Guidance on the interpretation and implementation of European Good Distribution Practice

Chapter 2 – Personnel

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Preface

It is of key importance that medicinal products are not only made to a high quality in accordance with Good Manufacturing Practice, but that the quality and integrity of these products are maintained through the entire supply chain to the patient. This is where Good Distribution Practice (GDP) comes into play.

The distribution network for medicinal products is often complex, involving many different parties. In addition to the challenges associated with this complexity, there is also a growing threat from criminal activities seeking to introduce falsified medicines into the legal supply chain. The European regulators recognised several years ago that there was a need to update the content of the 1994 GDP guideline to take into account advancements in practices and changes in legislation since it was issued. A consultation draft was issued in mid-2011 and, following the receipt of many comments from interested parties, a final revised version was issued in March 2013 with an effective date of 8 September 2013. A corrected version dated 5 November 2013 was published in the Official Journal on 23 November 2013 to be effective immediately. This version corrects factual mistakes identified in subchapters 5.5 and 6.3 of the March 2013 version and also gives more explanations on the rationale for the revision.

The new guideline has a much stronger focus on the quality system with clear responsibilities and processes and the application of risk management principles. More detailed guidance is given on most elements. New chapters relating to transportation and specific provisions for brokers have been added.

The Pharmaceutical Quality Group issued a monograph on Pharmaceutical Distribution in 1997 and initiated planning to revise this in line with the new regulatory guideline. Whilst undertaking this planning it was identified that the European Compliance Academy were also planning to produce some guidance in response to requests from members. The two organisations therefore decided to join forces and set up a joint steering committee led by Afshin Hosseiny with Philip Butson, Ashley McCraight and Oliver Schmidt.

An early decision was that we would initially target key chapters and issue each as it became available rather than wait until a complete guide had been prepared. This has enabled us to shorten the time to the provision of some guidance and also provides an opportunity for us to collect feedback and enhance the material before issuing a complete guide. The first versions of the chapters will have different formats and styles due to the different volunteer teams involved in their preparation which we have chosen not to edit into a common format for the time being. We would appreciate feedback on what works best for you, the user.

In this document, text from the EMA guideline is given in italic Calibri font, followed by guidance from the team in normal Times New Roman font.

Please provide any feedback and suggestions for improvement using the email address monographs@pqg.org or info@gmp-compliance.org.

For this particular chapter on Personnel, we would like to thank the hard work of the authoring team Sue Mann, Shashi Patel, Javier Franch Conejero, Patrick Gray, Duncan MacKenzie, and Milena Samban. Editing was undertaken by Philip Butson, Afshin Hosseiny and Ashley McCraight.
## 2.1 PRINCIPLE

**The correct distribution of medicinal products relies on people. For this reason there must be sufficient competent personnel to carry out all the tasks for which the wholesale distributor is responsible. Individual responsibilities should be clearly understood by all staff and be recorded.**

- **What is the rationale for this point in the guidance?**

Most supply chains are complex. Despite increasing use of computerised systems, people continue to be involved at all stages of the distribution process. People can have an adverse effect on activities if they are unaware of GDP requirements and how to behave accordingly. We rely heavily on people to perform numerous tasks correctly, including checking, recording, picking, transporting and delivering medicinal products. There is also reliance on people to respond appropriately to information that they receive that may affect product quality, so it is important that they are appropriately trained and competent.

- **What are the risks and benefits associated with this aspect of the guidance?**

**Benefits**

There is an expectation that each site / operation will have sufficient, competent personnel with the necessary qualifications and experience. This includes sufficient senior management personnel who are responsible for supporting all parts of the quality system, including ensuring there are adequate resources.

The Responsible Person (RP) is a named person within the organisation with specific responsibilities. The RP is responsible for the implementation and maintenance of the quality system and for ensuring that it continues to be fit for purpose.

The principle extends to individual responsibilities being clearly understood by staff and that these are recorded. This underpins the requirement for formal Job Descriptions, Organisation charts and a training programme to ensure every person fully understands their role, responsibilities and limit of authority. There should be no gaps or unexplained overlaps in the responsibilities of personnel.

**Risks**

The main personnel-related risks are:

1. Insufficient numbers of personnel to enable performance of all the tasks that need to be undertaken;
2. Insufficient training of personnel resulting in them not fully understanding their role, leading to activities either being omitted or being performed incorrectly;
3. A lack of training and/or experience resulting in poor handling of issues, such as deviations and complaints, which can result in issues being made worse and/or recurring;
4. Also, the responsibilities placed on any one individual should not be so extensive as to present any risk to quality.

Note that the organisation may appear to function satisfactorily for some time with these deficiencies only becoming apparent when the system is ‘stressed’, e.g., the workload increases or a significant event, such as a recall, occurs.

