Code of Practice The Responsible Person for GDP

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Contributors:

The Code of Practice has been developed by a Task Force initiated by the ECA Foundation

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O Objective

This Code of Practice has been developed to support the Responsible Person (RP) according to EU GDP Guide 2013/C343/01. It provides information about the Responsibilities and Duties of RPs as well as recommendation for education and ongoing training.

1 Scope

The EU Guide to Good Distribution Practice (2013/C 343/01) defines the Role and Responsibilities as well as the qualification and experience requirements for a Responsible Person (RP) to operate within a Wholesaling operation. However, currently there is no competency framework to guide the industry and RPs on how to achieve the desired standards and support their continuous professional development. This Code of Practice has been developed from existing good practices within the pharmaceutical industry and provides a framework for companies and individuals to benchmark their skills, knowledge and experience bringing a level of consistency across wholesalers in the EU. It also includes a job description example that could help RPs to define their role in the supply chain of medicinal products. This document is relevant to those working both in large organisations and much smaller wholesaling and distribution operations, however, the role, responsibilities and training should always be developed in line with the company's operations and business model.

2 Responsibilities and Duties of the RP

Chapter 2, article 2.2 of the GDP Guidelines defines the requirements, responsibilities and duties of the RPs; these have been listed in the table below. For each requirement (left column) a recommendation is provided in the right column. The recommendations are taken from the PQG/ECA Guidance on the interpretation and implementation of European Good Distribution Practice

Chapter 2 – Personnel

Requirement	Recommendation
The wholesale distributor must designate a person as responsible person.	The appointment of an RP must be carefully considered as this is a key role within the company, ensuring that a suitably trained and experienced person is selected. The details of this appointment are dependent on the size of the organisation, the complexity of the services and the product classes it manages. In small organisations that handle a limited number of product lines, it is generally acceptable for the licence holder to be the RP; whereas in a large multi- site wholesale distributor, a dedicated RP should be appointed, who is independent from the daily operations and has defined duties. If a company chooses to appoint a contract RP; then the contract RP should have the same level of knowledge and training in the products handled by the company and their procedures as a permanent RP. In practice, this limits the number of licences that a contract RP can effectively support. When a company considers appointing a contract RP, the selection process should include confirmation of the number of other wholesale authorisations the potential candidate is named on, to determine whether this person will have sufficient free time and flexibility to support the operations. It should be noted that some Competent Authorities refuse approval of proposed RPs to be named on a licence if they consider the candidate is already involved with too many other licences to fulfil his/her duties effectively. The contract RP should also consider his/her availability before accepting a new appointment. Note: See reference to COGENT RP Gold Standard: http://www.thegold-standard.co.uk/job-details/?jobid=297

Requirement	Recommendation
The responsible person should meet the qualifications and all conditions provided for by the legislation of the Member State concerned.	The nominated Responsible Person should be able to show an in depth understanding of the medicinal products he/she is responsible for. This includes overall quality requirements for different dosage forms (product presentations), reasons why certain storage conditions are required, and risks associated with any temperature excursions occurring during storage and/or transportation. The RP must be able to demonstrate up to date knowledge of GDP requirements, and how these are embedded within the systems and processes implemented at the wholesale distributor. Some key areas of knowledge and experience are listed below: **Knowledge** - Storage conditions/requirements for different types of pharmaceutical products in their facility; - Basic understanding of degradation pathways and typical stability profiles of pharmaceutical products; - GDP legislation and relevant guidance; (including any national requirements) - Requirements for storage facilities, temperature control and monitoring programmes, including mapping and qualification; - Quality Management Systems (QMS) and how to manage these effectively; - Understanding of current data integrity expectations - Handling of returns/complaints/recalls; - Bona Fide checks; - Risks associated with Falsified Medicines; - Expectations of a robust Technical (Quality) Agreement with contractors & outsourcing companies; - Narcotics and psychotropic substances, plus other "controlled" medicines legislation, e.g. homeopathic, veterinary, and requirements of the relevant Member State(s); - Auditing requirements and auditing techniques Note: RPs may contact manufacturers or conduct on line search to obtain quality relevant information about the products they are responsible for. **Experience** - Experience of picking /packing procedures and FEFO (First Expiry, First Out) principles; - Managing quality complaints and customer queries including service issues; - Active involvement in GDP regulatory inspections; - Sufficient familiarity with the GDP operations of the Licence Holder - Personally involved in internal audits to monitor the QMS and look for weaknesses then opportunities to improve. Also involved in customer audits of the site plus 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 - Sufficient understanding of typical IT systems used in GDP activities. - Security of storage, traceability during storage and onward distribution Note: RPs should consider working at the wholesalers for a period of time (e.g. 1-2 years) to gain good understanding of the subjects listed above.

