory system of quality assurance and the correct manufacture and control of pharmaceutical products and active ingredients rely upon people. For this reason there must be sufficient qualified personnel to carry out all the tasks for which the manufacturer is responsible. Individual responsibilities should be clearly understood by the individuals concerned and recorded as written descriptions.

General

9.2 The manufacturer should have an adequate number of personnel with the necessary qualifications and practical experience. The responsibility placed on any one individual should not be so extensive so as to present any risk to quality.

9.4 All personnel should be aware of the principles of GMP that affect them and receive initial and continuing training, including hygiene instructions, relevant to their needs. All personnel should be motivated to support the establishment and maintenance of high-quality standards.

Key personnel

9.7 Key personnel responsible for supervising the manufacture and quality control of pharmaceutical products should possess the qualifications of a scientific education and practical experience required by national legislation. Their education should include the study of an appropriate combination of (a) chemistry (analytical or organic) or biochemistry, (b) chemical engineering, (c) microbiology, (d) pharmaceutical sciences and technology, (e) pharmacology and toxicology, (f) physiology, or (g) other related sciences. They should also have adequate practical experience in the manufacture and quality assurance of pharmaceutical products. In order to gain such experience, a preparatory period may be required, during which they should exercise their duties under professional guidance. The scientific education and practical experience of experts should be such as to enable them to exercise independent

professional judgement, based on the application of scientific principles and understanding to the practical problems encountered in the manufacture and quality control of pharmaceutical products.

10. Training

10.1 The manufacturer should provide training in accordance with a written programme for all the personnel whose duties take them into manufacturing areas or into control laboratories (including the technical, maintenance, and cleaning personnel), and for other personnel as required.

10.2 Besides basic training on the theory and practice of GMP, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its practical effectiveness periodically assessed. Approved training programmes should be available. Training records should be kept.

10.3 Personnel working in areas where contamination is a hazard, e.g. clean areas or areas where highly active, toxic, infectious, or sensitizing materials are handled, should be given specific training.

10.4 The concept of quality assurance and all the measures which aid its understanding and implementation should be fully discussed during the training sessions.

Good manufacturing practices for pharmaceutical products (7)

18. Active pharmaceutical ingredients

Personnel

18.7 Each firm should employ personnel with the necessary qualifications and competence for the production and quality control of active pharmaceutical ingredients. There should be an adequate number of staff with appropriate education, technical knowledge, and practical experience related to the job they perform.

18.9 Staff at all levels should be adequately trained for the tasks and responsibilities assigned to them.

Good manufacturing practices for sterile pharmaceutical products (8)

Personnel

8.2 All personnel (including those concerned with cleaning and maintenance) employed in such areas should receive initial and regular training in disciplines relevant to the correct manufacture of sterile products, including hygiene and the basic elements of microbiology. When outside staff that have not received such training (e.g. building or maintenance contractors) need to be brought in, particular care should be taken over their instruction and supervision.

8.4 High standards of personal hygiene and cleanliness are essential, and personnel involved in the manufacture of sterile preparations should be instructed to report any condition that may cause the shedding of abnormal numbers or types of contaminants; periodic health checks for such conditions are desirable. The action to be taken in respect of personnel who might be introducing undue microbiological hazard should be decided by a designated competent person.

Good manufacturing practices for biological products (9)

Personnel

3.1 The manufacturing establishment and its personnel shall be under the authority of a person who has been trained in the techniques used in manufacturing biological substances and who possesses the scientific knowledge upon which the manufacture of these products is based. The personnel shall include specialists with training appropriate to the products made in the establishment.

3.2 Personnel required to work in clean and aseptic areas should be selected with care, to ensure that they may be relied upon to observe the appropriate codes of practice and are not subjected to any disease or condition that could compromise the integrity of the product microbiologically or otherwise. High standards of personal hygiene and cleanliness are essential. Staff should be instructed to report any conditions (e.g. diarrhoea, coughs, colds, infected skin or hair, wounds, fever of unknown origin) that may cause the shedding of abnormal numbers or types of organisms into the working environment. Health checks on personnel for such conditions should be required before employment and periodically thereafter. Any changes in health status that could adversely affect the quality of the product shall preclude the person concerned from working in the production area.

3.7 To ensure the manufacture of high-quality products, personnel should be trained in good manufacturing and laboratory practices in appropriate fields such as bacteriology, virology, biometry, chemistry, medicine, immunology, and veterinary medicine.

3.8 Training records should be maintained and periodic assessments of the effectiveness of training programmes should be made.

Good manufacturing practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans (10)

8. Personnel

Although it is likely that the number of staff involved will be small, people should be separately designated as responsible for production and control. All production operations should be carried out under the control of a clearly identified responsible person. Personnel concerned with development, involved in production and quality control, need to be instructed in GMP principles.

European Commission

The rules governing medicinal products in the European Union, Volume 4 Good Manufacturing Practice. Medicinal products for human and veterinary use (11)

Chapter 2: Personnel

Principle The establishment and maintenance of a satisfactory system of quality assurance and the correct manufacture of medicinal products relies upon people. For this reason there must be sufficient qualified personnel to carry out all the tasks, which are the responsibility of the manufacturer. Individual responsibilities should be clearly understood by the individuals and recorded. All personnel should be aware of the principles of GMP that affect them and receive initial and continuing training, including hygiene instructions relevant to their needs.

Training

2.8 The manufacturer should provide training in accordance with a written programme for all the personnel whose duties take them into production areas or into control laboratories (including the technical, maintenance, and cleaning personnel), and any other personnel whose activities could affect the quality of the product.

2.9 Besides the training on the theory and practice of good manufacturing practices, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its practical effectiveness should be periodically assessed. Training programmes should be available, approved by either the head of production or quality control, as appropriate. Training records should be kept.

2.10 Personnel working in areas where contamination is a hazard, e.g. clean areas or areas where highly active, toxic, infectious, or sensitizing materials are handled, should be given specific training.

2.12 The concept of quality assurance and all the measures capable of improving its understanding and implementation should be fully discussed during the training sessions.

Annex 1: Manufacture of sterile medicinal products

Personnel

14. All personnel (including those concerned with cleaning and maintenance) employed in such areas should receive regular training in disciplines relevant to the correct manufacture of sterile products. This training should include reference to hygiene and to the basic elements of microbiology. When outside staff who have not received such training (e.g. building or maintenance contractors) need to be brought in, particular care should be taken over their instruction and supervision.

Annex 2: Manufacture of biological medicinal products for human use

Personnel

All personnel (including those concerned with cleaning, maintenance or quality control) employed in areas where biological medicinal products are manufactured should receive additional training specific to the products manufactured and to their work. Personnel should be given relevant information and training in hygiene and microbiology.

Persons responsible for production and quality control should have an adequate background in relevant scientific disciplines, such as bacteriology, biology, biometry, chemistry, medicine, pharmacy, pharmacology, virology, immunology and veterinary medicine, together with sufficient practical experience to enable them to exercise their management function for the process concerned.

Annex 8: Sampling of starting and packaging materials

Personnel

Personnel who take samples should receive initial and on-going regular training in the disciplines relevant to correct sampling. This training should include:

- sampling plans,
- written sampling procedures,
- the techniques and equipment for sampling,
- the risks of cross-contamination,
- the precautions to be taken with regard to unstable and/or sterile substances,
- the importance of considering the visual appearance of materials, containers and labels,
- the importance of recording any unexpected or unusual circumstances.

Annex 11: Computerized systems

Personnel

1. It is essential that there is the closest cooperation between key personnel and those involved with computer systems. Persons in responsible positions should have the appropriate training for the management and use of systems within their field of responsibility which utilizes computers. This should include ensuring that appropriate expertise is available and used to provide advice on aspects of design, validation, installation and operation of computerized system.

Annex 13: Manufacture of investigational medicinal products

Personnel

4. Although it is likely that the number of staff involved will be small, they should be separate people responsible for production and quality control. All production operations should be carried out under control of a clearly identified responsible person. Personnel involved in release of investigational medicinal products should be appropriately trained in quality systems, GMP and regulatory requirements specific to these types of products. They must be independent of the staff responsible for production.

Annex 15: Qualification and validation (12)

4.5 Personnel

4.5.1 Operators who perform cleaning routinely should be trained in the application of validated cleaning procedures. Training records should be available for all training conducted.

US Food and Drug Administration (FDA)

Code of Federal Regulations. Title 21, Volume 4, Parts 200–299

Part 211: Current good manufacturing practice for finished pharmaceuticals (*13*)

Subpart B Organization and personnel

Sec. 211.25 Personnel qualifications

a) Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with cGMP requirements applicable to them.

b) Each person responsible for supervising the manufacture, processing, packing, or holding of a drug product shall have the education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality and purity that it purports or is represented to possess.

c) There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product.

Sec. 211.34 Consultants

Consultants advising on the manufacture, processing, packing, or holding of drug products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.

Code of Federal Regulations. Title 21, Volume 7, Parts 600–799

Part 600 Biological products: general (*14*)

Subpart B Establishment Standards

Sec. 600.10 Personnel

a) Reserved

b) Personnel. Personnel shall have capabilities commensurate with their assigned functions, a thorough understanding of the manufacturing operations which they perform, the necessary training and experience relating to individual products, and adequate information concerning the application of the pertinent provisions of this subchapter to their respective functions. Personnel shall include such professionally trained persons as are necessary to insure the competent performance of all manufacturing processes.

Note: It is advisable also that trainers look for other applicable regulations that require training, for example FDA's Electronic Records and Signature Regulation (21 CFR Part 11) requires that companies using electronic signatures provide training to their personnel on the regulation and associated procedures (*15*).

Association of Southeast Asian Nations (ASEAN) good manufacturing practices guidelines (16)

2.2 Training

2.2.1 All personnel who are directly engaged in the manufacturing activities and whose duties take them into manufacturing areas should be trained in the particular operations that the employees perform and in the principles of good manufacturing practices.

2.2.2 Training should be conducted by qualified individuals. Special attention should be given to training of personnel working in sterile and clean areas or with highly potent, toxic or sensitizing materials.

2.2.3 Training in good manufacturing practices should be on a continuing basis and with adequate frequency to assure that the employees remain familiar with the Good Manufacturing Practices requirements relevant to their functions.

2.2.4 Training in good manufacturing practices should be in accordance with written programmes approved by the production manager and the quality control manager.

2.2.5 Records of personnel training in Good Manufacturing Practices should be maintained and the effectiveness of training programmes should be assessed periodically.

2.2.6 After training, the employees performance should be appraised to determine whether they have proper qualifications for the jobs they are assigned to.

The Australian Code of Good Manufacturing Practice for Medicinal Products 2002 (17)

Training

2.8 The manufacturer should provide training for all the personnel whose duties take them into production areas or into control laboratories (including the technical, maintenance and cleaning personnel), and for other personnel whose activities could affect the quality of the product.

2.9 Beside the basic training on the theory and practice of Good Manufacturing Practice, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and **its** practical effectiveness should be periodically assessed. Training programmes should be available, approved by either the head of production or the Head of Quality Control, as appropriate. Training records should be kept.

2.10 Personnel working in areas where contamination is a hazard, e.g. clean areas or areas where highly active, toxic, infectious or sensitising materials are handled, should be given specific training.

2.12 The concept of Quality Assurance and all the measures capable of improving its understanding and implementation should be fully discussed during the training sessions.

3. Types of training and content areas

Who should be trained and what should they be trained in? This chapter identifies some of the audiences (groups of trainees) and the types of training appropriate for them.

To fulfil GMP training requirements, different types of specific training should be implemented in a vaccine manufacturing facility to meet the needs of different audiences. The courses that each group (or position) need to have and when the training should be given are defined in a training curriculum.

Training curricula should be written for operation, maintenance and laboratory personnel, supervisors, managers, and also for temporary employees and contractors. New employees are also an important audience so that they understand the rationale for the strict method of operation within the vaccine manufacturing industry. All employees whose work can have an impact on product quality, need to understand how their efforts are critical in producing safe and effective vaccines.

3.1 Orientation training for new employees

New employees are not truly competent to work in a regulated industry that makes critical products like vaccines until they have been trained and have demonstrated that they know and can perform what is required of them. New employee training is the foundation for more specific training that will follow.

The first part of a new-employee orientation-training programme should be as simple as possible, because experience has shown that new employees will not understand if they are presented lists of all the GMP rules during their first day in the company.

"Training new employees in cGMP is an extremely critical activity; one that cannot be taken lightly. This becomes even more important for employees never exposed to cGMPs" (*18*).

The following aspects may be considered when planning training for new employees. Because it is easy to overwhelm a new employee with information, it is advisable to accomplish new-employee-orientation training in two phases.

Phase I – A general orientation

This should be given to all new employees and include:

- history of the company
- organizational chart
- facilities (this could include a tour of the facility)
- company policies and company standard practices
- basic GMP concepts (e.g. contamination, procedures, deviations)
- general safety training.

Phase I training should be carried out during the employee's first day in the company.

Phase II – A more specific orientation based on where the new employee works

This training is aimed at new employees in each area, department or section whose activities take them into production areas or into control laboratories (including maintenance and cleaning staff), and for other personnel whose activities could impact on product quality.

Introduction to the department (this should include a tour of the department):

- location of the working area
- characteristics of the working area (flow of materials, personnel, product and waste)
- product knowledge
- job description
- work-specific training programme (see section 3.2 below)
- basic documentation.

Phase II training should also be considered for personnel if they are transferred from one department to another.

Phase II training should be started during the first week of the employee's employment.

3.2 Work-specific area training

Employees whose activities take them into production areas or into control laboratories (including maintenance and cleaning staff), and other personnel whose activities could impact on the quality of the product should receive work-specific training at the time of joining the company and on a continuing basis (see section 3.6).

The work-specific area training should cover three aspects:

- GMP training
- on-the-job training – standard operating procedures (SOPs) and technical skills training
- safety training.

GMP training

Once the basic concepts of GMP have been initially presented during the new-employee-orientation training, other GMP topics should be incorporated, explaining GMP in more practical detail. It is advisable to complete this training during the first two months following entrance in the company or in a specific working area.

Would it be effective to conduct the same GMP training programme for a new filling line operator, a new quality control technician and a new warehouse employee?

Obviously no. The filling-line operator needs to understand the GMPs for sterile products, the quality control technician needs to be aware of good control laboratory practices, while the new warehouse employee needs to know how to store, move and distribute materials and products according to GMPs.

GMP training should be provided to ensure that employees understand and follow the GMP requirements applicable to their jobs.

The specific GMP training should be developed according to GMP requirements for each area, for example:

- manufacturing of biological/biotechnological products (from cell banks preparation to purification)
- aseptic processing (vaccine formulation and filling)
- quality control
- quality assurance
- product development
- animal facilities
- visual inspection and packaging
- warehousing and distribution
- maintenance
- purchasing
- others.

On-the-job training (OJT)

This type of training is frequently underestimated and, in most companies, is not performed in a very professional way. In these situations, a new employee is simply assigned to the most experienced one to watch or "shadow" what the more experienced person does. In many cases, this ensures that the new person learns the same practices – some bad, some good – of the experienced person.

The supervisor is responsible for this training, and it is based on the SOPs and the acquisition of technical skills needed for the job. It is particularly important at this stage to teach the trainee not only what he/she should do and how, but why it must be done in such a way and in no other. "The two components of teaching are instruction and education: Instruction involves the teaching of how-to or what, and education involves the why of the training effort" (*19*).

A better way to do on-the-job training is to define what is to be covered. This is called structured on-the-job training and should include having a checklist of topics and the preferred sequence in which they are to be covered. This might be one or two pages and cover simple things like uniforms (how often to change, where to put dirty ones, where to get clean ones); entry into certain areas (what "restricted access" means, how to decontaminate shoes before entering a fermentation area, etc.). All of these topics may also be linked to procedures; this structured approach would also be considered valid training on procedures.

The difference between this and individual training on SOPs is that structured on-the-job training covers a number of topics/SOPs that are integrated in terms of how the person does his or her job. SOP training usually covers just one in more detail. Structured on-the-job training can be done in a similar way to SOP training.[1]

Training on SOPs

Training either new or experienced personnel on new SOPs, can be conducted as follows.

- The supervisor will provide the current copy of the SOP related to the task and allocate time for reading.
- The trainee will read the pertinent document.
- The supervisor will review the SOP with the trainee and will answer any questions regarding the documents.
- The supervisor will show the trainee how to do the task.
- The trainee will perform the procedure by himself/herself under supervision. The supervisor will review the work in such a way that positive performance will be reinforced. A checklist to evaluate the performance of the trainee can be very helpful.
- The trainee will perform the procedure without supervision.
- When the supervisor is satisfied with the trainee's performance, the supervisor and the trainee will sign the training record.

[1] Vesper J.L. Personal communication, March 2001

Safety training

Safety training will be developed from the specific safety requirements for the area. It will be given to all those employees in at-risk occupations. The safety department identifies those who need to have safety training, which may be given individually or to a group of employees in the same or related occupations.

The topics approached will be defined according to the existing risks and complexities. These should cover:

- the knowledge of mechanisms of exposure to the specific risk agent, including toxic chemicals and biohazards;
- the appropriate use of personal protection items;
- how to proceed in an emergency.

3.3 Supervisor training

It is the responsibility of the supervisor to provide clear direction, to lead by example, to set high standards of performance, to provide feedback (mostly positive), and to ensure adequate resources (especially time) (*20*).

The supervisor training should be conducted to guarantee that supervisors be adequately trained in:

- the areas they are going to supervise;
- the SOPs used in their department;
- their responsibilities under GMP, especially their responsibility for training, for reviewing documents, and for reviewing safety procedures to avoid danger to their staff.

It is advisable that new supervisors should be trained in the following topics:

- deviation handling
- change control
- GMP trends.

They should also be trained in aspects such as:

- communication
- motivation
- decision-making
- problem solving.

Existing supervisors should be trained to update and reinforce the knowledge and skills they have.

Because the supervisor is often considered a role model to those working in the area, many supervisors participate in area GMP training efforts as well.

3.4 Manager training

Understanding the importance of training in meeting regulatory requirements and improving the efficiency of vaccine manufacturing by managers is essential for implementing a successful training programme. Quality, motivation and education are very closely related and managers play an important role in motivating their staff.

"It is more important to train management than anyone else in the plant" (*21*). "Training should be carried out from the top to the bottom of the staff and with managers involved as much as possible" (*22*).

> *Managers and supervisors need to be trained in their responsibilities under GMPs and good laboratory practice (GLPs) for non-clinical studies. This includes knowing what their signature means from a legal perspective. High-level managers must understand the consequences of negligence, for example. If a serious quality problem occurs or if a serious problem exists in clinical trials, and it is later discovered that a manager was negligent in following the law or in directing others to follow the law, then he or she can be sent to prison, or the facility or the study can be shut down (*23*).*

They should also be updated in GMP trends.

Managers should learn to communicate effectively with supervisors and subordinates and also to learn diverse ways to motivate and encourage their staff. The following aspects may be included in the manager training (*24*).

- communication
- motivation
- decision-making
- leadership
- empowerment
- business skills
- team building
- managing change
- time management and delegation
- how to orient and train employees
- conducting productive department meetings
- performance appraisal and coaching.

An effective way to train managers is to invite speakers (managers) from other companies and representatives from national regulatory authorities.

The manager training programme should guarantee that new managers be trained and that existing managers remain familiar with their assigned functions.

3.5 Trainer's training

Not everyone who is knowledgeable in a given topic can be an effective trainer. The desire to train, help others, and continually learn are traits trainers have in common. In addition, trainers need to have and continually develop their skills as communicators and coaches.

Typically, trainers (both those who teach to groups in classrooms, as well as those who work individually with people during structured on-the-job training) should have an understanding of how adults learn and in providing effective feedback to trainees.

On-the-job and SOP trainers should be recognized experts in the area or in the tasks that they perform. They should also understand the best ways to teach tasks and procedures.

Group trainers should have "presentation skills" to use various training media (e.g. slides, overheads, flipcharts), methods (e.g. discussions, games, case studies, lectures), and know how to respond to questions and difficult situations.

One of the central topics to be covered when training trainers is the "Andragogical model" (adult learning theory) that states that adults are self-paced learners who need involvement, visualization, and a clear connection between new and existing information that they already have. Adults are eager and motivated to learn if they can see the value and benefit that the knowledge can contribute to their lives or situation (*25*).

The designers of training courses as well as trainers need to understand how adults learn best. The design and delivery of the training course should involve trainees in the process as much as possible, because, as is known, adults learn best when active learning methods are applied.

Trainers who are involved in producing training courses and materials should have training in course development (e.g. the instructional systems design process – see section 4).

3.6 Ongoing training

Ongoing training, also known as reinforcement training, refresher training, continuous or periodic training, is conducted to update, reinforce and refresh the knowledge and skills of employees. This can help maintain a high, consistent level of safe, effective and efficient performance.

> *If you put employees through the same simple programme they went through the previous year, it will add little to knowledge or the skills. On the other hand, if you are trying to help motivate someone to perform correctly – shaping attitudes – you need to look for a new way to get the information across. You should build on topics covered earlier, but present them in a way that gives the learners new insights* (26).

Ongoing training should include:

- GMP: New guidelines, current GMP changes and their interpretation and biopharmaceutical industry trends, including short reviews of specific GMP topics that may be applicable to current work-related issues and challenges.
- On-the-job training: Employees should be trained when a new SOP or method is issued, when a procedure or method is changed and requires users to perform differently, and when new equipment or instruments are to be used. If the performance according to a procedure or job task has degraded, the requirements should be reviewed and coaching given as needed to return the performance to the desired level.
- Safety training: Periodic reinforcement is necessary for protecting staff from hazards. This training should also be implemented in case of changes or modifications of the safety regulations, changes or modifications of the technological process, work resources, raw materials, materials, new potential risks or other factors that could affect the workers' safety and health.