- **How might this be implemented/ what does it mean?**

Each organisation / site should ensure there is a systematic approach, including an organisation chart together with clear and comprehensive job descriptions. Recruitment practices should ensure that appropriately educated and, where appropriate, experienced personnel are recruited and, following employment, a suitably customised training and development programme should ensure all staff, whether they work on or off site (including drivers), fully understand their role.
2.2 RESPONSIBLE PERSON

The wholesale distributor must designate a person as responsible person. The responsible person should meet the qualifications and all conditions provided for by the legislation of the Member State concerned (1). A degree in pharmacy is desirable. The responsible person should have appropriate competence and experience as well as knowledge of and training in GDP.


- **What is the rationale for this point in the guidance?**

The wholesaling, storage and distribution of medicinal products is subject to strict legislation which covers all aspects of wholesaling activities. Therefore, a person who is conversant in the legislation and able to implement and oversee the requirements within their organisation is essential, to ensure compliance is maintained. Any particular requirements regarding training and qualifications stipulated by a Member State must be known and met. Although a degree in pharmacy is generally desired, and in some Member States required, other qualifications may be accepted and, whatever qualifications an individual holds, it is vital that they have appropriate training and experience.

- **What are the risks and benefits associated with this aspect of the guidance?**

**Benefits**

The knowledge of the RP will help ensure that GDP requirements are met, thus ensuring the product is distributed to patients in good condition, in addition to meeting a fundamental requirement of the wholesale licence.

**Risks**

Without an RP a wholesaler is not compliant with legislation and risks losing its licence to operate. Without a knowledgeable RP in place, it is likely that some of the activities within a wholesale distributor would be or become out of compliance with the legislation, which could impact product quality and cause a risk to patient safety.

- **How might this be implemented/ what does it mean?**

The appointment of a RP must be carefully considered to ensure the correct person is put in place. This appointment is dependent on the size of the organisation, the complexity of the services to be provided and the product classes to be supplied. In a small organisation with a minimal number of product lines, it is acceptable for the licence holder to be the RP (as long as they meet the requirements in the Member State concerned), whereas in a large multi-site wholesale distributor, a dedicated RP independent from the daily operations would be required, as well as having defined delegated duties.

The nominated responsible person should be able to show an in-depth understanding of medicinal products and must be able to demonstrate knowledge of GDP, and how it is imbedded within the systems and processes implemented within the wholesale distributor. Some key areas of knowledge and experience are listed below:

**Knowledge**

- Storage conditions/requirements for different types of pharmaceutical products;
- Basic understanding of degradation pathways and stability profiles of pharmaceutical products;
- GDP legislation and relevant guidance;
- Requirements for storage facilities, temperature control and monitoring programmes, including mapping and qualification;
- Quality Management Systems and how to manage these effectively;
- Handling of returns/complaints/recalls;
- Bona Fide checks;
- Risks associated with Falsified Medicines;
- Expectations of a robust Technical (Quality) Agreement with any sub-contractors;
- Controlled Drug legislation and requirements of the relevant Member State(s);
- Trained auditor

**Experience**

- Experience of picking/packing procedures and FEFO (First Expiry, First Out) principles;
- Handling complaints and customer queries;
- Active involvement in GDP regulatory inspections;
- Audited internally to monitor the Quality Management System (QMS) and preferably also external audits covering the various stages in the distribution process;
- Supplier and Customer approval process;
- Creating/maintaining/auditing the documentation and records involved to ensure compliance with GDP

Competent Authorities will assess the experience of individuals proposed as RPs. An RP is unlikely to be accepted unless they have a minimum of one year’s experience of distribution activities. A longer period of experience, ideally in a management role, would be preferred.

**Contract RPs**

Contract RPs should have the same level of knowledge and training in company products and procedures as a permanent RP. This provides a practical limit on the number of licences that an RP can effectively support.

Licence holders should ask potential contract RPs about other licence commitments and be satisfied that they will be able to devote sufficient time to the support of their operations before appointment. It should be noted that Competent Authorities have refused RPs being named on what they consider to be too many licences. The contract RP should also consider carefully if they are able to fulfil these professional responsibilities for another company.

Note: See reference to COGENT RP Gold Standard: [http://www.thegold-standard.co.uk/job-details/?jobid=297](http://www.thegold-standard.co.uk/job-details/?jobid=297)

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**The responsible person should fulfil their responsibilities personally and should be continuously contactable. The responsible person may delegate duties but not responsibilities.**

- **What is the rationale for this point in the guidance?**

With the appointment of a person who has been nominated as having responsibility for the GDP compliance of a wholesale distributor, it is important for them to be contactable for two main reasons; firstly to seek advice in case of unexpected incidents to ensure any actions taken to resolve will still meet GDP requirements, and secondly to keep the RP informed of all activities being undertaken, so constant review of risks can take place. In large organisations, it is not always feasible for one person to be able to carry out all duties of the RP at all times. In such cases delegation of tasks can be defined and documented. The RP maintains overall responsibility at all times ensuring either he/she or the delegated deputy must be contactable at all times.