Requirement	Recommendation
A degree in pharmacy is desirable.	Competent Authorities will assess the experience of individuals proposed as RPs. A degree in Pharmacy helps ensure the RP has a good understanding of the quality requirements of medicinal products, in particular storage requirements and degradation pathways. However, other science-based qualifications will also be acceptable. NOTE: some regulatory Authorities do not require a degree in Pharmacy or related science-based qualification. An RP is unlikely to be accepted unless they have a minimum of one to two years' experience of distribution activities. A longer period of experience, ideally in a management role, would be preferred.
The responsible person should have appropriate competence and experience as well as knowledge of and training in GDP.	See above. The RP may gain some of the knowledge requirements by attending appropriate training courses, or by participating in audits performed by experienced auditors. The RP must ensure that all the training received is fully documented in training records. The RP must also keep up to date with recent developments in GDP and any other, relevant wider issues affecting the Pharmaceutical Industry.
The responsible person should fulfil their responsibilities personally and should be continuously contactable.	– It is recognised that the RP may not be able to carry out all his/her responsibilities personally and be continuously contactable, especially at large and/or complex sites. One strategy often adopted is to appoint one or more deputy RPs. This requirement can therefore be implemented with the following actions - Nominate a deputy and add to the Wholesale Dealer Authorisation (WDA) (or inform the local authority, following the local Member State procedures) - Issue a formal job description for the RP and his/her deputy, defining the responsibilities of the RP and deputy RP in a procedure. - Train deputy in the defined role, GDP and document this training - Involve the deputy regularly in RP activities including audits - Create a contact list to include telephone numbers for the RP and his/her deputy, the company's Managing Director, Marketing Manager and other senior management as appropriate - Ensure his/her contact details are available to all staff within the organisation. - Ensure RP can access company's electronic systems remotely - A contract RP may be able to provide an appropriate service and if appointed, he/she must be made aware of all ongoing activities and any issues arising
The responsible person may delegate duties but not responsibilities.	It is important to note that whilst the RP can delegate daily activities to appropriately trained personnel, the ultimate responsibility for those activities will remain with the RP. Any approval of completed activities should be performed by the RP nominated in the WDA.

Requirement	Recommendation
The written job description of the responsible person should define their authority to take decisions with regard to their responsibilities.	The RP's job description should list the responsibilities detailed in the GDP Guidance, plus any other company specific activities assigned to him/her. A copy of the company's organisation chart should be added to the job description to show where the role fits within the management structure of the wholesale distributor. A list of what decision-making authority the RP has without needing board approval should be documented. The Job description should be reviewed and updated whenever the nature of the business, the site authorisation and/or the regulatory requirements change. In order for the RP to fulfil his/her 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 operations and the activities undertaken. Elements to consider for this analysis should include but not be limited to: **Activities** - Procurement - Selling - Storage - Distribution (in house or sub-contracted) - Import / Parallel Import - Export - Returns - Recall & Destruction **Products** - Product portfolio (number of products handled) - Product volume (quantity of products handled) - Product categories (e.g. Prescription only, Pharmacy, Cold Chain, Narcotics and Psychotropic substances, Veterinary medicines) - 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) **Licences** - Number and type(s) of licences associated with the company and/or site as relevant. The job description and level of authority should not change if a contract RP is engaged.
The wholesale distributor should give the responsible person the defined authority, resources and responsibility needed to fulfil their duties.	See above. The wholesale distributor must ensure that careful selection of an RP is undertaken and that adequate resources are made available to ensure the RP can fulfil his/her duties regarding ongoing training to ensure compliance with current regulatory and GDP guidance The responsibilities and authority of the RP should be described in relevant company procedures and his/her job description. Where a contract RP is employed, these responsibilities and authorities should be described in a Technical Agreement between the RP and the WDA holder. A Contract RP is expected to have the same level of experience, training, responsibility and authority as a permeant RP in the organization these should be clearly documented in the Technical Agreement. Any differences would need to be justified.