Each company should determine the frequency for the ongoing training and the established frequency must guarantee that employees remain familiar with the specific tasks required by their job.

3.7 Remedial training

Remedial training is given when there is evidence that the original training was not adequate, resulting in a person who cannot correctly, safely, effectively or efficiently perform the task. Remedial training is frequently used incorrectly, as corrective actions to deviations or failures. "Retrain the operator" or "retrain the lab analyst" are seen much more often in investigation reports than actually warranted. "Retraining" is an easy, but usually invalid corrective action that is used when the real root cause of the problem is not obvious.

"Training is a powerful tool. It plays an important role. But using it inappropriately is a waste of time, money and opportunity. If training is not done properly, this can have significant regulatory and compliance consequences" (*26*).

Have this statement in mind when planning your remedial training. Be sure that training is the effective solution to the problem.

Remedial training should be planned when specific deficiencies related to training are identified during the performance of a job or task, or during the investigation of a deviation or an out-of-specification result, accident or near-accident. In many cases, remedial training may only need to emphasize why the correct, required way must be done and the potential outcome of shortcuts.

Before planning remedial training, consider the different causes of the performance problem. If the worker does not know how to perform the job or task correctly, training is the solution.

When remedial training is NOT the solution

Remedial training will not be effective, for example, when:

- the worker does not know how to perform and does not have the aptitude to learn the specific job or task: the worker was improperly selected;
- the worker does not want to learn: the worker does not have the motivation for performing his work correctly;
- the worker knows how to perform a job or task but cannot perform it properly: the worker does not have the resources for performing adequately; and
- the worker knows the correct procedure but is not following it: performance degrades because she or he does not believe that correct performance is important.

When remedial training is the solution

Remedial training should be carried out only if it is known that the person:

- is capable of doing the job or task;
- knows the job or task requirements;
- has the proper tools and information;
- is performing a job or task that is properly designed;
- is given adequate feedback and coaching about his/her performance;
- is properly rewarded and not improperly rewarded (e.g. saving time by taking a shortcut); and
- has the opportunity to practise.

If the person can perform the job or task, but not as efficiently as desired, he or she may need coaching and opportunities to practice.

Remedial training is also useful when employees have forgotten their knowledge and skills after a long absence from the job or by infrequent assignment to a job or task. This may be conducted in the following way.

- The supervisor provides the current copy of the SOPs in which the trainee was trained before.
- The trainee rereads the SOPs.
- The trainee performs, under supervision, the procedures he/she was originally trained in.
- The trainee performs the procedures without supervision and when the supervisor is satisfied with the trainee's performance, the supervisor and the trainee sign the training record.
- The supervisor also provides training in new SOPs that have been approved during the worker's absence.

If a person attends a training course that presents facts and information but does not pass the final knowledge assessment (if used), remedial training may be appropriate. Before requiring the trainee to participate in the training course again, be certain that the questions were reliable and valid – that is that they were clearly covered in the course material. Also, consider if the trainee had the appropriate reading and writing skills for the test. In some cases, giving the trainee the test verbally may resolve the problem.

3.8 Job-change training

Companies that have a defined, well-functioning training programme consider the training needs of someone who moved from one position in the company to a new position.

"The training must cover the particular duties performed in the employee's position. Adequate training must therefore be given to every employee when she or he is assigned to a new job function. That may seen an obvious point, but it is sometimes overlooked when experienced personnel are switched from one job to another" (*27*).

Work-specific training (GMP, on-the-job and safety training) should be conducted for the employee's new needs, taking into account the previous knowledge, skills and attitudes that they have developed. The supervisor and the GMP trainer or training coordinator should identify the specific training required and when and how it can be provided by creating an individual training plan.

Job change training may be organized and accomplished in the following way.

- Review the employee's training record.
- Review the training requirements for the new job position.
- Prepare a training plan for the employee based on the analysis of the employee training record vs the training requirements for the new job; consider the orientation to the department in case of movement to another department.
- Perform the trainee's assessment.

3.9 Temporary employee and contractor training

This type of training presents a special challenge for most vaccine manufacturers because, by their very nature, temporary and contract workers are transient – they are used when they are immediately needed and then leave. Temporary employees and contractors whose work takes them into production areas or quality control laboratories and those whose work can impact the quality of the product must be trained. For example, contracted cleaners, scale-maintenance contractors and construction-facility employees should be included in the facility training plan. Regulatory agency inspectors do not see a difference between a full-time employee and one who is working only a short time.

For example, when a new clean room facility is constructed or refurbishment is taking place, a construction facility employee training programme should be implemented. The agreement with the contract partner should include instructions to partner's employees. These can be construction control procedures based on GMP regulations and also on the company's policy. These procedures are to protect the room from being contaminated. The partner should ensure that their employees strictly follow the instructions during the contract work. Compliance with the rules results in assuring a high level of quality of the product to be produced in the clean room (*28*).

One way to somewhat reduce the amount of training for temporary employees and contractors is to ensure that a skilled, knowledgeable person is always working with them and double checking their work. If this approach is used, some basic GMP, job specific and safety training must still be given.

Training records for these personnel also require special attention. If the firm uses a computer data base to manage the training of its full-time personnel, it frequently does not include temporary or consulting personnel in that database. Paper records or a different electronic system may need to be used.

4. Developing and implementing training

> *Education must have an end in view, for it is not an end in itself.*
> *– Sybil Marshall*

4.1 Instructional systems design process

The ISD process is used to efficiently create training courses that meet specific, previously defined needs.

Imagine starting construction on a new building without any blueprints. What if you did not know specifically what was to be done in the building or the environmental conditions that it would face? What if, instead of hiring an engineering firm to create detailed drawings for the utility systems, you wanted to reduce costs by simply drawing a simple sketch?

Not many successful technicians or business people would construct a building without investing knowledge, time and professional resources. Such action would risk time, money and lives. There are organizations and people who would spend thousands of hours in personnel time and lots of money in well-intended training events that are not produced with a full understanding of the needs of the personnel, the organization and those delivering it.

In this section, we will discuss a systematic approach for training development so that it can become an investment for the organization and its employees.

This approach can be used in creating any type of training, from a simple knowledge-based course on how vaccines are produced, to a complex computer-based simulation that involves multiple users connected by Internet.

In the area of education and training, the method used is called instructional design. Other terms used by practitioners in the field, each with its own subtle differences, include instructional systems design (a term that seems to have its roots in the military), instructional technology and educational technology. For our purposes, we will consider that the terms are equivalent and use the term ISD to identify the systematic process approach.

Identifying the goal, training for results

A critical first question to be asked even before the first training course is created is: What is the goal of your training programme?

Despite what type of training is conducted, there is a cost involved (e.g. the time for each participant, room rental, trainer's salary, travel, training materials). If you train just for the sake of training, you have very little to show for the costs. If you train for results, that is, if you have a specific, well-defined goal, you need to plan and produce training courses and activities to obtain those results. By focusing on and achieving the goal, what you spend will be an investment.

4.1.1 What is ISD?

Producing training to effectively and efficiently meet a defined goal involves using a systematic process, to:

- identify the goal or the problem;
- identify what the trainee needs to know and do;
- design a solution (which would include training);
- implement the solution;
- understand whether the goals have been met and when.

In addition, ISD considers the needs of the individual learner and his/her unique needs (*29*).

ISD is the result of the integration of various disciplines and technologies, such as social science, information science, management science, and engineering. Professionals in the field usually have advanced degrees in areas such as education, instructional design, instructional technology or management.

While ISD is a systematic process, in practice, it is not a rigid one. It is a creative, interactive, flexible, dynamic, fluid and responsive process (*29*), especially when used by an experienced professional. At the same time, principles, guidelines and rules of thumb provide a method that new training personnel can use developing a successful course.

4.1.2 ISD compared to traditional instruction

There are two major differences between an ISD approach and the more traditional instructional approach (*30*).

The first difference is that ISD is driven by the needs of the learner and stakeholders, whereas traditional instruction is driven more by the instructor and the instructional content.

Take, for example, questions like: What does the learner need to know and be able to do? What must occur for the learner to use this knowledge and skill on the job? The answers are found in ISD. Traditional instruction would ask such questions as: How does this subject fit into the larger discipline? What is important about the content?

By focusing on the needs of the learners, the training results and outcomes should become more uniform throughout a diverse organization.

The second difference is that ISD follows a systematic approach to optimize the delivery and transfer of information, while traditional instruction does not. A college professor who is considered to be a successful teacher may have a number of students who fail the course. However, a performance-based course produced by using an ISD approach would be successful when all the learners meet the performance objectives and achieve success. Its goal is for none to fail.

4.1.3 The ISD model

Different variations on the basic ISD model exist, some with four, five or more "phases". The model presented here uses five phases, each having a number of tasks and subtasks.

The five phases in this ISD model are:

- analysis
- design
- development
- implementation
- evaluation and maintenance.

The ISD process builds on the work done in preceding phases and tasks. Some tasks are iterative, that is, they are repeated several times until a manageable unit of instruction is developed or the same steps are used on different areas of content. Table 2 shows the phases and tasks associated with the ISD model.

A feature of the ISD process is that "deliverables", that is, pieces of the process – reports, outlines, storyboards, etc. – are produced during each phase. These deliverables are used in the following phases. Additionally, data (from job, task and audience analyses) are retained for historical or future use. This benefits the organization in several ways.

- Documentation is produced on how the training course was developed and how the problem was solved.
- Documentation (as above) is available in the event of a compliance inspection (although it would be very rare for this information to be requested).
- The reports, outlines, storyboards and other "deliverables" developed by the accepted ISD process can be used by a different instructional designer who may need to complete a project originally begun by someone else.

Several of the phases are covered in more detail in the following chapters.

Table 2: Phases and tasks included in instructional systems design

Analysis	Design	Development	Implementation	Evaluation and maintenance
Define the scope	Consider what else is needed	Write detailed outline	Prepare instructors and monitors	Analyse evaluation data
Analyse job	Establish/confirm programme goals	Sketch or storyboard visuals, other materials	Schedule sessions	Adjust content, instructional methods and media
Analyse tasks, knowledge and skills	Develop sub-goals	Check quality	Deliver course	Update material as needed
Analyse audience	Establish objectives	Develop lessons, activities	Document attendance	Coach instructors as needed
Summarize findings	Select and organize topics (i.e. content)	Develop evaluation tools	Document instructional materials	Measure effectiveness through follow-up evaluations
Check quality	Develop manageable units of instruction	Produce visuals, other materials	Collect and assess evaluation data	
Prioritize needs	Plan evaluation strategy Write a high-level outline for lessons Select instructional methods Select instructional media Identify potential instructors Refine curriculum Check quality Prepare and approve written instructional plan	Plan implementation and roll-out Prepare instructor's or monitor's manual Conduct pilot course Approve the course		

Analysis

Data is collected and analysed during this phase (sometimes called "front-end analysis") to:

- describe the job and task(s);
- define the problem(s);
- quantify the problem(s);
- identify the audience(s) (i.e. trainees);
- identify knowledge and skill needs;
- identify what is currently being done; and
- prioritize the solutions.

Analysis is started after a performance analysis (or its equivalent) has pointed to a skill or knowledge deficiency. This could range from personnel needing an orientation on how vaccines are made to skills training on aseptic techniques.

The solutions generated during the analysis phase sometimes include more than just training interventions. Other performance-related factors, such as increased feedback from supervisors, job aides, or easier-to-use documents may also be required for the training to be effective and transferred back to the job.

Analysis is a complex and time-consuming process that can expand almost infinitely unless it is approached carefully with its scope defined at the outset. For example, instead of defining all the tasks a quality control representative does in his or her job, it may be sufficient to define the most critical, or frequently performed tasks that are necessary for competence.

The results of the analysis are very similar to a functional requirements document – a specification of what you want this training programme to be, to "look" like, and conditions that need to be met. This information will be used in defining the course goals, objectives and topics in the design phase.

Analysis is a critical part of the ISD process if the training is to achieve its goal or be part of a comprehensive solution to a specific problem.

Since the training session is to meet the needs of the audience(s), that is, the trainees, it is imperative to understand who they are. Some of the questions that are usually asked are:

- who are the persons that will attend the training session?
- what is the background of these persons?
- what types of courses did they receive before?
- what jobs do they perform?
- where are their skills and knowledge insufficient?
- what is the motivation for starting training?
- what is their previous experience?

- what is their (formal) educational level?
- how comfortable are they in reading and writing?
- how long have they been doing their jobs?

The answers to these questions are used to define instructional methods and media to be used, select meaningful examples, and identify any special learner needs.

Design

The design phase uses data collected and decisions made during the analysis phase to establish a blueprint of what the training course (and other performance-supporting actions) will look like and consist of. The blueprint, more formally called the *instructional plan*, will be the basis for developing and implementing the course. The instructional plan includes:

- goals
- objectives
- topics
- organized topics
- instructional methods, media and events
- requirements, constraints
- strategies for instruction, delivery and evaluation
- more closely defined costs and benefits.

The instructional plan is different from a "training plan", which is an overview of all the training efforts in a given area and a "lesson plan", a term sometimes used to describe the detailed notes a trainer uses in presenting a course.

Manageable, modularized instructional units of content are designed for maximum flexibility, ease of implementation and future modification. Objectives describing what the trainee will be able to do, in clear, observable terms are written down. Topics are organized and sequenced so the trainee can progress into more advanced levels after successfully completing the lower ones.

The design phase is where the methods for presenting and vehicles for delivering the instruction are selected. Factors such as content, numbers and characteristics of trainees, location and future needs are considered when method and media decisions are made.

An "instructional event" is simply more detail about what is to be done in a section of the training session, for example, "introduce the instructors".

Another important consideration when designing a course is prioritizing the essential topics to be covered in the training, so as to minimize the amount of time personnel are away from their primary work responsibilities, thereby reducing disruption. Creative and well-designed courses can make training effective, efficient and enjoyable for the trainees.

Prior to moving into development of the course, the stakeholders (for example the quality unit and management) need to approve the design for completeness, accuracy and suitability.

Section 4.2 provides additional details on some of the tasks involved in this phase.

Development

In this phase, the training course is produced, based on the details and specifications found in the instructional plan. Products of the development phase include the following:

- a detailed outline with instructional content and activities;
- sketches, storyboards, and other materials, reviewed before final production;
- instructional materials (e.g. visuals, videotapes, printed items, computer-based instructional modules, etc.);
- evaluation tools;
- an instructor's or facilitator's manual;
- other performance-supporting items, such as job aids;
- a pilot course with modifications made as needed; and
- an approved course ready to be delivered.

If the analysis and design have been thorough and complete, developing the training course is much faster and efficient. Having trainees and stakeholders involved at review points also helps to ensure the course will be well accepted.

A "pilot course" is carried out before the general implementation of the training. Using a small group of actual trainees helps the course developers and instructors make final adjustments before the course is approved.

Approval of the course should be made by stakeholders, content experts and, in the case of any GMP-related courses, by the quality unit. If these groups have earlier approved well-prepared design documents, there should be few issues that surface at this approval point.

Section 4.3 provides additional details about the design phase.

Implementation

This is the phase traditionally associated with "training"; this is where the instruction is actually delivered to the trainee(s). Often, an assessment of knowledge or demonstration of performance skill is included at the conclusion of the session to determine if the trainee has reached the learning objectives of the course.

The exact nature of implementation depends to a large degree on the vehicles for delivery. It will usually involve:

- preparation of instructors, facilitators, or monitors;
- course delivery;
- documentation of trainee participation;
- documentation of instructional material;
- assessment of trainees; and
- collection and review of evaluation data.

The scope of the implementation effort is related to the size and location(s) of the audience, the number of instructors or training stations (e.g. simulators or computer-based training devices) available, and the number of instructional sessions that need to be held.

Whereas the most visible spending of funds typically occurs in the development phase (and to a lesser extent in the design and analysis phases), the implementation phase can be extremely costly when the learners' and instructors' time is considered. This is often "invisible" or not considered by the firm. If the instructional design has been a good one, only the important, "must-have" skills and knowledge will be taught using the most effective and efficient instructional methods and media, thus optimizing the time that the learner spends in training.

Section 4.4 provides additional details about the implementation phase.

Evaluation and maintenance

Assessment and evaluation tools can help determine if instructional content, methods and media are adequate or if they need to be fine-tuned to more effectively and efficiently meet the objectives and goals. (Note: Assessment and evaluation is covered in more detail in section 5.)

A "follow-up" evaluation may also be desired months after the training is given to look for long-term changes and programme success.

If the course includes content that changes with time (e.g. regulations, interpretation of the GMPs, industry practices, etc.), this will also need to be reviewed and updated as necessary.

4.1.4 Summary

ISD is based on scientific and technological methods and tools. It requires people who can ask the right questions at the right time to define the needs and who can then use this information to create an effective and efficient training course to address the defined needs. The successful ISD practitioner should have not only needs knowledge, skills and creativity, but a perspective focused on the learners.

The ISD process tends to be a collaborative one: learners, subject matter experts, graphic artists, and other professionals are involved at various steps, each adding value and richness to the finished programme.

4.2 Designing a training course: additional details

A good design is essential for a process and facility as well for a training course. Consider the following analogy.

One of the most significant differences in comparing an older vaccine manufacturing facility with a modern one is in the layout and design of the facilities. In an older facility, the process tends to be designed around the existing rooms and large, fixed pieces of equipment. Production requires a significant amount of effort and a number of precautions.

In newer facilities (even if the same equipment from an older building is used), the layout and design facilitates the manufacturing process: materials, information and people flow more easily, resulting in fewer problems and higher productivity.

Training courses need to be properly designed as well, in order to make learning as effective and efficient as possible. The trainee should not have to struggle with how the content of the training sessions fits together.

In the previous section, the five phases of the ISD model were presented. In this section, we will focus on the second phase, design, and use of the data collected in the first phase, analysis, to design a training course. In doing this, we will identify the instructional content – the facts, skills, ideas and concepts – related to the objectives of the training session. We will also choose the instructional events (e.g. activities, case studies, examples) – features of the course that help facilitate learning (*31*) and media for presenting information.

Integrating instructional content and instructional events based on how people best learn can make the training course productive, fun and effective. Not doing this properly can result in time wasted, frustration and anxiety for both the learner and instructor.

4.2.1 Types of information that people learn: learning domains

In order to better understand how to design a course, we first need to cover some basic theory about learning and the types of information, i.e. domains that people learn (*32*). We will concentrate on four domains:

- motor (psychomotor or physical) skills
- information (or facts)
- intellectual skills
- attitudes.

This is not as complicated as it might sound. Think of how *you* best learn different types of information. For example, compare learning how to run a race and learning the names of countries and their capitals. How the information is presented and how learning is assessed depends on what you are trying to teach.

Running is a *motor skill.* It involves coordinated, physical actions. Sitting in a classroom, reading books, or watching videos will not help you very much. Actually running and having someone more experienced coach you will help you to better understand the mechanics of running. You would start out, for example, by learning ways to warm up, how to position your body, how to prevent injuries, what wasteful motions to avoid, and techniques to optimize your running for either speed or endurance. As your skills improve, you could learn some of the special techniques that successful marathon runners or sprinters use. The environment – being in a place where you can run – contributes to the learning process. You (and your coach) will know you have reached the goal of learning to run a race because you will be able to *do* it.

Learning about countries, the names of capital cities, and other factual information is a different type of learning. This can very easily be done in an environment unrelated to the subject matter. To be successful, the information must be structured in a way to help you mentally organize it in a meaningful way. This could be alphabetically or by geographic region. You (and your instructor) will know you have learned the facts because you can tell someone the capital of Peru or write the name of the countries and their capitals down on paper.

A third domain is learning about *intellectual skills.* This is the use of symbols, information, rules, guidelines and concepts. In the vaccine industry, this might be as "simple" as inspecting a vial in order to determine if it is acceptable or not. A more complex example could be determining the root cause of a failure and identifying the proper corrective actions to take. You know someone has learned these intellectual skills if he can demonstrate the skills in one particular (or limited) situation or in a variety of different situations.

The final domain of importance is *attitudes* – acquiring the mental state to make a choice for personal actions. These can involve a combination of personal, ethical, legal or moral values. For example, deciding whether or not to follow a procedure as it is written, or taking a shortcut. Another example would be a supervisor realizing that he or she is a role model for those working in the department and acting accordingly. A person demonstrates his attitudes by the choice(s) he makes in a particular situation.

Now that we have seen examples of four different types or domains of learning, we can use this information in organizing how the topics are presented.

4.2.2 Preparing the instructional plan

As mentioned earlier, the blueprint that is created when designing a course is called an instructional plan. To prepare the plan, the following steps are taken.

1) Decide on learning objectives (discussed in more detail below).
2) Look at each objective and *identify the learning domain* in which it fits best.
3) For each objective, *identify what the learner must know and be able to do* to meet that objective. What you are discovering is the *instructional content* or the *topics* that are to be covered in the training. Recommended approaches are found in Table 3. Data from the analysis phase are used.
4) *Organize the topics* for the objective based on the model shown for the objective's domain (identified in Step 2). Recommended models for the different types of content are shown in Table 3.
5) For each objective, *organize the instructional events* using the appropriate model. These are also described in Table 3.
6) Select the instructional media used to help deliver the information to the learners.