- **What are the risks and benefits associated with this aspect of the guidance?**

  - **Benefits**

    Having a RP or a deputy contactable at all times helps ensure effective management of operations and any incidents that may occur. Having a deputy RP also provides a good basis for succession planning within an organisation.
**Risks**

If an RP is not available to manage incidents, then decisions made by others may not be in line with the GDP requirements and could compromise patient safety and the company’s licence for which the RP is legally accountable.

**How might this be implemented/ what does it mean?**

- Nominate a deputy and add to the licence
- Issue a formal job description for the RP and his deputy
- Train deputy in the defined role, GDP and document
- Involve the deputy regularly in RP activities including audits
- Create a contact list to include telephone number for the RP and his deputy and the company’s Managing Director, Marketing Manager and other senior management as appropriate
- Ensure RP can access company’s electronic systems remotely
- A contract RP can help provide an appropriate service

*The written job description of the responsible person should define their authority to take decisions with regard to their responsibilities. The wholesale distributor should give the responsible person the defined authority, resources and responsibility needed to fulfil their duties.*

**What is the rationale for this point in the guidance?**

The role of the RP is a vital position within a wholesale distributor, and therefore must be appropriately defined in a job description. The RP’s responsibilities and duties are legal requirements and clearly defined in GDP for which he/she is personally liable. To fulfil these responsibilities he/she must have sufficient authority and resources to discharge them effectively.

**What are the risks and benefits associated with this aspect of the guidance?**

**Benefits**

Providing the RP with a written definition of their role and responsibilities provides both the wholesale distributor’s senior management and the RP with clearly defined expectations and outcomes for the role. A detailed job description is a regulatory requirement.

**Risks**

Without the roles and responsibilities of the RP being defined, it could lead to key GDP tasks and activities not being performed, or adequately reviewed. The wholesale distributor might think that the RP is dealing with a required activity, whereas the RP thinks that it is being done by another member of the organisation and they will be informed of any issues or escalation requirements. This will result in gaps with the wholesale distributor’s compliance with GDP.

In the event of a contract RP not having a job description it is more likely that gaps in compliance will occur, and could put both the RP and the company at risk.

**How might this be implemented/ what does it mean?**

The job description of the RP should list the responsibilities detailed in the GDP Guidance, plus any other company specific activities assigned to them. A copy of the company organisation chart could be added to the job description to show where the role fits within the management structure of the wholesale distributor, with a list of what decision making authority the RP has without needing board approval.

The RP’s job description should be reviewed and updated whenever changes in the nature of the business occur or changes to the licence are made.
In order for the RP to fulfil their duties and responsibilities, appropriate resources should be provided by the wholesale distributor. The level of resource required will depend on the size and complexity of the wholesale distributor and the activities being undertaken. Elements to consider for this analysis would be:

- **Activities**
  - Procurement
  - Selling
  - Storage
  - Distribution (in house or sub-contracted)
  - Import / Parallel Import
  - Export
  - Returns

- **Products**
  - Product portfolio (number of products handled)
  - Product volume (quantity of products handled)
  - Product categories (POM, P, GSL, Cold Chain, Controlled Drugs)
  - Product classes (sterile/non-sterile, liquid/semi-solid/solid, medical gases)
  - Unlicensed Medicinal Products / Specials

- **Sites**
  - Number of sites
  - Types of site (Distribution only, Storage and Handling)

The responsible person should carry out their duties in such a way as to ensure that the wholesale distributor can demonstrate GDP compliance and that public service obligations are met.

- **What is the rationale for this point in the guidance?**

In order for a wholesale distributor to demonstrate compliance with GDP, all activities performed must be documented and recorded. These must be done in accordance with defined processes (SOP's) to ensure that records are made consistently. The RP should document the activities performed at the time of performing them, including signature and date.

- **What are the risks and benefits associated with this aspect of the guidance?**

**Benefits**

Documenting activities is essential to GDP compliance but it also provides a clear audit trail of the activities undertaken, when they were undertaken and by whom. As well as providing suitable evidence that an activity took place at a particular point in time, documented records are very useful for conducting investigations into deviations and for performing root cause analysis.

**Risks**

Without documenting activities undertaken, it will not be possible to undertake an investigation thoroughly if something goes wrong, or be able to provide evidence that the activity was in fact undertaken.