Requirement	Recommendation
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.	Each activity performed by the RP should be included in a procedure which forms part of the company's Quality Management System. The procedures should define what activities are required, when they are required, who is responsible, how they should be carried out and what needs to be documented. Use of controlled forms/templates linked to procedures helps to ensure that the required information is provided in a consistent manner. The specific tasks performed by the RP should also be documented formally and signed and dated by the RP. All responsibilities of an RP also apply to any contract RP.
The responsibilities of the RP include:	For this section the term RP also includes any contract RP employed by a company.
ensuring that a quality management system is implemented and maintained;	To fulfil this responsibility, the RP must be actively involved in the development, implementation and ongoing management of the QMS to ensure continued compliance with GDP. The RP should be aware of any proposed changes that may have an impact on the QMS and/or regulatory compliance and always be looking for opportunities to make improvements and ensure best practices are embedded in the quality system. The RP should attend management review meetings where quality metrics are discussed, concerns regarding any negative trends highlighted and corrective actions agreed and monitored. Where the RP cannot attend a meeting, he/she must ensure that they receive all outputs from the meeting for review and approval.
focusing 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 WDA and the systems and documentation supporting it. The RP should also be aware when any changes are proposed to the scope and details of an existing authorization then he/she has to ensure the site will remain compliant with the relevant GDP requirements. The RP should develop a procedure to define the GDP relevant records and how they should be checked for accuracy and quality. Some authorities may permit some of these checks to be delegated to appropriately trained personnel; however, overall accountability for accuracy of the records will remain with the RP. The RP must ensure he/she is fully aware of Data Integrity requirements and the ALCOA (+) principles applied.
ensuring that initial and continuous training programs are implemented and maintained;	The RP would typically be involved in establishing and approving the training programme for the company. It is also advisable 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 reviewed during the self-inspections and the RP made aware of any gaps/delays to training plans. The RP must also attend appropriate training courses to ensure continued current knowledge of GDP requirements and regulatory authority expectations.
coordinating and promptly performing any recall operations for medicinal products;	The RP plays a pivotal role in any recall operation by participating in the activities, communications and coordinating the link between the company, regulatory authorities and suppliers/customers where appropriate. The RP should coordinate a mock recall (at least annually) to challenge the company systems and use the learning points for improvement of the system. In doing so, details should be varied each time, so the system is challenged. It is important that all aspects of the work performed are covered e.g. export, cold storage. The RP should document mock recall findings and share with the management team. Any contract RP, if not involved in a mock recall, should be made aware of how successful or otherwise it was and any learning points.

Requirement	Recommendation
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, as a minimum, the RP should be made aware of and ideally involved in all significant quality complaints, plus any that may relate to falsified medicines. The RP should also be involved in trending of complaints to ensure he/she is aware of the level and frequency of complaints, and use this data to improve operations reducing the number of complaints. The RP should develop Technical Agreements with each client which detail the responsibilities for receiving, investigating and reporting complaints. It is particularly important that any medical complaints, adverse reactions and concerns are referred to the appropriate Marketing Authorisation Holder (MAH).
ensuring that suppliers and customers are approved;	Before selection and awarding of any contracts, the RP must ensure that due diligence checks are performed on proposed suppliers and customers, including bona fide checks. The RP should develop a procedure defining the selection and approval process and how to perform periodic bona fide checks 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. The RP where possible should time their checks in accordance with when the nationally available information is updated. These activities should be included in the regular internal audits to provide ongoing assurance that the system is working.
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 be a signatory on the corresponding Technical/Quality Agreement. The selection must confirm the sub-contractor is legally allowed to offer the services being proposed. Where the RP is a contract RP, then this responsibility should be clearly defined in the Technical Agreement he/she has with the WDA holder. The RP should also develop an ongoing monitoring program for management of the subcontractors including periodic review and audits as appropriate.
ensuring that self-inspections are performed at appropriate regular intervals following a prearranged program and necessary corrective measures are put in place;	The RP should develop an annual self- inspection program for the company supported by risk assessment and be personally involved in a number of the 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 formally trained in auditing skills to help ensure this process is both robust and effective.
keeping appropriate records of any delegated duties;	It is important that all delegated duties are recorded; whether these be permanent or as a temporary arrangement. Records should include, in sufficient detail; what, who, when and for how long, so that no misunderstandings occur. It is recommended all delegated activities are defined in a procedure.
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 when the wholesaler owns the product, all decisions taken must be documented and justified. This is particularly important if the RP has no access to the Marketing Authorisation Holder. It is important to be clear that the disposition decision by the RP is different to the manufacturer's Qualified Person (QP) batch certification. The RP disposition is based on the information available for product transportation and storage condition, including the goods receipt procedure; however the MAH QP (if known) or the MAH should be made aware where possible of any factors that could impact the safety, quality or efficacy of the product.