4.2.3 Goals and learning objectives

Before instructional content and events can be specified and organized, you need to define the goals and learning objectives of the training course.

Goals are specific and measurable statements on the desired outcome of the training course. The goals are the one or two reasons why this training course is being provided.

Learning objectives are behaviourally based statements on what the learner should be able to do after completing the training course.

The training course should be designed so that, by accomplishing the objectives, the learner can achieve the goal.

Typically, objectives have three parts.

1) **Performance**: A description of what the learner should be able to do. Performance is action based; it should be observable and measurable.
2) **Conditions**: The important conditions under which the activity is to be performed. This could include tools or references that can or cannot be used.
3) **Criterion**: The quality or level of performance that is expected of a successful performance. This specification may be in, for example, units per hour or errors allowed. (This is sometimes called the standard.)

Example #1: Considering an "intermediate"-level GMP training course for supervisors, the goal and learning objectives (with the learning domains identified) are as follows:

Goal: Interpret and apply good manufacturing practice (GMP) expectations in a variety of situations.

Objectives: At the end of the course, supervisors should be able to:

- define 10 key words and concepts related to good manufacturing practice (factual information);
- given GMP regulations, guidelines and industry practice, list six GMP expectations for training (factual information);
- given a pharmaceutical situation, give four examples of how quality auditors and regulatory inspectors evaluate conformance to GMP expectations (intellectual skills);
- identify seven basic GMP rules and provide three examples of how GMP expectations are relevant to her/his job responsibilities as supervisor (intellectual skills);
- describe how supervisors (at all levels of responsibility) are involved with making products that meet GMP expectations (intellectual skills).

The objectives given above include the three parts: the **performance** ("define", "describe", "identify"); the **conditions** ("given a situation", "given regulations") and the **criteria** ("10 key words and concepts" "six GMP expectations").

Example #2: List a goal and learning objectives (with the learning domains identified) for a course on aseptic gowning as follows:

Goal: A person in an aseptic product manufacturing facility will gown in the approved sterile uniform without contaminating it.

Objectives: At the end of the course the learner will:

- explain why it is necessary to enter the gowning room wearing the appropriate uniform without jewellery (factual information);
- given all the elements of a sterile uniform, clothe with minimal non-viable particle contamination and no microbial contamination as determined by RODAC (replicate organism detection and counting) plating on the uniform (motor skill);
- given a failure situation, take actions that will not contaminate the gowning room or the aseptic area (intellectual skill).

The second objective contains the performance ("clothe"), the conditions ("given all the elements…"), and the criterion ("with minimal non-viable particle contamination and no microbial contamination…").

4.2.4 How much should be covered in a training session?

Actually, there is a limited amount of time available for training and trainees cannot, practically, learn everything. Therefore, during the design phase, when selecting the topics to cover, the course designer may have to make decisions about **what to cover** and **what to leave for later or not cover at all**.

One way to make this decision is to ask, when looking at each topic:

"Is this critical to the outcome of the task or the goal of the training course?"

This question helps determine if the information is a "must know or need-to-know" or a "nice-to-know".

"Nice-to-know" information could be covered as part of a later or more advanced training course, in a brochure or handout.

4.2.5 How does OJT fit into this?

OJT (discussed in more detail in section 3.2) is an instructional method that, when done properly, includes several of the domains shown in Table 3.

Sometimes, unfortunately, in some organizations, the trainee is assigned to a more experienced worker with the trainee expected to sit by and observe the more experienced worker. This is "passive learning" and is neither effective nor efficient.

OJT is a powerful method when it is properly used and designed. As described earlier, "structured OJT" should include:

- a trainee with the appropriate prerequisite skills and knowledge;
- a demonstration of the task or process (i.e. motor or intellectual skills);
- explanations of the task's "what" and "why" (factual information);
- explanation of the performance expectations (factual information);
- practice – with feedback – beginning with the sub-skills or movements and continuing through the entire task.

The experienced worker (or mentor who is instructing the trainee) should understand and be able to fulfil his or her role as an instructor and coach. Not all people are interested or can perform this type of role well.

In the case of OJT, use a structured approach with skilled mentors who have been instructed in the OJT process.

4.2.6 When training to change attitudes

Be certain that the learners respect the people conducting the training and those otherwise involved with the training process. The learners need to "connect" with or relate to role models that that they can respect.

For example, one company, when trying to change attitudes involving quality improvement, chose a very senior executive to help with the training. While the company's management was comfortable with the choice, operations and technical personnel viewed this person as a part of the problem. In the previous year, the senior executive had rejected well developed engineering and equipment proposals that were designed to solve several significant quality issues.

During the pilot course, it was discovered that involving this executive was very damaging to the entire programme, thereby hindering the learning process for the trainees. To correct the problem, learners were interviewed as to whom *they* most respected in the firm. This person then agreed to assist with the training.

One of the most powerful messages from trainers and supervisors is unspoken – the things workers and colleagues at all levels see being done on a daily basis. Being a role model and making consistent, well thought out decisions helps create and reinforce positive attitudes about GMP, safety, ethics and other important topics.

4.2.7 Additional definitions

Table 3 introduces three terms that have not yet been discussed.

Instructional events: The specific activities in the training session used to accomplish the objectives and goals that are done by the instructor (e.g. introduce the goals and objectives for the course), or learners (e.g. "brainstorm a list of examples of things that can cause contamination").

Advanced organizer: A framework or outline that is provided to the learners early in the lesson to give them an idea of what is to follow. For example, if the topic is contamination of sterile products, the advanced organizer would outline the ones you are going to talk about and how they are related: viable (microbial) and non-viable (pyrogenic, inert, etc.).

What's in it for me: A basic reason for learning the information or skill. For most adults, this tends to be a motivator for learning. It could range from "if you don't do it right, you will not get your pay increase" to "would you want your son or daughter to use products that were not made according to good manufacturing practice?"

Table 3: Recommended models for identifying and organizing instructional content and events. (Based on Gagne, 1985)

Domain	Content identification	Organization of instructional content	Organization of instructional events
Information	1) Identify key idea or theme.	1) Show the key idea or theme (the "big picture").	1) Inform learners of desired outcomes through: • learning objectives • why this is important • what can happen if information is not known • "What's in it for me?"
	2) Find supporting details related to key idea.	2) Show supporting details for the key idea.	2) Summarize previous knowledge; provide "advanced organizer" as an introduction; give a structure that information will be built around.
	3) Find sub-details to support the previously identified details.	3) Show the sub-details.	3) Present key idea. Then give supporting information.
	4) Find the structure for how all the pieces fit.	4) Show how each piece relates to the other pieces and supports the key idea.	4) Provide concrete examples and applications relevant to learners.
			5) Ask learners to repeat what they have learned.
			6) Provide feedback to learners. Coach. Amplify previously given information.
			7) Assess learners' performance.
			8) Provide opportunities for learners to practice "telling" information in a variety of situations.
			9) Provide continued feedback to learners.

Table 3: Recommended models for identifying and organizing instructional content and events. (Based on Gagne, 1985) *(cont'd...)*

Domain	Content identification	Organization of instructional content	Organization of instructional events
Intellectual skill	1) Identify skills and knowledge required to reach the lesson's objective(s); these are the prerequisites.	1) Teach the most basic skills and knowledge first.	1) Inform learners of desired outcomes through: • learning objectives • intellectual skill demonstration or how it is used • why this is important • consequence of not performing correctly • "What's in it for me?"
	2) Continue to identify prerequisites and the skills and knowledge needed to reach the prerequisites.	2) Once learners have achieved mastery, move to the next skill or knowledge in the hierarchy.	2) Recall prerequisite rules and concepts already covered.
	3) Arrange skills and knowledge in a hierarchical fashion with the most basic skills and knowledge taught first.		3) Describe features, symbols, tools used.
			4) Show examples (examples that are wrong), and applications.
			5) Have learners do it and demonstrate their use of the intellectual skills.
			6) Provide feedback to learners. Coach. Amplify previously given information as needed.
			7) Assess learner's performance.
			8) Provide opportunities for learners to practice "telling" information in a variety of situations.
			9) Provide continued feedback to learners.

Table 3: Recommended models for identifying and organizing instructional content and events. (Based on Gagne, 1985) *(cont'd...)*

Domain	Content identification	Organization of instructional content	Organization of instructional events
Motor (or physical) skill	1) Break the skill down into smaller sub-skills or individual movements.	1) Teach each sub-skill or individual movement in its naturally occurring sequence.	1) Inform learners of desired outcomes through: • learning objectives • motor skill demonstration • why this is important • consequence of not performing correctly • "What's in it for me?"
	2) Identify the specific sequence of how the skill is performed.	2) Once learners have mastered the sub-skill, move to the next sub-skill or movement in the sequence.	2) Identify tools/resources to be used.
			3) Show conditions at the start of the operation.
			4) Show sub-skills or individual movements.
			5) Learner practices sub-skills in sequence, with feedback.
			6) Learner demonstrates complete skill with feedback, coaching.
			7) Assess learner's performance.
			8) Learner continues to practice and apply skills to other situations.
			9) Provide continued feedback to learners.

Table 3: Recommended models for identifying and organizing instructional content and events. (Based on Gagne, 1985) *(cont'd...)*

Domain	Content identification	Organization of instructional content	Organization of instructional events
Attitudes	1) Identify the behaviour a person with the "correct" attitude should display.	1) Find a person the learners respect or with whom they can identify.	1) Inform learners of desired outcomes: • learning objectives • why the attitude/correct choice is important • what can happen if correct choice is not made • "What's in it for me?" NOTE: Gagne (1985) suggests that there may be times when providing the objectives may be counterproductive. If objectives or the desired outcome are NOT shared with the learners, there should be a valid and specific reason for not doing so.
		2) Put the person (from Step 1) into a situation where they are forced to make a choice relating to the attitude.	2) Introduce human model.
		3) Show the person making the correct choice.	3) Recall situation or action.
		4) Show the person receiving positive feedback.	4) Human model demonstrates or describes choices.
			5) New situation is provided to learner; learner provides choices, makes choice.
			6) Learner is given feedback on choice.
			7) Assess learner's performance.
			8) Learner is given other situations and practices.
			9) Provide continued feedback and reinforcement to learners.

4.2.8 Selecting instructional media

Instructional media are the tools used by the trainer (and sometimes the trainee) during the training course.

To be effective, instructional media do not have to be fancy or expensive: chalk boards, diagrams, photos or drawings are all very useful tools when used by a well-prepared instructor.

Drawings or still photos are useful when showing static (unchanging) conditions, such as what a properly-gowned person looks like before entering a processing area.

A sequence of still photos (or drawings) or videos are useful when showing motions or sequences. For example, still photos made while putting on a sterile gown can be just as effective as a video of the action.

Video is most useful when you need to show a smooth sequence, for example, certain types of aseptic techniques and manipulations.

Instructional media, such as interactive multi-media programs – delivered using computer-based training (CBT) the Internet or CD-ROMs – while costly to design and develop, can offer substantial cost savings during the implementation phase compared to traditional forms of leader-led instruction. Internet, CD-ROM, web conferencing, and other forms of distance learning can be highly cost-effective when:

- there is a large number of trainees;
- the trainees are located in different places;
- the trainees are available for training at different times;
- there is a lack of qualified trainers;
- the same content must be presented consistently; and
- the content for the course is "stable" and not frequently changed.

Note: The World Health Organization now has 19 training modules available on CD, on basic GMP and GMP inspection, together with a short video, trainer's notes, group session material, tests, and personnel development form. While specifically designed for GMP Inspectors it can be easily modified for manufacturing personnel. An additional 11 modules on water for pharmaceutical use, HVAC and validation have been added.

4.3 Developing a training course

When designing a training course, the instructional plan identifies the topics to be covered and an instructional method, such as a presentation, case study, demonstration and other activities that convey information to the trainee. In this phase, the course developers prepare the instruction according to the instructional plan.

This chapter provides additional information on selected instructional methods (i.e. the ways in which training is delivered) and instructional media (i.e. the resources and tools used to deliver the information), but does not attempt to cover all such methods and media in detail.

As you develop (as well as design) a training course, you strive to keep the trainee involved as much as possible. A guiding principle in designing and developing courses is:

- 20% of what is said is remembered
- 50% of what is seen and said is remembered
- 90% of what is done is remembered (*33*)

A Chinese proverb summarizes this idea about active learning:

"Hear and forget.... See and remember.... Do and understand".

4.3.1 Instructional methods

Presentation or lecture

Presentations or lectures are one of the simplest ways of presenting information. Unless the presenter is extremely skilled, it can also be limited in its effectiveness.

A presentation is one of the several instructional methods used during a training session. For example, people exposed to contamination, a short (10–15 minute) presentation, involving slides, questions and answers, photos and examples could precede an activity related to different types of contamination.

When doing a presentation, reinforce the lecture with visuals, such as key words on flipcharts, overhead transparencies or slides. This helps those who learn visually. Since people learn best when they are involved, ask the trainees questions and for examples and experiences of their own.

Group discussions

Group discussions promote active involvement of the participants. Group discussions are useful for active thinking and learning. They are also useful when a subject is complex and there are multiple points of view. Group discussions require that most of the trainees have some relevant working knowledge of the topic.

How to prepare and conduct group discussions

- Have a clear idea before the training session begins regarding the topics to be discussed.
- Divide the group into smaller groups.
- Assign a topic for discussion.
- Let trainees think about the topic to be discussed.
- Let trainees present the arguments to defend any point of view.
- Control the discussion. Ensure that all trainees have a chance to give their points of view.
- Encourage trainees to work as a group.
- Give feedback. Ensure that all trainees know what is right or wrong.

Skits

Skits can be used to promote discussion and thinking. Skits usually follow a script that is written in advance.

At the end of a skit, the facilitator can guide the discussion toward points that are important to cover. When considering using a skit, be sure of the reading abilities of the trainees.

How to prepare and conduct skits

- Bring copies of a skit, prepared by you or by others. You can also adapt some skits to your needs.
- Ask for volunteers to read the different parts aloud.
- Ask the actors to come up to the front of the class or, if they prefer, let them stay in their seats.
- Ask questions related to the topic under discussion.
- Divide the group into smaller groups to discuss the questions.
- Ask for answers from the whole class.
- Give feedback. Ensure that all trainees know what is right or wrong.

Example of a skit

You may find two skits in the article "The essence of training, Part 2: The Play's the Thing" (*34*).

Role-plays

Role-plays are suitable for tasks that are related to human relations skills. This is a very useful method for practising communication skills and in supervisors' and managers' training.

How to prepare and conduct role-plays

- Identify roles to be played and any particular instructions (e.g. an auditor who is extremely emotional while conducting a quality audit).
- Ask for volunteers – those who may be willing to share their point of view and experiences.
- Give role players any background to the situation and their roles.
- At certain points in the role-play and at the end, ask the role players about their experience or feelings during the roles.
- Comment during role-plays only if absolutely necessary.
- Let all trainees take part in the discussion at the end.
- Ask the group for their reactions about how situations were handled, such as what was successful and what was not successful, or how responses could be improved.
- "Expert feedback" can be used to tell the role players how successful they would have been in an actual situation.

Example of role-play

A role-play used in a train-the-trainer programme can be found in: "Preparing workplace trainers to maximize ROI" (*35*).

Trainee's role:

> Yesterday you completed a written test on troubleshooting and you're feeling rather angry. Maybe you didn't pay as much attention as you could have when the trainer was going over the material, but you didn't think it was all that important. After all, you know most of the troubleshooting procedures for this equipment already. In your view, this training is just an unnecessary formality. But when you got hit with that written test, you realized that your methods weren't necessarily the ones the trainer had gone over in class.

Trainer's role

> You've just checked _____'s troubleshooting written test and you're disturbed by the results. The trainee scored only 65 on the test, but everyone else scored 85 or higher. You've noticed that _____ has been inattentive during class, never volunteering answers or participating in the activities. This is too bad, because he/she is a solid employee with good skills. The problem is that_____ has his/her own way of doing things, and that way isn't always the best practice. Now he/she is coming to see you about the test. You can't change the grade, but you can re-administer the test. More important, you want to get the employee engaged in the training process. How will you do it?

Discussion panels

Discussion panels promote active involvement of participants, panel members and moderator. Panel discussions are different from group discussions in that the members of the panel are the primary sources of information, with the moderator selecting questions or guiding the discussion. In group discussions, everyone shares their information.

How to prepare and conduct a discussion panel

- Request trainees to present written questions relevant to a specific subject, before carrying out the discussion panel.
- Select the panel members and a moderator.
- Select the most relevant questions to be discussed.
- Allow the panel members to prepare the answers.
- Let the panel members answer the questions, led by the moderator.
- Let trainees give their views.

Case studies

Case studies use real-life or composites of real-life situations as teaching tools that promote the decision-making skills of the trainees. Case studies can also be used to show what can happen if a certain path is taken and how the results impact customers, employees, the firm, regulatory agencies, etc. This instructional method is useful in trying to shape attitudes.

With complex cases, it is helpful to move through the case in stages, adding more information as the case progresses. This helps to prevent overwhelming people with detail and also permits the instructor to steer the direction of the case so as to emphasize particular topics or issues.

How to prepare and conduct case studies

- Create an imaginary situation that resembles an actual case.
- Prepare any form needed to complete the task.
- Divide the group into smaller groups to conduct case studies.
- Present the problem to be solved.
- Ask trainees to find a solution and make a decision.
- Discuss their answers and give them feedback.

Demonstrations

Demonstrations are valuable in teaching motor (psychomotor or physical) or intellectual skills. They can be used to prepare people who are operating equipment or instruments or have some other sort of physical action. Demonstrations are extremely useful in teaching people who learn visually (as opposed to reading). Many people who have difficulty reading a complex procedure can watch a demonstration once and then perform flawlessly.

How to prepare and conduct demonstrations of motor (psychomotor or physical) skills

- Describe the skill to trainees.
- Explain why the skill is important and why they must learn it.
- Read the SOP, if used, that describes the skill.
- Give a demonstration of the skill. Be sure that the demonstration is correct.
- Use a written handout or operational checklist while you are demonstrating.
- Let the trainees see what you are doing and explain what you are doing during the demonstration.
- Let each trainee practice the skill.
- Provide feedback correcting mistakes and telling them how well they are using the skill.

Example: Gowning training

- Trainees will review the video training programme "Dressing for the clean room" with the trainer, or will receive a description of the gowning process, stressing why it is important.
- Trainees will review the gowning SOP.
- The trainer will explain the training sequence and then demonstrate the adequate gowning technique.
- Trainees will practice gowning initially out of the aseptic processing area. The trainer will work with trainees during the gowning practice to assure proper gowning technique is used.
- Trainees will demonstrate the ability to properly gown.
- Trainees will start the first steps of the qualification process in the specified area.

Simulations

Simulations prepare people for performing motor or intellectual skills. Trainees learn by performing the activities to be learned in a similar way to the real situations. Trainees learn by imitating or replicating some aspects of the world. Simulations are powerful techniques. Simulators or computer simulators (a type of instructional media) enhance motivation and have better transfer of learning but are frequently not available.

Games

Combining education and entertainment is a powerful tool when training adults. Games are ways that participants can have fun and learn at the same time. You can use your imagination and create your own games or you can use some of the games that are commercially available. Games are different from simulations in that games do not have a serious, real-life outcome.

Example #1*: Terms of compliance (LearningPlus) (See Annex 1)*

A leader-led game, involving all members of the group, designed to reinforce words and terms used in manufacturing and control of pharmaceutical or medical devices.

Rules for the game are as follows.

- Each group has 15 seconds to develop and give an answer.
- If correct, the group receives 5 points.
- If incorrect, the first group with the correct answer gets 5 points.
- The group with the most points gets some simple prize or applause from the whole group.

Examples of questions:

Question: What is cGMP the acronym for?

Answer: Current good manufacturing practice.

Question: What does "sterile" mean?

Answer: Absence of viable contaminating micro-organisms.

Example #2*: "GMP game show" (LearningPlus).* An example of a large-group activity that can be used for GMP training.

Rules for the game are as follows.

- Each group gets to add a 4th person of their choice.
- Each group has 20 seconds to write down their answer on the flip chart. If the answer is correct, the group gets 5 points (both, either or neither group can get the points).
- Each gets one "lifeline" by asking someone (specifically named) in the large group for the answer; another 20 seconds are given for the answer.
- The group with the most points wins.

For example:

Question 1: GMP stands for?

generate more paper

good manufacturing practices

great manufacturing practice

good manufacturing promotion.

Question 2 when conducting a visual inspection on vials of vaccine, the smallest particle that can usually be seen with the naked eye in optimal circumstances is:

1) 5 microns
2) 5 millimetres
3) 1/5 inch
4) 15 microns.

Quizzes and tests

Quizzes and tests can be used as a learning tool or as an assessment tool. "Pre-tests" can help focus trainees on what will be covered and also show those who may think they know everything about the topic what they do not know.

"Self assessments" are used frequently in self-study and computer-based courses to give the trainee a chance to evaluate how much they have learned. If they do not get the correct answers, they should review the material until they have mastered it.

(During OJT and leader-led training, the trainer does this type of evaluation by asking questions and listening to comments made during activities. Most trainers would review or follow up with trainees who were not grasping the topics covered.)

If the quizzes and tests are used for assessment purposes, going over the answers as a group can provide learning. Test papers that take the form of multiple choice questions that can be marked during an interactive answer session can be used to identify areas that require further explanation and discussion. This way, all trainees will know the correct answers before they leave the session.

4.3.2 Instructional media

Instructional media can be used to provide information for many of the instructional methods described above. For example, visual aids (e.g. a photograph) could be used in a presentation or as something that participants in a game would be asked to identify.