- **How might this be implemented/ what does it mean?**

Each type of activity performed by the RP should be included in a procedure which forms part of the Quality Management System. The procedures should define what activity is required, when it is required, who is responsible, how it should be carried out and what needs to be documented. Making use of controlled forms/templates linked to the procedure helps to ensure that the required information
The responsibilities of the responsible person include:

- **How might this be implemented/ what does it mean?**

  i) *Ensuring that a QMS is implemented and maintained;*

  To do this, the RP must always be sufficiently involved with the QMS to ensure ongoing compliance with GDP, especially with respect to proposed changes. Where the RP cannot attend management review meetings, he/she must ensure that they receive output of the meeting for review and approval.

  ii) *Focussing on the management of authorised activities and the accuracy and quality of records;*

  The RP must ensure he/she is aware of the details of the Wholesale Dealer Authorisation (WDA) and the systems and documentation are supporting them. The RP should develop a procedure to define what records should be checked for accuracy and quality. Some authorities may permit some of these checks to be delegated to appropriately trained personnel, however, the accountability of the accuracy of the records will remain with the RP.

  iii) *Ensuring that initial and continuous training programmes are implemented and maintained;*

  The RP would typically be involved in establishing and approving the training programme to be used. It is also typical for the RP to conduct some training sessions as it is a good way to receive feedback on various aspects of the QMS. Training records should be included in self inspections and the RP made aware if there are any gaps/delays to training plans.

  iv) *Coordinating and promptly performing any recall operations for medicinal products;*

  The RP plays a pivotal role in any recall operation and provides a key communication and coordination link between the company, regulatory authorities and suppliers/customers.

  v) *Ensuring that relevant customer complaints are dealt with effectively;*

  In small organisations, the RP may personally deal with all quality related complaints. In larger organisations, the RP should be made aware at minimum and ideally involved in all significant quality complaints, plus any that may relate to falsified product. The RP should also be involved in trending of complaints to ensure he/she is aware of the level and frequency of complaints. The RP should develop Technical Agreements with each marketing authorisation holder which defines types of complaints which require referral to them and the reporting timescales. It is particularly important that any medical complaints, adverse reactions and concerns are referred to the appropriate medical team promptly.

  vi) *Ensuring that suppliers and customers are approved;*

  The RP should develop a procedure defining the process for checking bona fides of
the suppliers and customers with reference to nationally available information. Regulatory approval for both suppliers and customers can change and the RP should have a system for understanding how this information can be obtained nationally to enable their database to be updated. Ensuring these activities are included in regular internal audits should provide ongoing assurance that the system is working.

vii) **Approving any subcontracted activities which may impact on GDP;**
The RP should be involved in the selection, audit and approval of any subcontracted activities and will be a signatory on the corresponding Technical/Quality Agreement.

viii) **Ensuring that self-inspections are performed at appropriate, regular intervals following a prearranged programme and necessary corrective measures are put in place;**
The RP should be personally involved in a number of self-inspections, as a minimum covering high risk areas and/or those with a poor compliance record. It is highly recommended that the RP has been trained in auditing.

ix) **Keeping appropriate records of any delegated duties;**
It is important that all delegated duties are recorded; whether these be permanently or as a temporary arrangement. Records should include, in sufficient detail; what, who, when and for how long, so that no misunderstandings occur.

x) **Deciding on the final disposition of returned, rejected, recalled or falsified products;**
The RP should develop a procedure defining the criteria for final disposition of returned, rejected, recalled or falsified products. This is a key role for the RP and all decisions taken must be documented and justified.

xi) **Approving any returns to stock;**
The criteria for acceptance of the returns back to stock should be defined in a procedure based on the details in the technical agreement with the Marketing Authorisation Holder (MAH). Where checks undertaken have indicated that certain returns can be approved back into stock; the RP needs to review each situation in detail, assure him/herself that it is acceptable to do this and personally approve this transaction.

xii) **Ensuring that any additional requirements imposed on certain products by national law are adhered to².**
It is a key part of the RP role to ensure they keep up to date with requirements for certain types of products e.g. Controlled Drugs. The RP should ensure he/she has easy access to web sites or other sources of information that provide alerts to any proposed changes to legislation that could affect any product in one of these categories.

² Article 83 of Directive 2001/83/EC
2.3. Other personnel

There should be an adequate number of competent personnel involved in all stages of the wholesale distribution activities of medicinal products. The number of personnel required will depend on the volume and scope of activities.

- **What is the rationale for this point in the guidance?**

Work volumes need to be balanced with the number of personnel to ensure execution of work activities is carried out as planned and in a controlled manner. Any imbalance can stress normal operations, creating the risk of errors that can adversely impact the patient.

- **What are the risks and benefits associated with this aspect of the guidance?**

  - **Benefits**
    - An adequate balance between the activities to be performed and the personnel to perform them will ensure a correct flow of the business. This will be beneficial in providing assurance of the quality of the product and reducing risk but also provide a high level of customer satisfaction by having an optimized service.
    - A good alignment / coordination between resources and workload allows time for other activities (e.g. training when the volume of work is low)

  - **Risks**
    - There are number of risks which may result from an imbalance between workload and personnel, e.g.:
      - Personnel may take short cuts in procedures with probability of errors.
      - Training plan may be compromised
      - Internal audit programme may be delayed or cancelled.
      - Absenteeism and turnover may increase which would exacerbate the problem.

- **How might this be implemented/ what does it mean?**

  It is the responsibility of senior management and the RP to jointly ensure a proper balance between resources and workload. Examples of how this may be achieved are:
  - Having ongoing dialogue with the staff regarding concerns and responding appropriately
  - Anticipate peaks in workload (e.g. seasonal activities) and manage coverage for holiday periods and hire staff to enable training to occur in good time.

  **Note:** Lean - SixSIGMA tools or similar processes can be used to help to align resources to the workload (i.e. pull methods, Kanban systems.)

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The organisational structure of the wholesale distributor should be set out in an organisation chart. The role, responsibilities, and interrelationships of all personnel should be clearly indicated.

- **What is the rationale for this point in the guidance?**

  - Responsibilities should be defined to ensure the processes are executed in a controlled manner and that there are no gaps created by responsibilities being unclear.
  - All operations, requirements and communication channels needed for routine activities, and to deal with non-routine situations, should be defined by the organisation. This can only be achieved when the functions and responsibilities are clearly identified.
**What are the risks and benefits associated with this aspect of the guidance?**

**Benefits**
An organisation where the responsibilities, functions and interrelationships are clearly defined
- Reduces risk of non-compliance due to lack of clarity of roles
- Minimises the chance of gaps in responsibilities occurring

**Risks**
Where roles and responsibilities are not defined, then the following risks exist:
- Activities can be duplicated
- Some activities may not be performed due to assumption that somebody else is responsible
- In emergency situations or in cases of deviations, the organisation may not be capable of reacting appropriately due to lack of clear responsibilities.

**How might this be implemented/ what does it mean?**

Examples of how this might be implemented are:
- By mapping the processes and identifying the stakeholders for each operation, information and document flow.
- Ensuring responsibilities, controls and actions to be taken are included in job descriptions, procedures or RACI (Responsible-Accountable-Consulted-Informed) diagrams.
- Managers must communicate responsibilities clearly during the induction training and clarify any KPIs/Quality indicators for which the person is responsible.

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**The role and responsibilities of employees working in key positions should be set out in written job descriptions, along with any arrangements for deputising.**

**What is the rationale for this point in the guidance?**

Written job description ensures individuals are clear on their role and responsibilities within the organisation and there should be no ambiguity.

**What are the risks and benefits associated with this aspect of the guidance?**

**Benefits**
- Personnel have a clear understanding of their role and the organisation’s expectations of them.
- Helps management to build a robust organisation and achieve a controlled, standardised operation.
- Assists Human Resources in attracting talent and developing personnel.

**Risks**
See previous section regarding risks where roles and responsibilities are not defined.

**How might this be implemented/ what does it mean?**

- The manager defines the responsibilities in conjunction with the Human Resources (Personnel) Department who would normally set the organisational framework for the document.
- Jobs descriptions should be subject to continual review to ensure they reflect the current expectations.
2.4. Training

All personnel involved in wholesale distribution activities should be trained on the requirements of GDP. They should have the appropriate competence and experience prior to commencing their tasks.

- What is the rationale for this point in the guidance?

The rationale for this requirement is that pharmaceutical wholesalers handle medicines which may have specific storage, security, and handling requirements. EU GDP describes specific requirements for storage, handling and transportation of medicines, therefore any lack of understanding of these requirements could result in customer dissatisfaction, risks to quality of product and commercial losses.

- What are the risks and benefits associated with this aspect of the guidance?

  - Benefits
    Trained personnel who have good understanding of the processes, procedures and product requirements will operate within the company’s QMS framework ensuring medicines safety, integrity and security during storage and transportation. Trained personnel will be able to understand and see problems when they occur and following proper reporting procedures inform the management so that appropriate action can be taken. Providing adequate training to staff enables them to perform effectively minimising risk of damage to products they are handling.

  - Risks
    Lack of training could result in:
    - Damage to the products
    - Security of the medicines being compromised, e.g. counterfeits entering the market.
    - Important pharmacovigilance (PV) data not being communicated
    - Significant commercial losses, e.g. recalls
    - The QMS failing, putting pressure on other areas (and individuals) through poor decision making
    - Suspension of the company’s licence (WDA)

Note: there is a particular risk associated with recruitment of temporary personnel who may be employed at very short notice with low levels of awareness of risks associated with the activities which will probably be new to them.