Visual aids

Flipcharts, overhead transparencies, 35-mm slides, photographs, wall charts and the like are all very effective media to reinforce what the speaker is saying; they help trainers explain their ideas in a different form than in words.

Some rules of thumb when preparing these media follow.

- When prepared in advance, flip charts are useful in presenting text and diagrams. If the presentation is to be done more than once, have at least two flip charts available – one with the course notes and another (or a blackboard) where the instructor can make spontaneous diagrams.
- Make sure they can be seen by everyone in the room. For flip charts, use black or blue markers with letters/characters 4–5 cm in size. For transparencies or slides, use a font size no smaller than 28 points. The letters used on the screen must be 25 mm high for every 2 m distance (*33*).

- Don't overload the slides with information – try to limit them to 6–9 lines of information.
- Simplicity is good: white or yellow text on a blue background is very readable.

A growing number of facilities have access to computers and data projectors which permit slides (e.g. Microsoft PowerPoint presentations) to be projected. These systems offer considerable cost savings over time on account of reduced costs for materials (e.g. slides) and development time.

People enjoy photographs or videos where they recognize locations or people. When feasible, include local scenes with people, facilities and equipment.

Printed materials and handouts

Some trainees, based on their past educational experiences and the organization's culture, like to take notes during the training on handouts or lecture notes. In this case, giving reduced images of the transparencies or slides to the trainees at the beginning of the session is very useful.

Some trainers prefer giving them out at the end of the session or making them available only to those who request them. Other trainers have them available when people are arriving so they can begin to focus on the topic that will be discussed.

Computer-based training

CBT is defined as "an interactive learning experience between a trainee and a computer in which the computer provides the majority of the stimuli, the trainee must respond, and the computer analyses the response and provides feedback to the trainee" (*36*). CBT turns a computer into a trainer by presenting course materials in a user-friendly way that encourages learning. There are different types of CBT programmes, for example, tutorials, drills, games, simulators and tests (*37*).

Examples of commercially available CBT programmes are the SeerPharma "DisCover" training programme on CD (www.seerpharma.com.au), Learnwright's (www.learnwright.com) "GMP Basics" and "GMP Intermediates: GMPs and Your Job" and Media Vision's interactive GMP video training.

Examples of video training programmes

CGMP-I basic knowledge is a course that provides the basics of cGMP. The programme segments are explained and tested by means of practical cases.

CGMP-II Advanced level is an interactive video training for experienced employees working in the pharmaceutical industry. This advanced level programme is a follow-up to the basic programme: CGMP-I.

Example of an in-house CBT programme

KYBER AG-66 (*38*) is an in-house software that provides technical and operational training to the users of the autoclave GETINGE GE 66.

In this CBT course, training is performed in an easy and friendly way through:

- six tasks that should be carried out in a limited time and in order of complexity;
- the simulation of autoclave faults;
- the detection of possible mistakes during the operation.

Authoring tools are used in preparing in-house CBT and web-based training programmes. These include tools like Shockwave and Flash from Macromedia (www.macromedia.com), and ToolBook from Click2learn (www.click2learn.com).

4.4 Implementing a training course

Unless the trainees in the training session have had experience in actually preparing a training course, they have no idea of the work, time and energy that have gone into designing and developing a course. The one-hour or two-hour session is all that they see.

Because of this, and because the training session is the means to carry out the course's goal (the reason why you are doing the training in the first place), the execution of the training session needs to go as smoothly and professionally as possible.

Experience and a sense of humour can help a trainer when things go wrong, such as a projector breaking during the middle of a presentation. However, being well organized and prepared can help prevent problems from occurring or minimize the disruptions they cause.

4.4.1 Selecting the instructors

"A trainer can be many things: a tutor, a supervisor, a manager or a counsellor" (*33*). The selection of trainers is a critical factor for the success of a training programme. A satisfactory performance does not qualify a person as a trainer because other skills are needed. To obtain the best results the trainer must have the following characteristics: (*24*)

- knowledge of the subject;
- a great desire to train;
- communication skills;
- ability to get people to participate; and
- a strong desire to meet trainees' needs.

For each training course, it is recommended that:

- minimum trainer requirements are established;
- each trainer attends a train-the-trainer course;
- the QC/QA unit analyse and approve the trainers; and
- the trainer's qualification be documented.

Depending on the training design, a trainer may need to have one or both of the two presentation styles:

- **Trainer-centred presenter:** A trainer who tells or informs trainees. It is a formal style, similar to a college or university lecturer.
- **Trainee-centred facilitator**: A trainer who functions in a way that allows participants to assume responsibility for their own learning; a trainer who listens to and guides trainees. It is a less formal style (*33*).

4.4.2 Preparing to deliver the course

If the course developer is also teaching the course, he or she should be very familiar with its organization and content; however, the trainer still needs to be prepared before delivering each course.

Even very experienced trainers prepare. Sometimes by going through the material slide-by-slide and activity-by-activity, they teach themselves the material out loud. Other trainers videotape a practice session, reviewing the video for ways to improve. Still other trainers think through the entire session, visualizing what the presentation will be like and preparing themselves for questions that could be asked.

Transitions between slides and topics are very important in showing how different pieces of information are related. Including bits and pieces from other training courses or from earlier in the same session helps to reinforce the learning.

If additional trainers are involved, there is usually a "train-the-trainer" programme that helps to standardize the way the training is done. An example of a simple train-the-trainers session would be as follows.

- Introduce the train-the-trainers session with its goal and agenda.
- Present the actual programme, with the trainers participating first as trainees.
- After the actual programme has been presented, go through the elements of the course, with particular attention to activities.
- Have the participants study the materials and then present parts of the programme to others.
- Identify questions that trainees may ask and what are the appropriate, consistent answers.

Sometimes, it is useful for trainers to work together, "team teaching" the first one or two sessions.

4.4.3 Preparing the training room (if used)

The particular course design will influence the materials, equipment and room arrangement. These all need to be prepared for and checked before the training session begins.

Some organizations use a checklist approach that includes:

- Room:
  - Is the room available?
  - Is the room large enough to comfortably accommodate the group size?
  - Are chairs comfortable?
  - Are the chairs and/or tables arranged in a manner that is appropriate for the course? (For example, in a "u" shape, small groups, or lecture style?)
  - Is enough table space provided for the trainees to spread out the materials that will be used during the course?
  - Is there enough visibility to let the trainees see the trainer and the visual aids?
  - Is the room temperature comfortable?
  - Is the room relatively free of noise and distractions?

- Equipment:
  - Is the equipment functioning properly?
  - Is the equipment located in the correct position?
  - Are the necessary extension cords available?
  - Do you have back-up or any accessories that could be necessary during a training session?
  - Has the overhead projector been focused before the training session begins?
  - Has all the equipment been tested together to assure compatibility before the training session starts? (When using computer projection and video equipment.)
  - Does the video tape to be used play on the equipment in the training room?

- Materials:
  - Are there enough handouts available for each trainee?
  - Do you have extra copies of handouts?
  - Are overhead transparencies or flipcharts easy to read for participants in the back of the room?
  - Are the correct types of markers available for flipcharts or boards in the training room?
  - Do you have additional pens or pencils and some paper available?

Assuring that everything is ready before the training session begins takes some time, but it will be well spent, preventing interruptions during the training session, allowing the trainer and trainees to focus on the training.

4.4.4 Delivering the training course

The trainer, whether presenting to a group or facilitating learning activities, can be more effective if he or she keeps in mind the following recommendations.

Begin the training session by:

- introducing yourself and your background;
- inviting trainees to introduce themselves to the group;
- indicating course objectives;
- reviewing the programme and schedule; and
- inviting trainees to be active.

During your training presentation do the following (*33*).

- Establish eye contact; it inspires confidence.
- Control nervous mannerisms; they can be distracting for trainees.
- Use visual aids; remember that one picture is worth more than a thousand words.
- Use simple language.
- Use pauses and silences.
- Summarize the main points.

Additional considerations when working with the trainees are as follows (*39*).

- Provide participants with an atmosphere of trust and safety.
- Help trainees overcome anxiety and other negative emotions that they often bring with them.
- Let participants feel comfortable, accepted and important so optimal learning can occur.
- Approach the training session with a playful attitude and using humour.
- Learn names and call each person by name.
- Assure participants that you are there to help them.
- Start and end the session on time.
- Take breaks (at least every 90 minutes) and allow people to leave the session spontaneously if needed.
- During break encourage the trainees to contact the trainer for questions, comments, suggestions, etc.
- Provide water for people to drink and other refreshments if appropriate.
- Organize your presentation with focus, practicality and stimulation.
- Experiment with your speaking style to see if it can be improved.
- Challenge trainees to think without coming across as arrogant or antagonistic.
- Use concise questions that will allow the respondent to elaborate the answer.

- Do not ask a person a question if you think he/she might not know the answer.
- Acknowledge all answers.
- Do not question the group in some predictable order.
- Call people randomly to keep people on their toes (alert).
- When responding to questions, be as specific as possible.
- If you do not know the answer to a question, admit it; do not evade the question.
- Ask the group for additional feedback after you have answered a question to ensure they understood the answer.

A list of questions, adapted from F.R. Abbatt, can be used in evaluating how well a teacher is doing the job (*40*). If the trainer can answer "yes" to most of the questions, then he or she is taking into consideration the main aspects of adult learning.

- Do you relate what you are talking about to the work the trainees will be doing?
- Do you give a lot of examples?
- Do you ask trainees to answer questions?
- Do you ask trainees to apply information in solving problems?
- Do you arrange for trainees to practice thinking and practical skills?
- Do you tell trainees how well they are doing?
- Do you point out any error or fault?
- Do you explain how trainees could do better work?
- Do you check that all your trainees understand each point?
- Do you frequently check whether every trainee has acquired the necessary skills and knowledge?
- Do you allow trainees to work at different speeds?
- Do you encourage trainees to learn in their own way?
- Do you use several instructional methods?
- Do you show the trainees that you care whether they do well or not?
- Do you prepare thoroughly for training sessions?
- Do you listen to trainees' comments about your training sessions?

5. Assessment and evaluation

If training is conducted to achieve a goal, it is reasonable to ask if the goals of the organization's training programme and the specific training course have been attained or not. Assessment and evaluation are conducted to determine if the goals have been met.

Assessment is sometimes used interchangeably with evaluation; however, there is a difference between them (*41*):

> **Assessment**: The measurement of an individual's skills, knowledge or attitude.
>
> **Evaluation**: An appraisal of the effectiveness of a training activity used to make decisions about a training course or programme.

Simply put, people are assessed while things are evaluated.

Assessment is performed in the workplace to determine if the trainee**:**

- has accomplished the goals and objectives of a training course;
- can perform the required tasks as defined in a procedure or method;
- can safely, effectively and efficiently perform the required tasks without constant supervision; and
- is applying in the job and workplace and performing as required what has been learned.

Evaluation is performed in the workplace to:

- make decisions about a new training course or instructional methods or media;
- improve a training course;
- determine what trainees think about the training session; and
- determine the organizational impact of the training.

5.1 Four levels of assessment and evaluation

The best known model for assessing trainees and evaluating training programmes was developed by Donald L. Kirkpatrick. It is a simple and practical approach that has evolved since its initial development. There are four levels used, with each level providing a different view of the trainee and the training efforts (*24*). These levels are:

- **Level 1. Reaction**: How did trainees react to the training session?

  This is an evaluation of what participants think and feel about the different aspects of a training programme, including the accomplishment of the learning objectives, the content, the trainers, methods and materials, schedule and usefulness. It tells the trainer what the trainees liked and benefited from and what they did not. Reaction evaluations should be used in every course.

- **Level 2. Learning**: What did trainees learn from the training session?

  This is an assessment of the knowledge, skills or attitude acquired or changed due to training. It is more difficult to measure than reaction as it involves some sort of testing that is performed at the end of the training course. This type of assessment can also help predict if the trainee will be able to apply the training in his or her job.

- **Level 3. Behaviour**: Do trainees use their new skills, knowledge and attitudes on the job?

  This is an assessment of the extent to which participants are applying what was learned during the training course back in their job; this is sometimes called "transfer". Behaviour is generally assessed 2–6 months after the training has been completed. Failure to transfer the training to the job does not necessarily mean that the training was deficient, as a number of factors, such as supervision, rewards, design of the job, motivation, tools and co-workers can influence behaviour on the job.

- **Level 4. Results**: How did the training benefit the organization?

  This is an evaluation of the impact that the training has had on the organization, conducted 6–24 months after the training. Results can show how training has contributed, for example, to a decline in deviations, waste, rejects or quality problems. Many things besides training can contribute or influence the impact that training has (or has not) had on the organization.

Here are some of Kirkpatrick's implementation guidelines for each level (24):

Reaction

- Determine what you want to find out.
- Design a form that will quantify reactions.
- Encourage written comments and suggestions.
- Develop acceptable standards.
- Measure reactions against standards and take appropriate actions.

Learning

- Use a control group, if feasible.
- Evaluate knowledge, skills or attitudes both before and after the training. For example, use a paper-and-pencil test to measure knowledge and attitudes and a performance test to measure skills.
- Use the results of the evaluation to take appropriate actions.

Behaviour

- Use a control group, if feasible.
- Allow enough time for a change in behaviour to take place.
- Survey or interview one or more of the following groups: trainees and supervisors and others who often observe trainee's behaviour on the job.
- Repeat the evaluation at appropriate times.
- Consider the cost of evaluation versus the potential benefits.

Results

- Use a control group, if feasible.
- Allow enough time for results to be achieved.
- Measure results both before and after training, if feasible.
- Repeat the evaluation at appropriate times.
- Consider the cost of evaluation versus the potential benefits.
- Be satisfied with the evidence if absolute proof is not possible to attain.

Table 4 shows a summary of the recommended steps to evaluate 3 out of 4 levels in a training programme. Level 4 has not been included because collecting and interpreting data is more difficult and time consuming, and simply surveying trainees does not provide enough useful data.

Important note: If the results of the training assessment (testing) could be used in deciding upon a person's wage, position or job status, some countries require that any such tests be reliable and validated. Before implementing testing, be certain you know and understand any such legal requirements that may apply.

5.2 Conducting level 1 evaluations

Most pharmaceutical and vaccine firms are using reaction or feedback forms after every classroom training event but less frequently after other training events (e.g. OJT and SOP training).

Examples of evaluation forms are shown below (Figure 1).

5.3 Conducting level 2 assessments

Many pharmaceutical and vaccine firms are using assessments of performance after SOP or OJT training to assure that the trainees can safely and effectively perform the task(s). Fewer firms use knowledge assessments after classroom or other training covering information or intellectual skills.

A key consideration in designing the assessment is that the closer the assessment is to how the person actually will do his or her job, the more assurance the trainer will have that the person will be able to perform as required. For example, after a training course on proper gowning technique, a trainee may be able to answer, on paper, many questions about gowning, such as the proper sequence for putting on the gown and the importance of not contaminating it. However, it is far more important that the person be able to *perform* the task of putting on a gown, in the proper sequence without contaminating it. Therefore, a *combination* of a knowledge and skill assessment would be the best way to determine what the person has learned.

Relationship to objectives

If properly written learning objectives were created in the design phase (see section 4.2), developing assessments are relatively simple.

Take the following examples.

Example #1: At the end of the course, supervisors should be able to:

- define 10 key words and concepts related to good manufacturing practice (factual information).

With the above objective, the assessment would be for the trainee (the supervisor, in this case) to write, select or match definitions to one or several of the key words or concepts that were covered in the course.

Example #2: At the end of the course the trainee will:

- given all the elements of a sterile uniform, clothe with minimal non-viable particle contamination and no microbial contamination as determined by RODAC plating on the uniform (motor skill);
- given a failure situation, take actions that will not contaminate the gowning room or the aseptic area (intellectual skill).

To demonstrate that the trainee has accomplished the first objective, he or she would actually put on the uniform in the correct sequence without compromising its sterility. A further confirmation of this would be through microbiological samplings using contact or RODAC plating of the uniform's surface and gloves while being worn by the trainee.

To demonstrate that the trainee has accomplished the second objective, the trainer would observe what the trainee would do if any problems were encountered (e.g. the gown falls on the ground or if a glove breaks). If nothing does go wrong while gowning, the trainer could ask "what if" questions, such as, "What would you do if your glove breaks while putting on your gown?"

Example #3: At the end of the course the trainee will:

- given a batch production record and all supporting documents, determine if the records are satisfactory to allow the release of the batch or identify the deficiencies and the actions that need to occur (intellectual skill).

This is a more complex objective. To determine if the trainee can accomplish this, a "simulation" batch record could be assembled that includes some of the typical issues and problems that the trainee would encounter. The trainee would be successful if he or she found all of the problems and defined the actions that should then occur.

In all of these examples, the objectives were used as the basis for the assessment and the assessment was closely matched to how the task was normally performed.

Assessment and evaluation is where the time spent in writing clear, specific and meaningful goals and objectives yields its benefit: the better written they are, the easier it is to write valid test questions.

Assessment methods

There are several assessment methods to evaluate knowledge, skills and attitudes:

- oral examination
- written examination (using paper or computer systems)
- simulations (actual or virtual using computers)
- performance-based assessment.

Each assessment method has some advantages and some disadvantages. The trainer should decide what knowledge, skill or attitude needs to be assessed and then select the best method of assessment. This should be determined during the design of the training course.

- **Oral examination**

  Each trainee is asked to tell the trainer what he/she knows about a topic or what he/she would do in a hypothetical situation that might happen in relation to his/her job. Another example would be a trainer pointing out control switches on a piece of equipment and asking the trainee to identify the control and how it is used.

- **Written examination**

  There are several types, including the following.

  – *Essays:* Trainees write one or more paragraphs to answer a question. Essays can be used to assess the trainee's knowledge and attitudes.

    Examples:

    Describe and compare the methods used for obtaining water for injection (WFI) according to United States Pharmacopoeia (USP).

    Based on your experience, write a short example of why it is important to always follow a procedure as it is written.

– *Short-answer questions*: Trainees write a few words to answer a question.

  Example:

  Name the methods used for obtaining WFI according to USP.

– *Multiple-choice questions*: Trainees select the answer from among several possible answers.

  Example:

  Which are the methods used for obtaining WFI according to USP? Mark all that apply:

  a) Distillation
  b) Reverse osmosis
  c) Ultra-filtration
  d) Continuous deionization

– *True/false questions:* Trainees answer true or false to each statement.

  Example: Mark which statements are true or false:

  Water for injection according to USP can be obtained by:

  __ Distillation
  __ Distillation and reverse osmosis
  __ Distillation, reverse osmosis and ultra-filtration
  __ Reverse osmosis
  __ Continuous deionization

– *Matching questions:* Trainees match corresponding items in two lists.

  Example: Match the methods used by writing the letter of your choice in the blank in no. 1, 2 and 3 below:

  a) distillation, reverse osmosis and ultra-filtration.
  b) distillation and reverse osmosis
  c) reverse osmosis
  d) distillation
  e) ultra-filtration.

  1) For obtaining WFI according to USP: ____
  2) For obtaining WFI according to the European Pharmacopoeia: ____
  3) For obtaining WFI according to the Japanese Pharmacopoeia: ____

- **Performance-based assessments:**

Trainees demonstrate their actual skills and knowledge on assigned tasks. These tests use well-trained observers with a checklist that resembles the actual work situation. The observer and the trainee receive instructions regarding objectives, performance standards and scoring procedures.

When using performance-based assessments, it is important for the observer to be consistent about providing coaching or information to all the trainees. When multiple observers are used in a department, all the observers should, before the assessments start, agree on what constitutes an "acceptable" performance. Sometimes trainers call this step, "calibrating the eyes of the observers".

Pre-test and post-test

Pre-tests are useful to help trainees to focus better on the course's materials and to point out some of the important topics that will be covered in the training course. Pre-tests are also useful in showing the difference that the training course makes in bridging the gap between what a person does not know coming into the course and what they know at the end of the course.

Action plans

For some types of training, particularly those in which information and facts are given, for example in a general programme about GMP, a useful exercise is for the trainees to create an action plan, that is, a list of ideas on how they are going to use the information back in their jobs.

The action plan could be retained by the trainees themselves or shared with others or their supervisors. In other situations, a copy of the action plan can be kept by the trainer and then returned to the trainee in 3–6 months for the trainee to review and determine if he/she has put the actions into practice.

Action plans can also be used to evaluate transfer (level 3, above). This type of self-reporting can then be verified by trainers or quality auditors, if desired.

5.4 Conducting level 3 assessments

Level 3 assessments determine if the trainee is applying what was learned during the training course back in their job. Checklists are useful tools in helping trainers or supervisors as they conduct their observations.

If a clear, concise goal was written for the course, such as, "clean the tank using procedure #123", you determine if the person is currently doing this satisfactorily. This could be done by observing the person as they are cleaning the tank, to make sure that all the steps are being performed as defined in the procedure.

Another way is to review the records and documents that the person generates. For example, if the goal of the training was to "record information according to the standards defined in procedure #321", you would review a laboratory notebook, data collection sheets, logbooks and the like to determine if they are correctly prepared.

Deviations or problems can indicate that a person is not performing a task properly on the job.

In all cases, if the person is not performing as desired, it does not necessarily mean that they were inadequately trained. They may have found shortcuts or other ways of doing things and have not been given feedback that those variations are not acceptable.

Relatively few pharmaceutical and vaccine manufacturers formally do level 3 assessments as part of their training efforts, however most firms do determine, during GMP/quality audits, if people are performing as desired. Regulatory inspections also do this.