- How might this be implemented/ what does it mean?

It is the responsibility of senior management in conjunction with the RP to ensure that the initial and continuous training of personnel is implemented. The RP should have direct input into the design and implementation of a GDP induction programme for all personnel. This should be based on the job description and the level of detail should reflect the position of responsibility within the QMS and organisation as a whole.

The induction training should be captured in a procedure and clearly outline the minimum requirements and tasks which may consequently be performed. It should also include details of the approval process.

Subsequent training in GDP should be planned and cover greater detail. This must be captured in the overall training programme for the organisation.
Mechanisms must be in place to ensure that persons not yet trained in GDP are not allowed or asked to complete any relevant tasks. This relies on good management oversight of the training programme and matrix for their direct reports. It also relies on personal integrity of individuals to resist the temptation to complete tasks for which they have not been inducted or trained and the training programme should emphasise this.

The national regulatory requirements for training RPs vary. As a minimum, good understanding of the GDP requirements is expected. As this is a developing scenario you should check on the current national regulatory expectations. E.g., in UK, a COGENT Gold Standard was developed by the industry supported by the MHRA. See: http://www.thegold-standard.co.uk/job-details/?jobid=297

Personnel should receive initial and continuing training relevant to their role, based on written procedures and in accordance with a written training programme. The responsible Person should maintain their competence in GDP through regular training.

- What is the rationale for this point in the guidance?
For a QMS to remain effective; training must be comprehensive and updated regularly to ensure GDP standards and regulatory requirements are continuously met.

- What are the risks and benefits associated with this aspect of the guidance?

  - Benefits
A well designed induction programme and on-going training helps ensure personnel are equipped with the correct knowledge to carry out their duties effectively and efficiently. This minimises the number of non-conformances or deviations that occur due to poor or incomplete training.

A RP who successfully maintains their knowledge of GDP and regulatory requirements is able to act as figurehead in driving the compliance of the organisation and can act as a key trainer of other personnel. This in turn helps drive continuous improvement of quality standards and procedures within the QMS.

  - Risks
See previous section regarding risks associated with a lack of training.

- How might this be implemented/ what does it mean?
The overall training programme is often captured in a training matrix. This method is effective and can be tailored to roles and departments. Training frequency and results of competency tests can also be captured along with prompts for retraining. A simple Excel spreadsheet can be effective providing it is regularly maintained and reviewed. Training should be clearly split into stages tied with activities that may or may not be consequently performed by the individual.

Training processes can be split into 4 stages:

1. Training needs identification
2. Training guides developed (SOPs)
3. Training implementation
4. Training outcomes evaluation

These different stages are further elaborated below.
1) **Training needs identification**  
This should be based on:  
- Organisational Analysis – e.g., Objectives, Resources, Organisational climate and culture  
- Job Analysis – i.e., job description & specification  
- Individual Analysis – i.e., knowledge, skills & abilities

2) **Training guides developed**  
The training plan provides the framework to describe details of the GDP requirements. These need to be described in SOPs. Key factors are:  
- All personnel are trained to adequately perform the assigned job and responsibilities  
- Training is performed according to approved SOP(s)  
- Employees are continually trained in procedures relevant to their responsibilities

Factors to consider for the training schedule include:  
- An annual training plan (incorporating GDP requirements) is prepared, then reviewed and approved by QA and the RP  
- Time is allocated for training sessions – taking account of any shift working patterns.

3) **Training programme implementation**  
   i. **New employee training**  
      Includes general training, basic and intermediate GDP training, safety procedures, work methods “on the job training”, and a qualification/certification process.
   
   ii. **Existing employee training**  
       Includes annual GDP continuing education training, new SOP training, SOP re-training and professional development training.  
       **Note:** the requirement for annual refresher GDP training may be more effectively achieved by having several short discussion sessions on recent quality incidents and the corrective actions taken to resolve the issue and prevent recurrence. This should be supplemented by specific training any GDP requirements.
   
   iii. **Corrective training**  
       In the case of human error or a deviation from an existing procedure, the relevant department head and/or QA will define the corrective training requirements.
   
   iv. **Management continuing education training**  
       Department heads and team supervisors will take part in management training sessions throughout the year, to enhance their management skills and techniques. These training sessions could be performed as a group or on a 1:1 basis with a personal coach.