An easy place to start with level 3 assessments is on record keeping because problems are simple to count and categorize.

5.5 Conducting level 4 evaluations

Few pharmaceutical and vaccine firms have formal evaluation plans.

Some areas where this has been used is in determining how procedures, training and practices contribute to "first time right" batch production records; fewer rejected batches, fewer recurring deviations, and fewer regulatory or audit observations of non-compliance.

Table 4: Evaluation of training programmes

		Kilpatrick's levels*		
	Evaluating steps	**Level 1: Reaction**	**Level 2: Learning**	**Level 3: Behaviour**
1.	Define the objectives of the evaluation course	Find out how the trainees feel about the knowledge and the skills of the course	Find out whether trainees acquired the performance	Find out whether trainees improved their job
2.	Identify data sources	Trainees	Trainees	Trainees Colleagues Supervisors
3.	Choose the method for collecting data: a) Frequency b) Use of control group c) Sample size	a) During and immediately after the course b) Does not apply c) 100%	a) Pre-test and post-test b) If feasible c) 100%	a) Long-term follow-up b) If feasible c) 100% or appropriate sampling
4.	Adapt or develop evaluation tools	Written feedback forms Oral feedback	Oral tests Written tests Computer-based assessments Performance assessments	Observation checklists Performance records Interviews, etc.
5.	Analyse data	Make course adjustments	Make course adjustments	Make programme adjustments Identify barriers to training

* Level IV is not included

Figure 1: Feedback forms

Example #1

Feedback form

Name of facility: _____

Date: _____

Training course: _____

Trainer: _____

We want to know what you think and feel about this course. We need your help and comments in order to improve the course for future trainees. Please circle your rating for the questions below.

1. To what extent do you think you will use the knowledge/skills that you have learned in this course?

1	2	3	4	5
Not at all				Very much

2. How appropriate were the methods used in this course?

1	2	3	4	5
Completely inappropriate				Completely appropriate

3. How satisfied were you with the materials used in this course?

1	2	3	4	5
Not at all satisfied				Completely satisfied

4. How satisfied were you with the trainer?

1	2	3	4	5
Not at all satisfied				Completely satisfied

5. What part of the course was most useful to you?

_____

6. Least useful?

_____

7. What other comments or recommendations do you have?

_____

Example #2

Feedback form

Name of facility: _____

Date: _____

Training course: _____

Trainer: _____

We hope you have found the GMP training course useful and enjoyable. To evaluate your satisfaction with this module, we would greatly value your comments and suggestions.
Please take a few minutes to answer the questions on this form.

1. How would you rate the GMP training course in terms of relevance to your job?

1	2	3	4	5
Poor				Excellent

2. Were the materials presented in an easy-to-follow format?

1	2	3	4	5
Poor				Excellent

3. Did the trainer present the information in a way to help you learn?

1	2	3	4	5
Poor				Excellent

4. Did the trainer stimulate your interest in learning?

1	2	3	4	5
Poor				Excellent

5. Which topic or topics were the most valuable to you?

_____

6. Which topic or topics were the least valuable to you?

_____

7. In what ways will the GMP training course improve your work?

_____

8. How do you think the GMP training course can be improved?

_____

9. Do you have any other comments about the GMP training course?

_____

Example #3

Feedback form

Course:

This feedback is anonymous; your name is not required. Your feedback is very valuable to us so we can continue to improve the modules. Please circle below only one number, the one that best matches your response or reaction. Please feel free to add comments on a separate page. Circle "0" for "no comment" or "not applicable".

Job related

		Strongly agree	Agree	Disagree	Strongly disagree	No comment or N/A
1.	The course helped me develop skills that are important to me.	4	3	2	1	0
2.	The course met my needs.	4	3	2	1	0

Anything missing? I thought the course could have the following added to it:

_____

If you circled a 1 or 2: What sort of courses do you need to help meet your needs?

_____

The trainer

		Strongly agree	Agree	Disagree	Strongly disagree	No comment or N/A
1.	The trainer managed the workshop well.	4	3	2	1	0
2.	The trainer presented the subject matter clearly and accurately.	4	3	2	1	0
3.	The trainer handled questions well.	4	3	2	1	0

Overall, I thought the trainer was: _____

If you circled a 1 or 2: What could the trainer do to improve?

_____

Course design

		Strongly agree	Agree	Disagree	Strongly disagree	No comment or N/A
1.	The course material was clear and well presented.	4	3	2	1	0
2.	The presentation materials used were useful.	4	3	2	1	0
3.	The practical work supported the presentation.	4	3	2	1	0
4.	The course duration was correct.	4	3	2	1	0
5.	The course covered the relevant subject matter.	4	3	2	1	0

Overall, the course was: _____

If you circled a 1 or 2, what could be done to improve the course?

_____

(Feedback form example 3 continued...)

Satisfaction

		Very high	High	Average	Low	Very low	No comment or N/A
1.	My overall satisfaction with the course is:	5	4	3	2	1	0
2.	My awareness of the subject matter ***prior*** to the course was:	5	4	3	2	1	0
3.	My awareness of the subject matter ***after*** the course is:	5	4	3	2	1	0

Any other comments? _____

If you circled a 1 or 2 for q1 or q3, what can be done to improve the course?

_____

Facilities/administration

		Strongly agree	Agree	Disagree	Strongly disagree	No comment or N/A
1.	The course area was conducive to learning.	4	3	2	1	0
2.	There were sufficient breaks.	4	3	2	1	0
3.	The arrangements for breaks were adequate.	4	3	2	1	0
4.	I was given clear joining instructions.	4	3	2	1	0

Overall, the facilities were: _____

If you circled a 1 or 2, what could the trainer do to improve?

_____

Course design

		Strongly agree	Agree	Disagree	Strongly disagree	No comment or N/A
1.	The course material was clear and well presented.	4	3	2	1	0
2.	The presentation materials used were useful.	4	3	2	1	0
3.	The practical work supported the presentation.	4	3	2	1	0
4.	The course duration was correct.	4	3	2	1	0
5.	The course covered the relevant subject matter.	4	3	2	1	0

Overall, the course was: _____

If you circled a 1 or 2, what could be done to improve the course?

_____

(Feedback form example 3 continued...)

Overall

		Strongly agree	Agree	Disagree	Strongly disagree	No comment or N/A
1.	I enjoyed the course.	4	3	2	1	0
2.	I would recommend the course to others.	4	3	2	1	0

Any other comments? _____

If you circled a 1 or 2, what can be done to improve the training module?

_____

Additional comments

_____

_____

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Thank you for the time spent completing this form.

Other aspects not related to the effectiveness of a training programme that should also be evaluated are:

- number of training activities conducted vs number of training activities planned;
- number of training activities conducted within the time frame;
- number of people attending programme vs number of people scheduled for the programme; and
- actual costs of training vs estimated costs.

6. Administrating a training programme

6.1 Training policies and procedures

Most firms have one or two different functional documents (i.e. policies and procedures) that define and describe their training efforts, including training on GMPs, SOPs, safety and environment protection.

6.1.1 Policies and procedures

Policies are high-level documents that briefly define the goal and general objectives related to training in the organization.

Procedures are functional documents that describe in more detail what is included in the training programmes, the organization(s) responsible for providing and supporting training, how and when the training is provided, what and how training-related records are kept, what assessments and evaluations are done and when, and who is responsible for these actions.

"A training SOP is an expectation of the agency and quality auditors because it is feasible and valuable: The leading companies in our industry each have one, and it is added to the control of each company's operations, products and decisions" (*15*).

A company may have one or several procedures on training, for example, one procedure covering different types of training and another covering training records. Obviously, one training procedure covering all training-related topics would be considerably longer than those that are more limited in scope.

6.1.2 Topics to include in a training procedure

Some of the topics that are generally covered in training procedures include the following:

- **scope**: what departments or sites are covered by the procedure;
- **trainees**: who receives training and when – new, current, management, supervision, contract and temporary personnel (see section 3);
- **curricula**: what training is required and when it is provided; this could identify who develops, maintains and approves curricula for all personnel receiving training;
- **training plans**: who develops and approves them;
- **course development and acquisition**: who does it; how in-house programmes are developed and how outside programmes are evaluated before they are purchased;

- **periodic reviews**: when are training materials reviewed for updating and who does it;
- **change control related to training materials**: how changes are proposed and approved; considerations for those who have previously gone through the training session;
- **training materials**: who keeps the approved master version of all materials and how it is done;
- **training administration**: who schedules, prepares materials, reserves facilities;
- **assessments and evaluations**: what is done, when they are used, how they are to be developed;
- **instructors and trainers**: how they are qualified and approved;
- **training records:** who develops, maintains and reviews training records; how they are maintained (e.g. paper or electronic system).

When writing training policies and procedures, the relevant GMP regulations and requirements should be reviewed to ensure that these expectations are included and updated.

6.2 Training plans

A training plan that outlines the specific training requirements should be developed each year. Training plans help manage a training programme and let training session participants, trainers and their managers schedule their time in advance. The following aspects should be considered when preparing it.

- Who is to be trained?
- What courses should be given?
- How many times will a course be given during the year?
- Are there certain times of the year when new hires, temporary or contract personnel are brought into the facility, requiring more training?
- Who are the trainers for each course?
- When and where will the courses be held?
- Which are the resources available?

For planning purposes, dates may be scheduled and later the training coordinator can establish the specific time. The needs and desires of trainees as well as supervisors and managers should be the primary consideration when establishing the plan; trainer resources, equipment and facilities must also be considered. The training plan should be approved before it is published.

Some organizations publish their plans in brochures that are widely distributed to their personnel. Other groups create posters with courses, dates and times to inform personnel in their facilities.

See an example of a training plan format (Table 5).

Table 5: Training plan format

Name of facility						
Training plan						
Year						
Objectives	**Training activity**	**Trainer**	**Participants**	**Dates planned**	**Length and no. times/year**	**Supplementary resources**

6.3 Documenting training

Often the training is done, but it is not properly documented. For this reason, it is not possible to know who was trained and when employees should be trained again.

Training records provide the evidence that the training was carried out. During the design of the training programme, training records should also be designed. Quality assurance should audit training records periodically.

"No documentation of employee training" was one of the major findings of Team Biologics presented by Steven Masssiello (Director, Office of Compliance and Biologics Quality, CBER, FDA) at the 24th International GMP Conference (*42*).

The approved training procedure should define how training records are prepared, reviewed and maintained.

It is advisable to keep the following training documents:

- training requirements
- employee-training records
- training attendance records.

6.3.1 Training requirements

A description of the required training for each job function should be prepared. It should include GMP, SOPs, safety and job skills, and should be developed for every employee whose work affects product quality, including supervision and management. This document is also called a *curriculum* for the position that lists the courses and when the training should be given.

An example of a training requirements form for SOP training is given in Table 6 (based on Daley, 1998) (*43*).

Table 6: Example of a training requirements form for SOP training

Name of facility	
Training requirements for SOP training Job description: Vaccine-formulation operator Department: Formulation	
SOP #	**Title**
05 001	Gowning for the clean room
05 002	CIP/SIP of aseptic processing system
05 003	Buffer preparation and batch sterilization
05 004	Gel preparation and batch sterilization
05 005	Thiomersal solution preparation and filtration
05 006	Filter integrity test
Filled by:	Date:
Reviewed by:	Date:

Some companies have job description training requirements forms that cover more than SOPs, such as, for example, GMP topics and job skills.

6.3.2 Employee-training record

This is a record of the history of the training and results obtained for each employee, which will detail the kind of training received, the date, and the names and signatures of the trainer and the trainee.

See Table 7.

Table 7: Examples of employee training records

Example #1

Personal training record					
Employee's name:			**Commencement date:**		
Date	**Employee's signature**	**Present status**[a)]	Item[b]	Duration (d – days or h – hours)	Supervisor's or trainer's signature

a) A = GMP auditor, T = trainee GMP auditor, S = specialist , O = observer
Skill level 0 = under training, 1 = can undertake under supervision, 2 = can undertake with no or minimal supervision, 3 = can train others

b) SOP number (including revision number) SOP#/rev#, or type of training (T) (give details e.g. if internal or external) or personal development (P), assign proficiency rating: T = trainee, must not undertake activity, P1 = proficient but must be supervised, P2 = proficient, may operate without direct supervision, P# = highly proficient, may train others.

Example #2

Name of facility					
Employee-training record					
Department:					
Name and surname:					
Job position:					
Date of joining:					
Date	Type of training	Session title	Trainee signature	Trainer signature or certificate of attendance	Remarks

6.3.3 Training attendance record

For each training session led by a trainer there will be a training record with the trainees' name, and signature, the trainer's name and signature, title and description of the training session, the approximate length of training and the date. See Table 8.

Table 8: Examples of training attendance records

Example #1

Training session record			
Company:			
Address:			
Subject:			
Name (please print)	**Title/organization**	**Opening Date: Time:**	**Closing Date: Time:**
		Signature:	**Signature:**

Example #2

Name of facility:			
Training attendance record:			
Title and description of the training session:			
If SOP, version date:			
Length of training:		Date:	
Trainer's name:		Trainer's signature:	
Surname	Name	Department	Signature

6.3.4 Computerized systems for tracking training

There is a trend to use software to track GMP training. Many companies enter the training records into a system for tracking training. "Learning management systems" is the term currently being used for these tools. See Table 9.

Table 9: Examples of some commercially available software for tracking training

Software for tracking training	Vendor names/remarks
Training Tracker III	Interpharm Press
Plateau	Plateau Systems Ltd
Registrar	Silton-Bookman. Developed for colleges to register students for classes but it has been adapted to track SOPs training as well as seminars and courses.
PharmSchul	A software for training administration, evaluation and documentation
People soft	ERP Software
Aurion	Aurion Corporation Pty Ltd

Many trainers are using packages developed "in house". For example, a computer-based system was developed to track and document employee training. It also enables tracking all personnel transactions of employees (*44*).

A paper-based system can be implemented with a little organization and care. This system uses a traffic light code: red untrained, amber trained but not assessed, and green fully trained. A date in the green shows when retraining is required (*45*).

Any record-keeping system should allow easy determination of all training that a specific employee has received and the ongoing training requirements for employees, including dates by which training should be accomplished.

Tracking or learning management systems should be qualified to demonstrate that they can consistently maintain data and produce reports that are reliable and trustworthy.

7. Questionnaire

Now that you have reviewed *A WHO guide to good manufacturing practices (GMP) requirements. Part 3: Training*, we would like to know your thoughts about this document. We would appreciate it if you would take a few minutes to answer the following questions and to return the questionnaire to the Global Training Network by mail or fax.

World Health Organization
Department of Immunization, Vaccines and Biologicals
Access to Technologies
Global Training Network
CH-1211 Geneva 27, Switzerland
Fax: +41 22 791 4384

1. What is your overall impression of the guide?

- ☐ 1. Poor
- ☐ 2.
- ☐ 3.
- ☐ 4.
- ☐ 5. Excellent

What section was most useful for you?

_____

What section was least useful for you?

_____

How could the guide be improved?

_____

2. Would you recommend this guide to others?

- ☐ Yes
- ☐ No
- ☐ I do not know

Please give a reason for your response

_____

What other comments or recommendations do you have?

_____

_____

_____

_____

_____

Annex 1:
List of training document titles from vaccine manufacturers

Centro Nacional de Biopreparados (BioCen), Cuba

GMP modular programme

New-employee training

Training needs analysis and planning of systematic on-the-job training

GMP training programme for personnel working in aseptic processing areas

Qualification and microbiological monitoring of the aseptic gowning process.

Preparation of personnel training files

Serum Institute of India Limited, India

Training policy

Training manual

GMP training programme

On-the-job training

Training procedure – quality assurance

Annex 2:

SOPs and other training documents contributed by vaccine manufacturers

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GMP training programme SOP No.: 039 0039 84
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Centro Nacional de Biopreparados (BioCen), Cuba 91

Qualification and microbiological monitoring of the aseptic gowning process. SOP 05A.102 91

Serum Institute of India: GMP training programme

Department: Quality Assurance (QA)		***Page: 01 of 03***
Title: GMP training programme		
SOP No.: 039 0039		**Revision No.: New**
Effective date: 01.08.1998	**Replaces: -**	**To be reviewed on: June 2000**

Distribution:

Three original sets shall be prepared.

One set will be maintained with Executive Director (QA).

Another set will be maintained with department head.

Third set is for approval of Central Drugs Laboratory (CDL), Kasauli.

Xerox copy may be taken and retained in respective departments for reference and display.

1. Purpose:

The objective of this SOP is to describe the training programme for all the production, quality control, quality assurance and stores personnel, to reinforce general GMP training.

2. Scope:

This SOP applies to periodic GMP training of all units associated with the manufacturing of the product.

3. Responsibility:

It is the responsibility of quality assurance personnel to provide and reinforce current good manufacturing practices (cGMP) training.

Individual departments may provide their own cGMP training as well. It does not have to coincide with quality assurance's programme. It is the responsibility of the quality assurance chief to ensure that this SOP is followed and updated as needed.

(Mrs Y.S. Wagh)	**(Mr M.M. Javadekar)**	**(Mr M.M. Javadekar)**	**(Dr S.S. Jadhav)**
Written by	**Checked by**	**Dept. head**	**Executive Director (Quality Assurance)**

SEAL

4. Materials and equipment: As needed for each topic.

5. Procedure:

5.1 Determine what kind of training is needed for personnel. Some possible topics might be: Documentation, basic microbiology, proper gowning techniques, possible sources of contamination, a writing workshop.

5.2 Each topic can last for three months, or be a theme for six months.

5.2.1 On the job training: Person will be trained in the work by directly taking him on the job under the supervision of the experts.

5.2.2 Questionnaire: Set of questions related to work and GMP formed by the departmental head and quality assurance shall be circulated and got answered by a concerned group of people to evaluate and to decide the mode and aspect of training.

5.2.3 Discussions/forums: Forums could be a good way to reinforce SOPs already in place, or to discuss what improvements could be made.

5.2.4 Class: Establish objectives for the class and display them. Be sure to have methods of encouraging discussion when finishing the class, be sure to address the objectives and what was taught during class.

5.2.5 Publications: Constant reminders of the topics are good reinforcements.

5.2.6 Contest: A lab-wide contest should be held to help people think about the topic on their own operators may work in teams of no more than four. Each contest may have its own specific rules, and will be judged by the quality assurance department.

5.2.7 Schedule: Department workshops will be scheduled during a one week period. Other workshops will be offered for groups of four or more at the groups' convenience.

Department: Quality Assurance (QA)		*Page: 03 of 03*
Title: GMP training programme		
SOP No.: 039 0039		**Revision No.: New**
Effective date: 01.08.1998	**Replaces: -**	**To be reviewed on: June 2000**

6. Documentation:

6.1 Keep a file of each topic. Include any overheads, handouts, quizzes, and contest entries.

Serum Institute of India Ltd.

212/2, Hadapsar, Pune – 411 028 (India)

Training attendance

Title:

Instructor: Date:

Name	Entered	Name	Entered
Department approval Date:		Quality Assurance approval: Date:	

7. Reference document: None.

(Mrs Y.S. Wagh)	**(Mr M.M. Javadekar)**	**(Mr M.M. Javadekar)**	**(Dr S.S. Jadhav)**
Written by	**Checked by** SEAL	**Dept. head**	**Executive Director (Quality Assurance)**

Serum Institute of India: on-the-job training

Department: Quality Assurance (QA)		***Page: 01 of 03***
Title: On-the-job training		
SOP No.: 039 0047		**Revision No.: New**
Effective date: 01.12.1999	**Replaces: -**	**To be reviewed on: 01.01.2002**

Distribution:

Three original sets shall be prepared.

One set will be maintained with Executive Director (QA).

Another set will be maintained with department head.

Third set is for approval of Central Drugs Laboratory (CDL), Kasauli.

Xerox copy may be taken and retained in respective departments for reference and display.

1. Purpose:

The objective of this SOP is to describe the method for training the person for doing the job assigned to him efficiently and correctly abiding the rules of GMP.

2. Scope:

This SOP applies every employee worker/officer at the time of his joining, at the time of change in the nature and the type of the job he is doing, at the time of change in the procedure and at the time of change of the department.

3. Responsibility:

It is the responsibility of the head of the department to train the people in his department and to maintain proper record of the training.

(Mrs Y.S. Wagh)	**(Mr M.M. Javadekar)**	**(Mr M.M. Javadekar)**	**(Dr S.S. Jadhav)**
Written by	**Checked by**	**Dept. head**	**Executive Director (Quality Assurance)**

SEAL

Department: Quality Assurance (QA)		*Page: 02 of 03*
Title: On-the-job training		
SOP No.: 039 0047		**Revision No.: New**
Effective date: 01.12.1999	**Replaces: -**	**To be reviewed on: 01.01.2002**

4. Materials and equipment: As needed.

5. Procedure:

   5.1 Whenever a new person is recruited he shall be given a formal Introduction training which will cover an overview of the company, the importance and general requirements of the job which the new recruit shall be performing and basic training so as to enable the recruit to acquire basic skills required for the designated job.

   5.2 After assigning the job, the recruit shall perform the duties under the direct supervision of the person designated for this purpose. The duration of this phase of the training shall be decided by the head of department (HOD). Then a recruit will be reviewed to find the extent to which he has acquired the skills. The recruit shall be given the additional training to overcome the lacunae if any. After the satisfactory completion of this training and proper recording of the same, the recruit can perform the assigned job.

   5.3 Again at the time of assignment of new job or any change in the procedure of the job being performed presently or at the time of change of the department, all the above steps mentioned in point No. 2 will be followed. The duration of the training may change depending on the nature of the new job and person's previous history regarding the exp. and the training record.

   5.4 All the above steps of training shall be mainly based on the standard operating procedures (SOP) followed in the department, where the person is working, in addition to GMP training imparted to him from time to time.

   5.5 Training records and data shall be reviewed and updated from time to time, as and when required as per the decision of the head of the department in a time span of not more than two years.

(Mrs Y.S. Wagh)	**(Mr M.M. Javadekar)**	**(Mr M.M. Javadekar)**	**(Dr S.S. Jadhav)**
Written by	**Checked by**	**Dept. head**	**Executive Director (Quality Assurance)**

SEAL

6. Documentation:

Keep a file of individual person giving a record of history of training he has undergone in a given format.

Serum Institute of India Ltd.

Name of the person: Token No.:

Date of joining:

Date	Description of training	Period of training	Given by	Employee sign	Review on/by	Remark

(Mrs Y.S. Wagh)	(Mr M.M. Javadekar)	(Mr M.M. Javadekar)	(Dr S.S. Jadhav)
Written by	Checked by	Dept. head	Executive Director (Quality Assurance)

SEAL

BioCen: training and qualification of gowning process SOP

Qualification and microbiological monitoring of the aseptic gowning process.	Code: SOP 05A.102
Approved by: **Marisely González Soler** **Albertina Y. Estrada Rodríguez** **(Name, signature, stamp)**	**Edition No.: 01 Date: 29.09.00** **Substitution date:**
Category of the substitution:	

1. Purpose:

To establish the methodology for the training, qualification and microbiological control of the gowning process for entering the aseptic processing area.

2. Scope:

It applies to all personnel working in the filling aseptic processing area: operators, technicians, specialists and the personnel from maintenance or the electronic group, which have access to it.

3. Responsibilities:

3.1 The person responsible for compliance with what is established in this procedure is the head of the plant for parenteral products.

3.2 The process control laboratory of the plant is responsible for carrying out what is established in this procedure.

3.3 The persons responsible for controlling and verifying the fulfilment of what is disposed in this procedure are the heads of the formulation, preparation of materials and aseptic filling areas.

4. Terms, definitions and symbols:

4.1 Terms:

GMP: Good manufacturing practices.

5. Equipment, materials and raw materials:

5.1 Equipment:

5.1.1 Semi-automatic disinfector ASEPTIMAC.

5.1.2 Electric hand dryer.

5.2 Materials:

5.2.1 Sterile aseptic area uniform.

5.2.2 Transit footwear for use in the locker-room.

5.2.3 Sterile footwear.

5.2.4 Sterile gloves.

5.3 Raw materials:

5.3.1 Class A 70% ethylic alcohol solution. Prepared according to SOP 05A.041 “Preparation of solutions for parenteral products plant 2”.
0,1 % soap solution, prepared according to SOP 05A.041, or soap, if it is lacking.

6. Procedure

6.1 Theoretical training in aseptic gowning:

6.1.1 The theoretical training in aseptic gowning will be given on one hand by a trainer to all the personnel newly admitted at the centre and the personnel from the clean room shall be re-qualified once a year.

6.1.2 The personnel to receive the training will review the videos “Now ...wash your hands” and “Gowning for the clean room” together with the trainer.

6.1.3 The trainer will stimulate the discussion among the trainees by questions related to both videos.

6.1.4 The trainer will read the valid gowning procedure for entering the clean room and will explain the dressing sequence.

6.1.5 The trainer will carry out a practical display of the aseptic gowning technique for all the personnel.

6.1.6 The personnel will practice the process of putting on the uniform and gloves in a training area, outside the clean room.

6.1.7 The trainer will supervise the gowning process in the locker-room three times, before performing the qualification tests and the microbiological monitoring, during which he will correct all the mistakes made by the personnel and will point out the correct way to do it.

6.1.8 With the elements acquired during the theoretical training, the personnel must demonstrate the knowledge to pass the first qualification stage.

6.2 Stage 1: Qualification in the aseptic gowning process.

6.2.1 The qualification in the aseptic gowning process will be performed once a year and will be completed with three consecutive satisfactory results.

6.2.2 The personnel shall dress in a specific area (locker-room at the entrance of the clean room) and will be supervised by the trainer. The personnel must show abilities and knowledge of the elements of GMP that must be used during the entrance to the clean room.

6.2.3 The trainer must observe the hand washing operation, the performance sequence and face washing. He must guarantee the absence of make-up and jewellery, observe that all the hair is inside the cap.

6.2.4 The trainer must observe the gowning procedure, the sequence for putting on the uniform. He must observe the application of the GMP required during the operation of putting on the sterile uniform.

6.2.5 The trainer must observe the putting on of the sterile gloves, if the changes foreseen in the SOP 05A.009 “Entrance and exit of the personnel from plant 2 of parenteral products” are made and how the operation is carried out considering the GMP elements.

6.2.6 The trainer must observe the inspection of the sterile uniform in front of the mirror by the personnel, before they enter the clean room.

6.2.7 The trainer must document the operation of aseptic gowning supervision in the form found in Annex 1. [Annex 1 is listed under #9 below.]

6.2.8 The personnel obtaining three consecutive satisfactory results will qualify in aseptic gowning and will proceed to the following qualification stage, which is the microbiological control of the sterile uniform after the personnel has put it on.

6.2.9 The personnel rejected in one of the three attempts must begin the training from the theoretical part, until three satisfactory results are completed in the qualification of the aseptic gowning technique.

6.2.10 The operations gathered in AC 1917 "Qualification and monitoring of the aseptic gowning processes", see Annex 1, are supervised by the designated trainer and approved by the audit and inspection Department of Quality Assurance.

6.3 Stage 2: Microbiological monitoring of the sterile uniform:

6.3.1 Once personnel have passed the three qualification stages of the aseptic gowning technique, the abilities to put on the uniform will be proved by performing the microbiological control of the uniform.

6.3.2 Personnel from the process control department of the filling plant will carry out microbiological sampling by the contact plate technique: RODAC according to SOP 05A.035 "Microbiological control of surfaces and personnel by the RODAC method in the clean room of plant 2 for parenteral products".

6.3.3 The plates will be identified with the following data:

6.3.3.1 Name of the sampled personnel.

6.3.3.2 Sampling site.

6.3.3.3 Sampling date.

6.3.4 Zones to be sampled:

6.3.4.1 Gloved fingers of the right hand.

6.3.4.2 Gloved fingers of the left hand.

6.3.4.3 Right forearm of the sterile uniform.

6.3.4.4 Left forearm of the sterile uniform.

6.3.4.5 Upper end of the zipper of the sterile uniform.

6.3.4.6 Lower end of the zipper of the sterile uniform.

6.3.4.7 Extreme front of the left boot.

6.3.4.8 Extreme front of the right boot.

6.3.5 Samples will be incubated at 31°C for 72 hours in the process control laboratory, according to SOP 05A.035.

6.3.6 After three days of incubation of the plates, personnel from the process control laboratory shall inspect them and register the data in the AC 1917, see Annex 1.

6.3.7 The person in charge of the process control laboratory will inform the trainer of the results of the reading of the plates.

6.3.8 The personnel approved will have not more than 5 colony forming units per plate, in each of the three results and will have passed qualification stage 2, microbiological monitoring of the sterile uniform.

6.3.9 The personnel having more than 5 colony forming units per plate, will be rejected and must repeat the training starting from the theoretical training in aseptic gowning.

6.3.10 The trainer will inform and discuss with the personnel the results of the microbiological tests.

7. Documentation requirements

7.1 AC 1917 " Qualification and monitoring of the aseptic gowning processes".

8. References/applicable documents

8.1 SOP 01.060 "Redaction, contents, format and identification of the standard operating procedures (SOP)".

8.2 SOP 05A.009 "Entrance and exit of the personnel from plant 2 of parenteral products".

8.3 SOP 05A.035 "Microbiological control of surfaces and personnel by the RODAC method in the clean room of plant 2 for parenteral products".

8.4 "Validation and environmental monitoring of aseptic processing" *Journal of Parenteral Science & Technology*, Vol. 44, No. 5, September–October 1990.

8.5 SOP 05A.041 "Preparation of solutions for plant 2 of parenteral products".

9. Annexes

9.1 Annex 1 AC 1917 "Qualification and monitoring of the aseptic gowning process", referred to in paragraphs 6.2.10 and 6.3.6.

Prepared by: Sara Hernández Armas Post: Second head of the plant	Signature: Date: 26.09.00
Revised by: Roberto Figueroa Pérez Post: Head of the plant	Signature: Date: 28.09.00
Approved by: Marisely González Soler Post: Technical Director of Production Albertina Y. Estrada Rodríguez Post: Director of Quality Assurance	Signature: Date: 29.09.00 Signature: Date: 29.09.00
Valid from:	

Annex 3:
Training records and requirements contributed by vaccine manufacturers

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Personnel training record 99

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Training control record (see Annex 4, in SOP 00.018) 103

Chiron: training registration form

Training registration form		
☐ GMP	☐ On-the-job	☐ Safety information
☐ SOP	☐ Supervision	☐ Safety training
Session title:		
SOP reference:		
Department:	Training performed by: _____ Signature: _____	
Length:	Date:	

Family name	Name	Dept.	Signature

CSL: GMP training requirements

GMP training requirements

Complete this form if a new person has joined the department or if the training requirements of a current staff member have changed. Please use the attached summary of GMP training sessions to aid you in selecting the most appropriate sessions. If you have any queries contact Richard Archibald, Quality Operations Pharmaceutical x1716.

Tab or arrow keys to move around this form, "X " key to mark and unmark check boxes

Employee name: & details		
First:	**Surname**	**Employee No.**

Division:	Dept. No.:	CSL level	Ext. No

Is this person new to the department? Yes ☐ / ☐ No*

Has this person transferred from another Dept/Broad Meadows* Yes ☐ / ☐ No*

Section I – GMP training

		Please tick appropriate box			Please tick appropriate box
Stage 1	Awareness of code GMP		Stage 2.8	GMP for general cleaning staff	
Stage 2.1	Documentation		Stage 3.1	Gowning, for aseptic processing areas	
Stage 2.2	Housekeeping and hygiene		Stage 3.2	Cleaning of aseptic processing areas	
Stage 2.3	Aseptic processing		Stage 3.3	Effective use of LFWSs and class II biosafety cabinets	
Stage 2.4	Handling of materials		Stage 3.4	Autoclaving	
Stage 2.5	Maintenance		Stage 3.5	Sampling	
Stage 2.6	Building quality Products		Stage 3.6	Pipetting and diluting	

Department manager _____Date _____

Return completed form to CSL learning centre email: geoff_lewis@csl.com.au

CSL: GMP training requirements continued

Summary of GMP training course

This summary is intended to help you select the most appropriate courses for your staff. If you have any queries, please contact Richard Archibald, Quality Operations Pharmaceutical x1716.

Stage 1

1. Awareness of code of GMP (1.5 hours)

Introduces participants to the code of GMP and that quality is everyone's responsibility. Highlights the importance of building quality into products by applying the key GMP principles "right thing" in the "right place" at the "right time". Includes video of GMP and photographs of GMP breaches.

For staff involved in manufacturing, quality operations, clinical trials, regulatory affairs, IS, engineering, distribution, stores and contractors.

Stage 2

2.1 Documentation (1.5 hours)

Shows participants the documentation requirements of GMP through the use of video and activities. Explains the type of documents e.g. SOPs, records etc., their importance and use.

For staff involved in manufacturing, quality operations, clinical trials, regulatory affairs, information services, engineering, distribution, stores and contractors.

2.2 Housekeeping and hygiene (1.5 hours)

Includes the importance of housekeeping and hygiene in maintaining product quality. The requirement to clean and monitor areas according to procedures.

Video and activities included in the session.

For staff involved in manufacturing, quality operations, engineering, distribution, stores and contractors.

2.3 Aseptic processing (1.5 hours)

Outlines types and sources of contamination in an aseptic processing area. Explains the basic features of an aseptic processing area and how standards are maintained. Includes video and activities.

For staff and contractors working in aseptic processing areas.

2.4 Handling of materials (1.5 hours)

The importance of correct labelling and storage of materials and what information should be included on labels. Also how correct handling prevents contamination and how status labels are used. Includes video and activities.

For staff involved in manufacturing, quality operations, engineering, distribution, stores and contractors.

2.5 Maintenance (1.5 hours)

Describes how maintenance of plant and equipment is essential to product quality. Includes documentation that is required e.g. procedures, logs. Explains responsibilities of machine operators and maintenance staff in relation to plant and equipment. Includes video and activities.

For all maintenance staff as well as production, QC, distribution staff using and maintaining equipment.

2.6 Building quality products (refresher course) (1.5 hours)

Outlines the key requirements of the code of GMP and consequences if not followed. Includes highlights from all previous stages. Includes video and activities.

For staff who have completed their required stages 1 and 2.

2.7 GMP for general cleaning staff

Outlines the importance of maintaining a clean and tidy facility and describes the responsibilities of general cleaning staff.

All staff employed in a cleaning role.

Stage 3

3.1 Gowning for aseptic processing areas (2 hours)

Overview of gowning requirements for aseptic processing areas. Includes requirements of change room facilities, handling and packaging of sterile gowns etc. Includes a demonstration of gowning and a video.

For all staff and contractors who work in aseptic processing areas and their supervisors.

3.2 Cleaning, of aseptic process areas (1 hour)

Describes special techniques, equipment and cleaning agents used to clean aseptic processing areas. Outlines what should be included in a cleaning SOP. Includes a video.

For staff who work in aseptic processing areas and their supervisors.

3.3 Effective use of LFWS and Class II (1.5 hours)

Biological safety cabinets

Explains the functions of LFWS and biological safety cabinets, how testing, and servicing maintains them and how to use them correctly. Includes video and activities.

For staff who use these cabinets and their supervisors.

3.4 Autoclaving (1.5 hours)

Describes the basic events in an autoclave cycle and the conditions required for sterilization by autoclaving. Includes features of an autoclave, use of indicators and need for procedures and records.

For staff who use autoclaves and their managers.

3.5 Sampling (1.5 hours)

Explains why samples are taken and outlines importance and key elements of how to sample correctly. Also includes the need to label and store samples correctly and explores the consequences of incorrect sampling. For staff who take samples and test samples.

3.6 Pipetting and diluting (2 hours)

Describes different types of pipettes which may be used and the techniques required to use them correctly. Includes an explanation of calculating dilutions, and assessment is by practical activities using different pipettes.

For staff who use pipettes, dilutions and their supervisors.

GlaxoSmithKline: personnel training record

Page N°:.....

Personnel training record

Name:			Surname:		
Service:		Function:		Hiring date:	
Date	**Type**	**Subject/reason**	**If SOP: version date**	**Participant signature**	**Trainer signature or certificate of attendance**

Annex 4:

New employee orientation programme contributed by vaccine manufacturers

Contents

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New employee orientation programme 101

Centro Nacional de Biopreparados (BioCen) Cuba 103

New employee training 103

GlaxoSmithKline: new employee orientation programme

Each employee joining the company and submitted to GxP regulations must follow a GxP training programme.

Phase 1: GxP induction

Participants: all new employees (including those not submitted to GxP regulations)

Timing: first day in the company

Duration: 45mn

Content: Quality and GxP definition, quality assurance and regulatory authorities, training process.

Coordinator: QA

Phase 2: GxP basics

Participants: Manufacturing, packaging, QA, QC, R&D, IT

Timing: within the first two months

Duration: see specific modules description

Content: see specific modules description

Coordinator: QA

- GxP basic 1

  Participants: manufacturing, clinical lots, quality assurance

  Duration: 3 days

  Content:

  – day 1: GMP definition, regulatory authorities, document practices, change control, classified areas
  – day 2: particulate contamination, clean rooms practices and microbiological contamination
  – day 3: cleaning practices, personnel behaviour

- GxP basic 2

  Participants: Quality control

  Duration: 2 days (N.B. people involved in sterility test must follow an additional one day training on this subject).

  Content:

  – day 1: GMP definition, procedures, training, laboratory practices, data and results management, OOS[a]
  – day 2: qualification and validation

[a] Out of specification.

- GxP basic 3

  Participants: packaging

  Duration: 2 days

  Content:

  - day 1: GMP definition and application, sterility
  - day 2: vaccines

- GxP basic 4

  Participants: Research and development

  Duration: 0.5 days

  Content: GxP definition and application

- GxP basic 5

  Participants: Information technology (validation and development of GxP systems)

  Duration: 0.5 day

  Content: GxP definition, good documentation practices

Phase 3 (in parallel with phase 2): Departmental training plan (training and qualification)

Participants: all employees submitted to GxP regulations

Timing: starting day 1

Duration: according to each department training plan

Content: for each departmental activity, the training plan describes the SOPs, theoretical and practical training which must be followed before the employee is considered trained and/or qualified to operate autonomously.

Employees have access to internal technical/GMP training and if needed, external training.

BioCen: new employee training

New employee training	Code: SOP 00.018
Approved by: Albertina Y. Estrada Rodríguez (Name, signature, stamp)	Edition No.: 01 Date: 29.09.00
	Substitution date:
Category of the substitution:	

1. Purpose:

To establish guidelines for the new employee training, making sure that each one has the essential qualification required to perform his/her tasks according to good manufacturing practices and the international quality standards.

2. Scope:

It is applicable to all employees recently admitted in any of the areas, so its application shall include all departments from the Institution, the areas directly related to production having priority.

3. Responsibilities:

3.1 It is responsibility of the general management of the Institution to establish the qualification and policy for human resources.

3.2 The economic/administrative direction shall be responsible for the fulfilment and control of the follow-up of the new employee training process by means of the interaction of the education and human resources departments with the rest of the BioCen areas.

4. Procedure:

4.1 New employee training

It is applicable to all the newly admitted employees and has the objective of achieving the adequate incorporation of the employee to the institution giving him/her the basic knowledge about the characteristics of the Institution, its organization and duties, as well as elements of good manufacturing practices and the quality system approved.

It comprises:

1st phase or phase I.

4.1.1 Acquiring knowledge on the objectives of the Organization.
4.1.2 Acquiring knowledge on the structure of the Organization.
4.1.3 Organization of the personnel.
4.1.4 Quality system. Duties. Individual and collective responsibilities in the system.
4.1.5 What are good manufacturing practices?
4.1.6 Industrial safety and hygiene.

2nd phase or phase II.

4.1.7 Characteristics of the area.
Compliance with good manufacturing practices in the area.
Standard operating procedures (SOP).
4.1.7.1 Acquiring knowledge on the duties to perform in the job.

4.2 This training will be programmed within 72 hours after its indication by the department of human resources.

4.3 The duration will not extend beyond 30 days after its indication.

4.4 The department of education shall hand out a report with the training programme for both phases and its starting date (see Annex 1). [Annex 1 is listed under #7 below.]

4.5 Once phase I of the training is over the employee will be sent to his working area, where the head or designated trainer will begin phase II training.

4.6 When phase II is concluded, if approved, the employee shall hand to the department of human resources his report card to proceed with the rest of the steps for his final incorporation into the Institution.

4.7 Once the procedures are concluded, the department of human resources shall send the training control record to the department of education for its filing in the education record of the employee.

4.8 A copy of the training control record (Annex 1) shall be placed in the working record of the employee by the department of human resources.

4.9 Evaluation

4.9.1 The training shall be evaluated in its two phases by an exchange of the group of specialists trainers with the employee, as well as by written evaluations of some topics.

4.9.2 Each evaluation shall be shown in the training control record using keys 3, 4 and 5 for the approved ones and 0, 1 and 2 for those who did not approve.

4.9.3 The employee that does not approve any one of the training phases must repeat it.

4.9.4 The employee that does not approve the training in the second session cannot begin his contracted employment at BioCen, since he does not fulfil the selection criteria.

4.9.5 All the evaluations shall be signed by the trainers of the given topics and they assume the ethical and moral responsibility.

4.10 Training programme

4.10.1 The Department of Education in coordination with the immediate chiefs and trainers shall establish in writing the issues included in the initial training of the employees, in both phases, emphasizing those related with labour ethics in the Centers of the Scientific Pole, the knowledge and complete fulfilment of good manufacturing practices in general, the regulations and the quality elements contained in the quality manual approved in BioCen.

4.10.2 This department shall offer the necessary advice in the methodological issues to guarantee the strict fulfilment of this programme.

4.10.3 Once this training is concluded the employee shall be given a leaflet with the most important issues of the topics approached.

5. Required documentation:

AC 1987 "Training control record".

6. References/applicable documents:

6.1 *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Good manufacturing practices for pharmaceutical products*. Geneva, World Health Organization, 1992 (WHO Technical Report Series, No. 823. Annex 1).

6.2 *WHO Expert Committee on Biological Standardization. Good manufacturing practices for biological products*. Geneva, World Health Organization, 1992 (WHO Technical Report Series, No. 822. Annex 1).

6.3 *Quality management and quality system elements – guideline*s. ANSI/ASQC Q9004-1-1994.

6.4 *Quality management and quality assurance standards – guidelines for selection and use. Cap 5.4*. ANSI/ASQC Q9000-1-1994.

6.5 *Diplomado Europeo de Administración y Dirección de Empresas. Tema La Dirección de Recursos Humanos*. Módulo 3. Universidad Politécnica de Madrid,1995–1996.

6.6 *Internal finished product facility audit checklist. Quality audit manual*. Part J. Interpharm Press, p. 88, 1995.

6.7 *Basic contract manufacturer/developer audit checklist. Quality audit manual*. Interpharm Press, 1995.