4) **Training Outcomes Evaluation**  
It is an expectation that all training be assessed for effectiveness where the person is expected to remember the specific requirements. Where possible, in a practical situation, a new skill acquired can be demonstrated by the trainee to show that they understand how to perform the task. This should be demonstrated on more than one occasion to provide greater assurance. Where the training is designed to transfer important knowledge, course assessments should be included with a clear pass/fail mark and an established process to follow for those who are unsuccessful. This may be achieved using a short questionnaire or a multiple choice quiz.
The RP can maintain their understanding of the current requirements by:

- External site visits
- Attending regulatory and industry symposia and conferences
- Building a network of RP colleagues
- Referring to national regulatory websites for current updates

In addition, training should include aspects of product identification and avoidance of falsified medicines entering the supply chain.

- What is the rationale for this point in the guidance?

In an industry increasingly at risk of falsified product entering the market and posing a risk to patient safety, specific training in identifying falsified medicines must be incorporated into the organisation’s training programme. Supply chains of medicines are increasingly more complex and offer more opportunities for falsified medicines to enter. This is particularly a risk in parallel imports and imports from third countries where multiple brokers or distributors may be involved.

- What are the risks and benefits associated with this aspect of the guidance?

- Benefits
Staff well trained in identifying falsified medicines help protect the patient and ensure that falsified product is isolated prior to it reaching the open market. The organisation also benefits from reduced impact on supplies and costs of recalls.

The industry as a whole benefits from any falsified product being seized where the sources of introduction can be identified and those responsible prosecuted.

- Risks
Products which enter the distribution chain under the guise of reputable brands may quickly find themselves in the hands of the patient and place them at risk of low efficacy and safety. The further a falsified product goes through the distribution chain, the more complex and difficult any recall of the product is.

- How might this be implemented/ what does it mean?
A written procedure for checking of in-coming products should include specific checks relating to unique identifiers, sites of manufacture and distribution in accordance with the documented supply chain.

Personnel should be given training in understanding the complexities of supply chains with emphasis on how these may be exploited by counterfeiters. This should be re-enforced by examples of falsified product and how they may be distinguished from genuine product.

Good communication and working relationships with the Marketing Authorisation Holder should be established, for example ensuring any changes to product identifiers, sites of manufacture and issuance of Certificates of Analysis are informed to the distributor. This should be captured in the Quality/Technical Agreement between the relevant parties. Particular attention should be paid to partly opened packs, damaged pallets and opened boxes as possible indicators of falsified products.
Personnel dealing with any products which require more stringent handling conditions should receive specific training. Examples of such products include hazardous products, radioactive materials, products presenting special risks of abuse (including narcotic and psychotropic substances), and temperature-sensitive products.

- **What is the rationale for this point in the guidance?**

Hazardous products represent risks both to the initial distributor personnel and all other personnel subsequently handling them in the supply chain. This places a particular emphasis and responsibility on the need to protect them very well.

- **What are the risks and benefits associated with this aspect of the guidance?**

**Benefits**

Personnel specifically trained in these requirements will reduce the risk of non-conformances and any occupational health issues for both themselves and other personnel within the supply chain.

**Risks**

If handled incorrectly there is a risk to product quality and to personnel involved in the handling them. This may be particularly an issue when disposing of medicinal product.

- **How might this be implemented/ what does it mean?**

i) Use published guidance on cold chain

ii) Ensure precautions in hazard data sheets are incorporated into procedures.

iii) Obtain information from the manufacturers about sensitivity of the products to heat, light, humidity etc. Note: this should be in the technical agreement.

A record of all training should be kept, and the effectiveness of training should be periodically assessed and documented.

- **What is the rationale for this point in the guidance?**

Complete training records enable management to track training needs of individuals and the company as a whole and therefore address any knowledge or experience gaps as required. Some procedures are critical to product quality, therefore effectiveness of training on these is of paramount importance, e.g., checking data records for cold chain products. In the absence of training assessment product quality is clearly at risk. Documentation of this assessment allows for weaknesses in the training programme to be identified and corrected in a timely manner.

- **What are the risks and benefits associated with this aspect of the guidance?**

**Benefits**

Documentation of all training ensures that individuals and the organisation as a whole are able to demonstrate that activities carried out are being performed by trained personnel. Well documented training facilitates root cause investigations and in the review of the effectiveness of training. It also enables any gaps in the overall training programme to be identified and addressed to strengthen processes and GDP compliance. Records of training should provide assurance to the regulators and customers during their audits that staff have been trained adequately.
- **Risks**
  Risks associated with an absence of appropriate training documentation include:
  - Management is unable to monitor the effectiveness of training
  - Levels of GDP knowledge or standards decrease
  - Increased errors and risk to patients
  - Business efficiency and service levels will be impacted.

- **How might this be implemented/what does it mean?**

  The procedure for training should detail how the records should be kept and how assessment should be carried out.

  Training records normally include:
  - A title of the topic and a reference to the material used. E.g., SOP No. with version number.
  - The trainee’s name
  - The trainer’s name
  - Date
  - Trainee’s signature showing they have received it.
  - Sign off/completion statement from the trainer.

  **Note:** Many companies include this information in their matrix records to help management and some display it publically. Training records for each individual along with results of any assessments should be kept in their personal training folder.

  This should be accompanied by an overview of the training requirements for their job role within the organisation. Where training is performed by external provider’s details of the trainer’s credentials and experience should be kept on file along with the training material used.

  Different assessment methods are possible e.g.
  - Check knowledge with a test.
  - Observe competence in practice
  - State when the person is a trained Trainer.

  The organisation needs to decide and record what level of assessment is required for different procedures/activities. For example, training in GDP will probably require a knowledge test whereas training in use of data logger will probably require assessment of practical competence.

  The RP should be involved or have sight of the output of training assessments and these data should be trended and used to benchmark standards.

  Periodic assessment of training ensures that standards are maintained and that the manner of delivery remains appropriate.
2.5. Hygiene

Appropriate procedure relating to personnel hygiene, relevant to the activities being carried out, should be established and observed. Such procedures should cover health, hygiene and clothing.

- What is the rationale for this point in the guidance?

In any organisation, good health is essential for individuals to perform their tasks efficiently, correctly and to a good standard. In order to ensure this, an organisation has to ensure these standards are defined. To assist people involved, in order to fulfil their task, clothing where appropriate may need to be provided as well as ensuring the maintenance of the work wear.

- What are the risks and benefits associated with this aspect of the guidance?

- Benefits

  - Health
  
  Good health will ensure that individuals are fully focused on their activity. They are also able to conduct the work efficiently especially in areas which may involve a lot of physical activity.
  
  Personnel not in good health, especially those suffering conditions which could be passed onto other staff, e.g., flu, diarrhoea, should be discouraged from attending work so as to avoid affecting other colleagues. This is a vital consideration where a pandemic e.g. bird flu etc. is involved.
  
  - Hygiene
  
  Appropriate facilities on site, e.g., washrooms, canteen/designated eating areas, storage of personnel items and change areas strategically placed are necessary for the hygiene of individuals. Also rules relating to cleaning of any provided work wear are essential to maintain a good standard of clothing. Good presentation of individuals is important as it identifies them as employees and makes them feel good about themselves as well as to any outside visitors. This is particularly important where individuals are involved in delivering to patient homes.
  
  - Clothing
  
  Protection of individuals especially in areas such as picking, packing, and transportation of medicinal products is important. This will not only assist individuals, who will be able to work comfortably in the correct work wear and be protected e.g. hard hats for head protection from products stored at high levels; safety shoes etc., but also protect products from potential damage as staff are able to work without concerns of their safety, thus taking time and care with products they are handling.

- Risks

  - Health
  
  Poor health of individuals may result in poor performance of their given tasks. This may lead to errors which will ultimately result in increased workload.
  
  The potential of affecting other staff may result in insufficient personnel i.e. literally not enough people to perform all the tasks required. The organisation may try to continue using staff who do not fully understand what the role is, or may not have been trained on how to perform tasks correctly and completely and what to do if something goes wrong.
The organisation may appear to function satisfactorily for some time; however, as soon as there are any “stresses” on the system these issues will become very obvious.

- **Hygiene**
  The risk of poor hygiene is much the same as above. It will in addition lower staff morale, result in contaminated products and poor work practices.

- **Clothing**
  Poor clothing is a risk particularly in areas where a lot of physical activity is involved. The biggest risk is to the organisation where an injury to an individual may result, which will cost the organisation financially as well as affecting work efficiency.

### How might this be implemented/ what does it mean?

Each organisation / site should ensure there is appropriate documentation relating to all the above areas. Clear and comprehensive job descriptions and a training programme that is tailored are needed to ensure that all staff, whether they work on or off site (including drivers), fully understand their role.

Locate washrooms in appropriate areas to ensure that hands are washed after using toilets. Canteens or designated eating areas with lockers for food storage and drinks machines etc. should be provided so that no food, drinks etc. are brought into the work areas. Chewing, drinking or eating should not be allowed in any areas other than these dedicated areas. Also, no personal medication is allowed in the operational areas. Likewise a designated smoking area should be provided.

Health and Safety person(s) should be appointed on site to ensure these aspects of the organisation are in compliance.

Suitable clothing/work wear will vary with the tasks being performed by individuals. Some suggestions are as follows:

- **Pick/Packing operators** – Strong pair of closed shoes with hard toecap, and good protective coveralls with no pockets. If working in cold pack areas then suitable gloves and fleeces/coats should also be included.

- **Forklift operator** – same as pick/pack operator, but must have a hard hat as well if the storage areas have high racking.

- **Drivers** – smart trousers and jackets preferably with company logo. However if drivers delivering to homecare patients, then clothing may need to be more discreet.