6.8 *Software contract manufacturer/developer audit checklist*. *Quality audit manual*. Interpharm Press, p. 189, 1995.

6.9 *Current good manufacturing practice for finished pharmaceuticals. Part 211. Subpart B Organization and personnel. Quality audit manual.* 1995.

6.10 *Management: A book of readings*. Koontz H, Weihrich H. Part 5. Chapter 19. Third ed. 1995.

6.11 Manual de Administración de la Calidad ISO 9000. *Editorial Panorama*. 1995.

6.12 SOP 01.060 "Redaction, contents, format and identification of the standard operating procedures (SOP)".

7. Annexes

7.1 Annex 1. AC 1987 "Training control record". Referred to in paragraph 4.8.

Centro Nacional de Biopreparados Quality Assurance **Training control record**		AC: 1987 Edition: 01 Date: 98.05.29 Page 1 of 1
Administrative data		
Names and last names	Identity number	
Home address	Working area	
Phase I		
Date of beginning phase I:	Date of conclusion of phase I:	
Topics	**Evaluation**	**Trainer's name and signature**
Characteristics of the centre and organization of the personnel		
Quality system		
Good manufacturing practices		
Industrial safety and hygiene		
Fit _____ Unfit _____		
Date: _____	Employee's signature: _____	

Phase II		
Date of beginning phase II:	Date of conclusion of phase II:	
Topics	**Evaluation**	**Trainer's name and signature**
Duties in the job		
GMP to fulfil in the area		
Approved procedures		
Fit _____ Unfit _____		
Date: _____ Employee's signature: _____		

Prepared by: Juan Carlos Vega Post: Head of the Department of Education and Scientific Information	Signature: Date: 15.04.98
Revised by: Carlos Flores Caro Post: Economic/Administrative Director	Signature: Date: 18.04.98
Approved by: Albertina Y Estrada Rodríguez Post: Director of Quality Assurance	Signature: Date: 29.05.98
Valid from:	

Annex 5:

Work-area specific programmes contributed by vaccine manufacturers

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BioCen: GMP training programme for personnel working in aseptic processing areas

GMP training programme for the personnel working in aseptic processing areas	Code: SOP 00.025
Approved by: Albertina Y. Estrada Rodríguez (Name, signature, stamp)	Edition No.: 02 Date: 08.10.00
	Substitution date:
Category of the substitution:	

1. Purpose:

To establish the training and qualification of the personnel working in aseptic processing areas.

2. Scope:

It applies to all the personnel linked with the aseptic processing areas: operators, technicians, specialists, cleaning and maintenance personnel and the personnel in the quality control laboratories (sterility test).

3. Responsibilities:

3.1 The trainer in GMP is responsible for the preparation and updating of the contents of the training.

3.2 The coordinator of the GMP programme is responsible for revising the contents of the training.

3.3 The department of education is responsible for the fulfilment of this programme, guaranteeing its materials and maintaining its records updated.

3.4 The process control laboratory in each plant is responsible for carrying out the microbiological monitoring for the qualification of the gowning process.

3.5 The quality assurance management is responsible for its approval.

4. Procedure:

4.1 Frequency:

All the personnel working in the aseptic processing areas shall receive the training in gowning and behaviour before entering the area and shall be re-qualified once a year. New workers will also receive the course on *GMP. Sterile products*, except the cleaning personnel who will receive training in cleaning and hygiene. Reinforcement training will be provided with a yearly frequency, in both cases.

4.2 Contents and development of the programme:

4.2.1 Contents of the programme:
The following courses and training are part of the specific guidance in GMP for sterile products that the personnel working in the areas of aseptic processing will receive.

Topics	Type of activity
Gowning for the clean room	Practical training
Behaviour in the clean room	Discussion of the video and the regulation
Course on GMP. Sterile products	Theoretical course
Cleaning and hygiene	Theoretical–practical training

4.2.2 Development of each topic in the programme:

4.2.2.1 Gowning practices in the clean room. Stages	
Showing of the following videos: Hand washing Gowning for the clean room	The personnel shall review the videos together with the trainer.
Review of the procedures for entry and exit from the clean room	The trainer will explain the gowning sequence and will make a practical display.
Practice of the personnel	The personnel will practice initially in the training area. The trainer shall work with the personnel to assure a correct technique is used.
Practical demonstration	The personnel shall demonstrate ability in the gowning process. The personnel shall dress in the specific area. The trainer shall observe and document the process in the AC1917 "Qualification and monitoring of the aseptic gowning processes".
4.2.2.2 Behaviour in the clean room. Stages	
Showing of the following video: Behaviour in the clean room	The personnel shall review the videos together with the trainer.
Review of the regulation for behaviour in the clean room	The trainer will explain the importance of an adequate behaviour in the clean room and discuss the regulation with the personnel.

4.2.2.3 GMP course. Sterile products	
Topics	**Content**
Introduction	Different types of sterile products and the difference between products with terminal sterilization and aseptic production are explained. An explanation of general microbiology is given and the meaning of contamination by viable and non-viable micro-organisms and pyrogens for the product and for the user.
Clean rooms and equipment	The basic design, operation and monitoring parameters of the clean rooms are explained to the operators. The characteristics of the equipment are explained. The effect of the operator on the area is also presented and the entrance of materials is discussed.
Personnel	The importance of the relevant behaviour, hygiene and gowning in the clean room is taught.
Maintaining the environmental control in the clean rooms	How to protect the clean room from contamination and the disinfecting process are discussed.
Manufacture of sterile products products are given.	The elements to prevent contamination during the manufacture of sterile
4.2.2.4 Cleaning and hygiene. Stages	
Microbiology	An explanation on general microbiology is given and the observations of micro-organisms isolated in the aseptic processing areas are carried out.
Cleaning and hygiene techniques	Cleaning and hygiene techniques are taught. Showing of the video "GMP in cleaning and disinfecting".
Practical check	Discussion of the results of the microbiological monitoring
Evaluation	A theoretical and a practical evaluation are performed.

4.3 Evaluations:

4.3.1 Each one of the training evaluations will be documented by the trainer or the supervisor; the evaluations of each worker are carried out every year.

Topics	Type of evaluation
Gowning for the clean room	According to SOP 05A.102
Behaviour in the clean room	According to SOP 05A.012
Course on GMP. Sterile products	Theoretical exam
Cleaning and hygiene	Theoretical and practical exam

4.3.2 The trainers shall send to the education department the results of the evaluations for documentary control according to what is established in the SOP 00.022.

4.3.3 The education department reports the results of unsatisfactory evaluations to the directors, head of plants or areas with the purpose of having the necessary measures taken for the remedial qualification and the follow-up of the workers.

5. References/applicable documents.

5.1 SOP 01.060 “Redaction, contents, format and identification of the standard operating procedures (SOP)”.

5.2 SOP 00.022 “Preparation of the training records of the workers”.

5.3 SOP 05.017 “Personnel entrance and exit from the aseptic processing area”.

5.4 SOP 05A.102 “Qualification and microbiological monitoring of the gowning procedure”.

5.5 SOP 05A.012 “Supervision in the aseptic processing areas”.

5.6 REG 05.003 “Regulation for the use of the aseptic processing area of the Plant for Formulation, Filling, Lyophilisation and Packing of Parenteral Products”.

5.7 REG 05A.001 “Regulation for the use of the aseptic processing area of Plant 2 for Parenteral Products”.

5.8 Video Micron “Gowning for the clean room”.

5.9 Video Micron “Now….wash your hands”.

5.10 Video Micron “Behaviour in the clean room”.

5.11 Video Micron “The GMP of Cleaning and Disinfecting”.

Prepared by: Emma Uramis Díaz Post: GMP Compliance Specialist	Signature: Date: 28.09.00
Revised by: Juan Carlos Vega Post: Head of the Department of Education and Scientific Information	Signature: Date: 29.09.00
Approved by: Albertina Y Estrada Rodríguez Post: Director of Quality Assurance	Signature: Date: 08.10.00
Valid from:	

GlaxoSmithKline: training programme for clean room operators

1. Objective

The purpose of this programme is to insure that all staff operating on aseptic processes or in aseptic areas, receive job skill training and are qualified as having the necessary skills, knowledge and performance to ensure proper job performance for their assigned work.

2. Scope

This programme applies to all manufacturing people, including process and maintenance, as well as QA, QC staff working in aseptic areas and/or on aseptic operations. It concerns new operators to be qualified and existing trained operators.

3. Qualification steps for new operators

The following steps have to be covered for a new operator before he/she can be considered as "qualified".

All steps are performed under the supervision of a qualified trainer. All steps have to be recorded.

People who have access to aseptic area but do not participate in critical operations have to fulfil only the firsts three steps of the qualification flow (training, questionnaire and three gowning tests).

1. Attend the basic training:
   - GMP induction
   - GMP basics
2. Attend training on the following procedures:
   - Good aseptic practices
   - Cleaning
   - Gowning
3. Perform and satisfy the questionnaire test.
4. Perform and satisfy three gowning tests.

   If these steps have been fulfilled successfully, the operator can enter the aseptic area, under supervision, without participating in critical operations. From this moment, the operator will be monitored for gowning and finger touch.
5. Attend specific department training (according to specific training plans) to prepare media operator exercise.
6. Perform and satisfy a media operator exercise.

   This exercise must mimic the media fill/form/bulk process and it is designed to test the operator aptitude to manipulate under aseptic conditions.

7.4 Questionnaire test:

Each operator must satisfactorily answer the questionnaire test each year.

7.5 Aseptic process simulation:

All qualified operators have to participate at least once a year in an aseptic process simulation.

7.6 Qualification prescription:

Qualification is lost if the operator does not enter the aseptic area for more than three months. Re-qualification as for a new operator must be performed.

 **Quality control** Bacterial vaccines	**Training procedures** **Translation**	**SOP AKA-BAK-01-007** Revision No.: 3 Page: Enclosures: 8 Replaces: 03.07.1996 Prepared by: PKH/ESW Authorized: 26.11.2000 QA

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 **Quality control** Bacterial vaccines	**Training procedures** **Translation**	**SOP** **AKA-BAK-01-007** Revision No.: 3 Page: Enclosures: 8 Replaces: 03.07.1996 Prepared by: PKH/ESW Authorized: 26.11.2000 QA

1. Summary

This SOP describes the training procedures in Quality Control, Bacterial Vaccines Unit. Training of technicians, scientists, and retraining after a leave of absence are outlined. The appropriate tables for documenting the training are given as enclosures. The use of initials and signatures is described, and the establishment of CVs, etc., for new personnel is mentioned.

2. Purpose

The purpose of this SOP is to describe the training procedures for the personnel in Quality Control, Bacterial Vaccines Unit (QC-BAC). And to describe the introduction to newly appointed personnel and the training for technician trainees including registration in the initial files and preparation of a CV. And to describe retraining upon leave of absence.

3. References

KVA/I-010: Instruction on initials/signatures

KVA/I-016: Instruction on GMP training

KVA/I-035: Instruction on unit folder

KVA/I-071: Instruction on documentation showing that instructions are read and understood.

4. General information

All information on the personnel is kept in a separate unit folder marked “AKA-BAK, bacterial vaccines, unit folder”. This is placed in the manager’s office. The manager is responsible for preparation and updating of these documents.

5. Curriculum vitae (CV)

CVs contain personal data, a job description and information on education, courses and previous employment. CVs are prepared on both permanent personnel and substitutes in the unit.

These are updated by the secretary and a copy is filed in the unit folder with the manager. A job description of all employees must be prepared (please find template on the internal network).

The job description for scientists is prepared by the head of the department, while the rest are prepared by the manager. The job descriptions are filed in the unit folder.

Information on participation in supplementary education is handed to the secretary (e.g. a copy of the course certificate signed by the participant). The secretary will do the updating. A copy can be filed in the unit folder as well. CVs, job descriptions and a list of supplementary education must be signed by the person involved.

6. A list of signatures in QC-bacterial vaccines (QC-BAC)

The list of initials and signatures (enclosure 1) covers both permanent personnel and substitutes. The list is updated currently when new personnel are appointed and when personnel resign. Newly appointed must always use the given initials in their daily work (even though use of other unique initials was previously allowed).

7. Newly appointed personnel

A technician has the main responsibility for the introduction of newly appointed personnel. The technician must provide the necessary work tools (including, pipettes, calculator, scissors, locker, etc.) before the new employee arrives.

The new employee must be shown round the laboratory on the first day. Safety equipment, locker and toilet facilities, placing of original SOPs, etc., are introduced.

A medical technician takes the blood sample for determination of diphtheria, tetanus and polio titre. Vaccination status and the result of the blood test are informed to the manager, who then will enter the result of the blood test in the table of vaccination status (enclosure 2, AKA-BAK-01-001 in the unit folder) and evaluate if revaccination is necessary. Once a year or once every second year, a blood sample of all employees in the unit is taken for determination of titres (see schedule of the month).

The manager ensures that official initials are provided to the new employee and that a CV is prepared. Finally, the new employee is included in the list of signatures.

This table is filed together with the SOP copy of the laboratory, so that technicians are reminded to carefully read the SOP before they carry out the analysis.

8. Theoretical training of newly appointed technicians in QC-BAC

8.1 Departmental SOPs (QC-ADM)

The manager decides which SOPs have to be read and understood. Copies of the relevant departmental SOPs are filed in the laboratory folder containing general SOPs. These are always signed for as read and understood in enclosure 2, which is filed together with these copies.

8.2 General SOPs (AKA-BAK-01)

The general SOPs of the unit are gone through (enclosure 3 is filed in the folder for documentation of training), and the new employee must hereafter read the general SOPs on his/her own. The technician then signs for the theoretical understanding of the SOP in the attached table (enclosures 2+3). Enclosure 2 is filed together with the copy of the SOP placed in the laboratory. Thus, the technician is familiar with where to retrieve relevant information and is then able to carefully read the SOPs when necessary.

8.3 Equipment SOPs (AKA-BAK-02)

If equipment is used for an analysis, the equipment SOP is read before the analysis is carried out the first time. A technician goes through the applied equipment, usually in connection with the performance of the analysis. Employee signs to indicate understanding the equipment SOP in a table (enclosures 2+4), enclosure 2 is filed together with the equipment SOP, and enclosure 4 is filed in the folder for documentation of training.

8.4 Analysis SOPs (AKA-BAK-03/04/05)

The responsible scientist goes through the analysis SOP to ensure that the technician is familiar with the principle of the analysis and to ensure that the technician is familiar with the type of information that is relevant for the documentation of the analysis. The technician and responsible scientist sign for both the theoretical understanding and the going through of the SOP in the attached table (enclosure 2).

8.5 Work tasks and the paper work in the unit

The responsible technician goes through the paper work in the unit (see AKA-BAK-01-008) and explains the structure of the two fireproof cabinets. The content of the folders is gone through and the new employee is also informed of the archive in the basement. The schedule of the month, responsibilities and work tasks are also introduced.

8.6 Updating of SOPs

When updating SOPs in the unit or when publishing new SOPs, these changes/renewals are presented at one of the unit's weekly meetings. The scientist who has been involved in the updating of the SOP decides whether the changes require that updated SOPs are to be read carefully or if an oral presentation at the unit's weekly meeting is considered sufficient information. New SOPs must always be read by relevant persons. The scientist enters the following in the SOPs "Theoretical training" sheet (enclosure 2):

- new revision number;
- date of presentation;
- whether the SOP should be read or not, and relevant names of technicians.

If careful reading is required, the SOP is read by relevant persons before they carry out the analysis or use the equipment and the names involved are signed.

Technicians who are absent from the weekly unit meeting MUST read all meeting summaries immediately after return in order to remain posted on progress in the unit. If SOPs have been introduced at a meeting and if there is any question of doubt after having read the SOP, it is the technician's responsibility to get an answer to these things from either another technician or from a scientist, before the analysis is carried out. Furthermore, the weekly meetings are used for forwarding information, internal education, discussions and problem solving.

9. Practical training of newly appointed technicians in QC-BAC

9.1 Chemical and immunochemical analyses (AKA-BAK-03/04)

Before training of new technicians in a new method of analysis, the analysis is always presented by a trained technician. This is entered on the journal sheet as, for example, “followed by yy”. Further progress depends on the analysis level of difficulty. The chemical and immunochemical analyses are divided into two groups according to level of difficulty (see enclosure 5):

Group 1: Analyses, which must be carried out twice or several times under supervision by trained technician

Group 2: Analyses, which must be carried out as parallel runs, assay with finished analysed samples (see enclosure 5 for numbers)

Regular journal sheets are used for the analyses. These are always marked with either “performed under supervision of xx” or “parallel runs”, so it is obvious that the journal sheets are part of a training procedure. Journal sheets on which approval of practical training in group 1 and 2 analyses is based, must comply with the requirements of the analysis mentioned in the analysis SOP, so that they can be marked “approved”. The results from group 2 analyses will not be used for product release. However, results from group 1 analyses are used as the final result of that sample. The numbers of all analyses including approved and not approved/failed analyses are entered in enclosure 6, It is the newly appointed technician’s responsibility that this happens. Enclosure 6 is filed together with the current SOP.

All journal numbers which have been carried out in relation to the practical training are evaluated during the evaluation and approval of the practical training in an analytical method. Two or more approved assays carried out under supervision must exist for group 1 analyses. Furthermore, the test results are evaluated by comparison with the original result for group 2 analyses. The group 2 results must not deviate more from the original result than is expected from the validation of the analytical procedure.

The evaluation and approval of the practical training is done by the responsible scientist, and is documented by signing enclosure 6. The technician or technicians who have been responsible for the practical training must also sign enclosure 6 to document complete practical training. It applies to all training that a technician is only trained when he or she is confident with the analysis. The number of analyses mentioned in enclosure 5 are considered as a minimum. The technician must be approved by the responsible scientist before routine analyses are carried out. If the technician is trained in AKA-BAK-04-010, he or she is allowed to read vero-plates in AKA-BAK-05-010 and vice versa.

9.2 Animal experiments (AKA-BAK-05)

The training in handling and dosage (i.c., i.p. and s.c.) of animals (mice and guinea pigs) is done together with the personnel in QC Biological Service. The table (enclosure 7) is signed to document this training. Training in animal experiment follows the procedure for group 1 analyses (section 9.1), which means training under supervision. The journal sheets are marked "performed under supervision by xx". As mentioned above, the responsible scientist must approve the technician's practical training in enclosure 6, before the technician is allowed to perform animal experiments independently.

As mentioned in section 10.1 it also applies here that no one is practically trained and approved before he or she feels confident and ready to perform the analysis independently.

10. Training of technician trainees in QC-BAC

10.1 Theoretical training

Technician trainees follow the theoretical training described in section 9. The trainee reads the SOPs for analyses and these are always introduced by a scientist, before the trainee is involved in the analyses.

10.2 Practical training

The practical training follows section 9. Group 1 analyses can be carried out as parallel testing on analysed sample material if needed. The regular journal sheets used for training as mentioned in section 9.1 are also used for the analyses. During training of technician trainees it must be borne in mind that they are being educated and therefore probably need more guidance and supervision. The documentation for training of technician trainees is the same as described in section 9.1. They can on equal terms with newly appointed technicians carry out routine analyses after approved practical training.

First, technician trainees are usually trained in some of the chemical and immunochemical analyses before the training in animal experiments can be done. Not all technician trainees are trained in animal experiments, but the theoretical introduction of animal experiments will take place.

10.3 Other training

If possible, the trainee is introduced to other SSI working places. Primarily this will involve short stays in production and research laboratories or other laboratories in the quality control department.

11. Training of newly appointed scientists in QC-BAC

Newly appointed scientists must read and understand the following SOPs (sign for this in enclosure 2 attached to the SOPs and instructions):

QA politics, descriptions and instructions, which have been found relevant by the manager.

- General SOPs in the department, AKA-ADM
- General SOPs and analysis SOPs in the unit (AKA-BAK-01/03/04/05)

Training in approval of analysis results from this analysis can begin after having read and understood the analysis SOP. The training is done according to the following (see enclosure 8):

- For every analysis a current journal sheet is gone through in regard to the principle of the analysis and the criteria of acceptance.
- The training scientist then signs enclosure 8 for training of approval in the current analysis.

The sheet for analytical result of a toxoid and a vaccine is introduced together with a trained scientist as well. The sheets for analytical result are signed by both, and the training scientist signs enclosure 8 as well.

12. Training upon longer absence from analytical work (minimum 8 months)

The SOPs for the analyses in which the technician has been trained are reread. New versions of equipment and general SOPs which are put into force during absence must also be read and enclosure 2 is signed for this.

Technicians perform the analyses they were trained in before leave of absence, once under supervision; “performed under supervision by xx” is marked on the journal sheet and the practical training is re-approved in enclosure 6 by the responsible scientist. This practical retraining must be done if the technician has had leave of absence for more than eight months from the analysis work. When returning from leave of absence of a minimum of eight months, the scientist reads all analysis SOPs before approval of analysis result. Other SOPs that are put into force in the leave of absence period must be read. The read and understood list for every SOP is signed (enclosure 2).

13. Enclosures

Enclosure 1: List of signatures

Enclosure 2: Theoretical training ("read and understood")

Enclosure 3: List of general SOPs

Enclosure 4: List of equipment

Enclosure 5: Plan for practical training of technicians

Enclosure 6: Practical training

Enclosure 7: Training in handling of animals

Enclosure 8: Training of scientists

14. Distribution and approval

Original: Head of unit in QC-bacterial vaccines

Copies: QC-bacterial vaccines x 4
QA
QC, head of department
QC-biological service

Prepared by: Pia Kreutz Hansen Pia Kreutz Hansen, QC-Bacterial Vaccines	Date: 21.11.2000
Approved by: Ellen Sloth Wilhelmsen Ellen Sloth Wilhelmsen, QC-Bacterial Vaccines	Date: 22.11.2000
Approved by: Anne Marie Barnkob Anne Marie Barnkob,Quality Assurance Department	Date: 26.11.2000
Translation verified by: Ellen Sloth Wilhelmsen Ellen Sloth Wilhelmsen, QC-Bacterial Vaccines	Date:

Serum Institute of India: training procedure – quality assurance

Department: Quality Assurance		***Page: 1 of 7***
Title: Training procedure – quality assurance		
SOP No.: 039 0050		**Revision No.: New**
Effective date: 01.08.1998	**Replaces: -**	**To be reviewed on: June 2000**

Distribution:

Three original sets shall be prepared.

One set will be maintained with the Executive Director (QA).

Another set will be maintained with the department head.

The third set is for approval of Central Drugs Laboratory (CDL), Kasauli.

A Xerox™ copy may be taken and retained in respective departments for reference and display.

1. Purpose:

To ensure that the employees working in quality assurance department receive the training appropriate to their duties and their responsibilities. This procedure also provides formats for documentation of the training.

2. Scope:

This procedure applies to the training of all employees working in the Quality Assurance Department at the Hadapsar factory.

3. Responsibility:

Quality Assurance managers will be responsible for:

1. Documenting the job description of the employees working in the department.
2. Identifying the training needs of the employees working in the department.
3. Ensuring that employees receive suitable training.
4. Ensuring appropriate assessment, retraining and reassessment.
5. Maintaining the records of training.

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4. Procedure:

4.1 Departmental procedure:

4.1.1 The Quality Assurance Department will prepare SOPs for the training, to ensure that all the employees of the department, receive the training on:

4.1.1.1 Safety, health and environment aspects.

4.1.1.2 Basic and current good manufacturing practices.

4.1.1.3 Based on the job description, they receive the training on.

4.1.1.4 Process and the operations carried out in the department.

4.1.1.5. Any other areas of operation as identified by the department manager.

4.1.2 Training will be conducted by appropriately qualified expert staff. In addition to the departmental manager, the experts in the areas of safety, occupational health, quality assurance, engineering, commercial, information technology and other relevant areas will impart the training.

4.2 Job description:

4.2.1 The Quality Assurance manager will prepare the generic job description for each grade applicable to the department.

4.2.2 For managerial staff, the job description will include the résumé of his/her qualifications, number of years in profession, work experience, professional training (external and internal).

4.2.3 The job description will be recorded in a format given in Annex 1.

4.3 Identification of training needs:

4.3.1 The Quality Assurance manager will identify the training needs of the employee appropriate to his/her job requirements.

4.3.1.1 The training needs will be identified as “awareness” or “competence”.

4.3.1.2 “Awareness” denotes the understanding and knowledge of the subject matter.

4.3.1.3 “Competence” denotes the capability of the person to carry out the task with skill and knowledge appropriate to the job.

4.3.2 The generic training needs will be recorded in the format which is attached as Annex 2. The generic training pertains to the knowledge based requirements.

4.3.3 The specific training needs of each employee will be recorded in the format given in Annexes 3, 3A and 3B. The specific training pertains to skill based requirements.

4.4 Methods of types of training: The training will be given by the use of:

4.4.1 Structured training modules.

4.4.2 Group discussions and case studies.

4.4.3 Quiz.

4.4.4 Other appropriate methods.

4.5 Types:

4.5.1 Induction training:

Each new recruit will be given induction training in:

4.5.1.1 Site policies and procedures in safety, occupational health, fire and loss prevention and environment protection aspects. This training will be imparted by site safety and health adviser or a person nominated by him.

4.5.1.2 Basic GMP, current GMP and site polices and procedures on GMP. This training will be imparted by Quality Assurance manager and departmental manager or a person nominated by them.

4.5.1.3 New recruit will be inducted in the operating department only after he/she has undergone basic safety and GMP training.

4.6 Mode of training:

4.6.1 Class room training:

4.6.1.1 The sessions will be conducted to impart the knowledge.

4.6.1.2 The structured training modules will be used.

4.6.1.3 Preferably the training modules will be prepared using PowerPoint, a presentation program by Microsoft Windows.

4.6.2 "On the job" training:

4.6.2.1 The sessions will be developed on the basis of departmental SOPs.

4.6.2.2 The training will be conducted "on the job".

4.6.2.3 Appropriate class room sessions will be conducted to impart the knowledge about the theory, principles, system descriptions, etc.

4.6.3 The training will be conducted by internal as well as external faculties. Audio-visual aids will be used as appropriate.

4.6.4 The attendance of the training will be recorded in the record form, the format of which is shown in Annex 4.

4.7 Evaluation:

4.7.1 The effectiveness of the training will be evaluated to ensure that it meets intended requirements.

4.7.2 Assessment will be done to evaluate the "awareness" and/or "competence" appropriate to the job requirement of the employee.

4.7.3 Class room training will be assessed by written test, group discussions, quiz and other appropriate means.

4.7.4 The "awareness" or the knowledge will be assessed by the percentage of marks obtained. The trainee should obtain more than 75% marks. The trainee scoring less than 75% marks will be retrained and reassessed.

4.7.5 The format of written assessment record is given in Annex 5 and Annex 5A.

4.7.6 SOP or operation based "on-the-job" training will be assessed for competence.

4.7.7 "Competence" will be evaluated by the manager or his deputed nominee.

4.7.8 It will be judged by observation, assessment and certification against the checklist of operations for which competence is required for the performance of his/her job.

4.7.9 This will be recorded in the format given in Annex 6.

4.8 Frequency:

4.8.1 Each employee will be given refresher training at an appropriate frequency identified on the basis of:

4.8.1.1 Nature of the job.

4.8.1.2 Change in the nature of the job and responsibilities.

4.8.1.3 Performances as assessed in terms of "competence" or "awareness".

4.8.1.4 Retraining – changes in SOP.

4.8.1.4.1 Whenever a change is made in the SOP or whenever the SOP is revised. (Revision frequency for SOP is two years.)

4.8.1.4.2 Whenever the method of operation/analysis changes, on-the-job training module will be revised (as per the format given Annex 5A) and retraining will be given to the concerned employee.

4.8.1.4.3 The competence for retraining on the revised SOP will be assessed and recorded in the format given in Annex 6. Whenever changes are made in the operating parameters/ conditions (some examples; changes in time, temperature, pressure, pH, analytical parameters in terms of concentration, nature of solvents etc.), the concerned employees will be informed about the changes as well as the background/ reasons for the changes. Such changes are considered as minor changes.

4.8.1.4.4 This explanation and conveyance of the information to the employee will be recorded in the format given in Annex 7.

4.9 Retraining and reassessment:

4.9.1 Retraining plan will be decided on the basis of performance assessment carried out during the evaluation. Where appropriate, reassessment will be carried out at suitable intervals.

4.9.2 For example, the retraining should be considered if specific deficiency is identified while performing a task, or the identification of deficiency detected during the investigation of process deviation or out of specification (OOS) incident.

4.10 Documentation:

4.10.1 Job description.
4.10.2 Generic training need identification plan consisting of topics, grades and function.
4.10.3 Specific training need identification plan for each employee.
4.10.4 Training attendance record.
4.10.5 Training modules.
4.10.6 Index of training modules.
4.10.7 Written assessment test records.
4.10.8 On-the-job training module record.
4.10.9 On-the-job training assessment record.
4.10.10 Record for minor changes in SOP.

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SEAL

Annex 6:

Supervisor training programme contributed by a vaccine manufacturer

GlaxoSmithKline, Belgium

Supervisors submitted to GxP regulations follow the same programme as other employees (Phases 1 to 3). In addition to that, a Phase 4 GMP programme is followed during the first six months in the company.

Phase 4: GxP advanced (training, GxP)

Participants: managers submitted to GxP regulations

Timing: in the first six months

Duration: one day

Content: cGMP rules and interpretation, procedures, deviation, change control, cGMP trends

In addition to the Phases 1–2–3–4 programmes, managers have access to:

- external and internal technical/GMP training organized by human resources department or QA;
- a GMP letter (GMP flash): issued on a two-month basis by QA, this letter outlines the current pharmaceutical GMP practices, interpretation and inspection outcomes;
- a SOP review: four times a year, general procedures are presented and discussed with the management;
- general GMP information: short presentations on current technical/GMP topics are held regularly with internal or external speakers.

Annex 7:

Manager training programme contributed by a vaccine manufacturer

Serum Institute of India Ltd.
212/2, Hadapsar, Pune – 411 028, India

Manager training programme

Manager could be defined as a person who converts resources into results.

Specific training programmes are arranged for managerial grade personnel with special emphasis on following aspects of managerial functions.

- leadership skills
- communication skills
- technical skills
- interpersonal skills
- planning skills
- decision-making skills
- motivation skills
- team building skills
- selling and influencing skills
- time management skills.

Annex 8:
List of articles and publications

1) *A WHO guide to good manufacturing practices requirements. Part 1: Standard operating procedures and master formulae*. World Health Organization, Geneva, 1997 (WHO/VSQ/97.01).

2) *A WHO guide to good manufacturing practices requirements. Part 2: Validation*.World Health Organization, Geneva, 1997 (WHO/VSQ/97.02).

3) Levchuk JW. Training for GMPs. *PDA Journal of Parenteral Science and Technology*, 45(6), 1991:270–275.

4) The 2003 Training Top 100 Ranking. *Training*, 40(3), March, 2003:40.

5) Marguardt MJ, King SB, Ershkine W. *International comparisons: ASTD's annual accounting of worldwide patterns in employer provided training*. Alexandria, VA, American Society for Training and Development, 2002.

6) *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Good Manufacturing Practices for pharmaceutical products*: *main principles.* Geneva, World Health Organization, 2003 (WHO Technical Report Series No. 908. Annex 4).

7) *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Good Manufacturing Practices for pharmaceutical products*. World Health Organization, Geneva, 1992 (WHO Technical Report Series No. 823. Annex 1).

8) *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Good manufacturing practices for sterile pharmaceutical products*. World Health Organization, Geneva, 2002 (WHO Technical Report Series No. 902. Annex 6).

9) *WHO Expert Committee on Biological Standardization. Good manufacturing practices for biological products*. World Health Organization, Geneva, 1992 (WHO Technical Report Series No. 822. Annex 1).

10) *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Good Manufacturing Practices: supplementary guidelines for the manufacture of investigational pharmaceutical products for clinical trials in humans*. World Health Organization, Geneva, 1996 (WHO Technical Report Series No. 863. Annex 7).

11) Commission of the European Communities. Medicinal products for human and veterinary use: The rules governing medicinal products in the European Union. *Good Manufacturing Practices*. Volume 4. 1998.

12) Commission of the European Communities. Medicinal products for human and veterinary use: The rules governing medicinal products in the European Union. *Good Manufacturing Practices*. Vol. 4, Annex 15, July 2001 (available on the Internet at http://www.pharmacos.eudra.org/F2/eudra/ex/vol-4/home.htm, accessed May 2003).

13) US Code of Federal Regulations, Title 21, Volume 4, Current Good Manufacturing Practice for Finished Pharmaceuticals, Part 211. Food and Drug Administration, DHHS [revised as of 1 April 2004] (available on the Internet at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm, accessed 20 January 2005).

14) US Code of Federal Regulations, Title 21, Volume 7, Part 600, Biological Products: General, Food and Drug Administration, DHHS [revised as of 1 April 2004] (available on the Internet at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm, accessed 20 January 2005).

15) Vesper JL. Defining your GMP training program with a training procedure. *Biopharm*, 2000, 13(11):28–32.

16) ASEAN Good Manufacturing Practices Guidelines. National Agency of Drug and Food Control, Indonesia, 1996.

17) *The Australian Code of Good Manufacturing Practice for Medicinal Products*. Therapeutics Goods Administration Australia. August 2002.

18) Henson E. CGMP training for new employees: Considerations and case studies. *Journal of cGMP Compliance*, 1998, 2(2):75–80.

19) Akers J et al. CGMP education and instruction: A corporate approach to employee training worldwide. *Pharmaceutical Technology*, 1993, 17(3): 51–60.

20) Kieffer RG. My thoughts on teaching and training. *PDA Letter*, 2000, XXXVI (2):30–31.

21) Tetzlaff RF. FDA inspection of GMP training programs. In: *GMP Training and Education Association*, Biannual Conference, 1991.

22) Ulbak E. Training for GMP in aseptic processing. *Proceedings of the PDA International Congress Advanced Pharmaceutical and Biopharmaceutical Development, Manufacturing and Control in Europe and the USA; February 14–18.* Basel, Switzerland, 1994:1–9.

23) Immel B. Excellent GMP training programs. *Pharmaceutical Technology,* 1997, 21(3):166–176.

24) Kirkpatrick DL. *Evaluating training programs. The four levels*. San Francisco, Berrett-Koehler Publishers, Inc., 1998.

25) Knowles MS. *The modern practice of adult education: Andragogy versus pedagogy*. Cambridge, UK, Cambridge University Press, 1988.

26) Vesper JL. Performance: The goal of training or why training is not always the answer... *Biopharm*, 2001, 14(2):44–46.

27) Tetzlaff RF. Developing a systematic approach to GMP training. *Pharmaceutical Technology*, 1982, 6 (11):42–51.

28) Hirabara S, Bandou H. Training of construction company employees. *Proceedings of the PDA Nihon V Annual Congress*. Tokyo, PDA Nihon, 1997:82–87.

29) Reiser RA. Instructional technology: A history. In: *Instructional Technology Foundation*. Hillsdale, NY, Lawrence Erlbaum Associates, 1987:11–16.

30) Johnson KA. The foundations of instructional design. In: *Instructional design: New alternatives for effective education*. New York, Macmillan, 1989:3–15.

31) Hannum W and Hansen C. *Instructional systems development in large organizations*. Englewood Cliffs, NJ, Education Technology Publications, 1989.

32) Gagne RM. *Principles of instructional design*. New York, Holt, Riehart, and Winston, 1985.

33) *Introduction to training trainers to train*. Hampshire, Micron Video International Limited, 1997.

34) Immel BK. The essence of training, Part 2: The play's the thing. *Biopharm,* 1998, 11(6):62–70.

35) Beauchemin KV. Preparing workplace trainers to maximize ROI. *PDA Journal of Pharmaceutical Science and Technology*, 1999, 53(6): 288–290.

36) Gery G. *Making CBT happen*. Gery Performance Press, 1989:6. Cited by: Docherty SE, Shackleton PA. Designing and customizing computer based training for cGMPs. *Journal of cGMP Compliance*, 1999, 3(4):40–45.

37) Alessi SM, Trollip SR. The process of instruction. In: *Computer-based instruction. Methods and development*. Englewood Cliffs, NJ, Prentice-Hall Inc., 1985:63.

38) Kyber AG. *Entrenador por computadora para operación de autoclaves GETINGE GE 66, Manual del usuario*. La Habana, Biocen, 1994.

39) *Conducting training effectively* (available on the Internet at http://www.gmp1st.com/effecttr.htm, accessed 16 August 2000).

40) Abbat FR. Introduction to teaching methods. In: *Teaching for better learning. A guide for teachers of primary health care staff.* 2nd ed. WHO, Geneva, 1992:49.

41) *Training evaluation: A guide to the evaluation of training courses on immunization and other disease control activities*. World Health Organization, Geneva, 1995 (WHO/EPI/TRAM/95.3).

42) Masiello S. 24th International GMP Conference. March 2000. Cited by: Immel BK: When things go wrong Part 1: The consequences of non-compliance. *Biopharm,* 2000, 13(8):38–44.

43) Daley JA. Determination and tracking of required cGMP training. *Journal of cGMP Compliance,* 1998, 2(2):11–17.

44) Wilkin T. Training effectiveness in the 21st century. *Proceedings of the PDA International Congress Global Pharmaceutical Manufacturing in the 21st Century, February 17–19, Osaka, Japan.* PDA,1997:125–134.

45) Newbery A. PharmTech discussion group archives. Re: Software for tracking training (available on the Internet at http://wwwpharmweb.net/forum/0068/2000/msg02055.html accessed 7 September 2000).

Recommended articles and publications

Akers MJ. Good aseptic practices: Education and training of personnel involved in aseptic processing. In: Groves MG and Murty R eds, *Aseptic Pharmaceutical Manufacturing II. Application for the 1990s*. Buffalo Grove, IL, Interpharm Press, 1995:181–221.

Austin PR. Training of employees. In: *Encyclopedia of clean rooms, bio-clean rooms, and aseptic areas,* 1st ed. Livonia, Michigan, Acorn Industries, 1995:546–554.

Beauchemin K, Gallup D, Marge G. "Read and understand" vs "a competency-based approach" to designing, evaluating and validating SOP training. *PDA Journal of Pharmaceutical Science and Technology*, 2001, 55 (1):10–15.

Beer CL. Gowning training: the use of video recording together with microbial assessment. *J of Parent Sci & Tech*, 1991, 45(3):128–131.

Bunn G, Hart AP. Guidelines for assessing training competency levels. *Journal of cGMP Compliance,* 1998, 2(3):40–44.

Concon P. Compliance training. *Proceedings of the 2nd PDA/AFM Pan American Conference on Pharmaceutical Manufacturing, Cocoyoc, Morelos, Mexico, 1997, June 1–4*. PDA/AFM, 1997.

Dixon AM. Training clean room personnel. *Journal of Parenteral Science and Technology*, 1991, 45(6):276–278.

Documentation systems for training. *Proceedings of the Validation and Drug Marketing Seminar. ONUDI/IMEFA/MINSAP*, La Habana, Cuba, 1994.

Gallup D, Beauchemin K, Gillis MA. Comprehensive approach to training in a pharmaceutical facility. *PDA Journal of Pharmaceutical Science and Technology,* 1999, 53(4):163–167.

Gallup D, Beauchemin K, Gillis M. Competency-based training program design, *PDA Journal of Pharmaceutical Science and Technology*, 1999, 53(5):240–246.

Guidelines for planning training activities for immunization and disease control service. Geneva, World Health Organization, 1995 (WHO/EPI/TRAM/95.2).

Inazu K. Effective GMP education and training. *Proceedings of the PDA Nihon V Annual Congress*. Tokyo, PDA Nihon, 1997:90–94.

Johns MA, Terry JL, Anderson RS. Producing high quality vaccines: Training in Good Manufacturing Practices. *Proceedings of the Consultative Group Meeting, CVI, December 9-1.* Dakar, Senegal, CVI, 1996.

King PG. Improving c GMP training programs. *Journal of cGMP Compliance,* 1998, 2(4):56–63.

Kirkpatrick DL. *Another look at evaluating training programs.* Alexandria, VA, American Society for Training & Development, 1998.

Kitt MT. An approach to GMP training. *Journal of the PDA*, 1979, 33(6):341–345.

Markovitz DC. Conducting effective GMP training: Do's and don'ts for success. *Journal of cGMP Compliance*, 1999, 3(4):59–62.

Markovitz DC. Practical preparation for effective cGMP training: 6 steps to success. *Journal of cGMP Compliance,* 1999, 3(3):68–72.

Peine IC. Training and health. In: *Quality assurance compliance. Procedures for pharmaceutical and biotechnology manufacturers*, 1st Edition. Buffalo Grove, IL, Interpharm Press, 1994:259–271.

Pemberton M. GMP compliance from a production manager point's of view. *Biopharm*, 1998, 11 (8):34–37.

Sands RT. CGMP training with a wink and a nod. *PDA Letter*, XXXV (8), 1999: 38–39.

Trainer´s guide for cancer education. National Cancer Institute. US National Institutes of Health (available on the Internet at http://cancer.gov/clinicaltrials/resources/trainers-guide-cancer-education, accessed 7 January 2005).

Vesper JL. Considering users when implementing new pharmaceutical technology. *Pharmaceutical Engineering*, 1993, 13(3):92–95.

Vesper JL. *Training for the healthcare manufacturing industries*. Engelwood, CO, Interpharm Press, 1993.

The World Health Organization has managed cooperation with its Member States and provided technical support in the field of vaccine-preventable diseases since 1975. In 2003, the office carrying out this function was renamed the WHO Department of Immunization, Vaccines and Biologicals.

The Department's goal is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases. Work towards this goal can be visualized as occurring along a continuum. The range of activities spans from research, development and evaluation of vaccines to implementation and evaluation of immunization programmes in countries.

WHO facilitates and coordinates research and development on new vaccines and immunization-related technologies for viral, bacterial and parasitic diseases. Existing life-saving vaccines are further improved and new vaccines targeted at public health crises, such as HIV/AIDS and SARS, are discovered and tested (Initiative for Vaccine Research).

The quality and safety of vaccines and other biological medicines is ensured through the development and establishment of global norms and standards (Quality Assurance and Safety of Biologicals).

The evaluation of the impact of vaccine-preventable diseases informs decisions to introduce new vaccines. Optimal strategies and activities for reducing morbidity and mortality through the use of vaccines are implemented (Vaccine Assessment and Monitoring).

Efforts are directed towards reducing financial and technical barriers to the introduction of new and established vaccines and immunization-related technologies (Access to Technologies).

Under the guidance of its Member States, WHO, in conjunction with outside world experts, develops and promotes policies and strategies to maximize the use and delivery of vaccines of public health importance. Countries are supported so that they acquire the technical and managerial skills, competence and infrastructure needed to achieve disease control and/or elimination and eradication objectives (Expanded Programme on Immunization).

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