Requirement	Recommendation
approving any returns to saleable stock;	The criteria for acceptance of any returned medicines back to saleable stock should be defined in a procedure based on the details in the Technical Agreement with the Marketing Authorisation Holder (MAH) (where available). 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. All decisions should consider risk to patient before accepting product back as saleable stock.
ensuring that any additional requirements imposed on certain products by national law are adhered to.	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. Narcotics and other "controlled" medicines including but not limited to homeopathic and veterinary. 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 storage and distribution of any product in one of these categories. Note: the specific requirements for some products, e.g. Narcotics, veterinary products and homeopathic products are different in member states, therefore the RPs must make sure they are familiar with the local requirements and legislations for the products they are handling.

Designated Responsibilities

The following table contains a matrix of responsibilities. Certain requirements out of the EU GDP Guideline are listed and it is indicated if the Responsible Person, Senior Management or Authority is responsible for the topic

Chapter	Topic	Senior Management	Responsible Person	Authority (EU or MS)
1	Implementation of Quality management System	x		
1.2 and 2.2	Appointment of Responsible Person	x		
1.2 & 2.2	Ensuring that a quality system is implemented and maintained		x	
1.2	Resources	x		
1.4	Management Review	x		
2.1 & 2.2	Conditions provided for Responsible Person by the legislation			x
2.2 (i)	Ensuring that a quality management system is implemented and maintained		X	
2.2(ii)	Focusing on the management of authorised activities and the accuracy and quality of records		X	
2.2(iii)	Ensuring the initial and continuous training programme for all personnel involved in distribution activities		X	
2.2(iv)	Coordinating and performing promptly any recall operations of medicinal products		X	
2.2(v)	Ensuring that relevant customer complaints are dealt with effectively		X	
2.2vi	Ensuring that suppliers and customers are approved		X	
2.2(vii)	Approving any subcontract activities impacting GDP		X	
2.2(viii)	Ensuring that self-inspections are performed at appropriate regular intervals following a prearranged programme and necessary corrective measures are put in place		X	
2.2(ix)	Keeping adequate records of any delegated duties		X	
2.2(x)	Deciding on final disposition of returned, rejected, recalled or falsified medicines		X	
2.2(xi)	Authorising the return to saleable stock of any returned medicines		X	
2.(xii)	Ensuring that any additional requirements imposed on certain products by national law are adhered to, as foreseen in Article 83 of Directive 2001/83/EC.		X	
2.2	Maintaining his/her competence in GDP through regular training		x	
8.	Receiving a copy of self-inspection reports	X	x	

3 External Responsible Person (Contract RP)

3.1. Some companies may use external/contract RPs who provide an independent service. The duties and responsibilities do not differ from the ones that are applicable to permanently employed RPs at a company. To fulfil the tasks, a detailed contract is required to ensure that all duties and responsibilities are met. This contract must name the contract RP not just his/her company or consultancy and in addition to the requirements, should also address the required availability and expectations from the RP for contacts when required and time on site. A contract RP can be in a unique position, operating with a high level of responsibility within an organization. The contract RP must ensure he/she has spent time at the site to fully understand the activities performed before agreeing to act as RP and signing a contract. In particular, the contract RP must ensure that they have easy/full access to all required information and documentation. The contract RP must also have suitable training records available to demonstrate that they fully understand the organization and activities undertaken.
It is the licence holder's responsibility to demonstrate that the selected contract RP is suitable within their particular business model. The licence holder should review the performance of the contract RP on a regular basis and take action if there is evidence of unsuitability. The licence holder should also support ongoing training of the contract RP.

3.2 Delegation
In general, the task of a RP can only be delegated to another RP who has been named by the company and has appropriate level of experience and training.

4 Organisational Duties to be established by the company employing the RP

To perform his/her duties and responsibilities, an RP needs support from the company and its senior management. The following organizational tasks should be implemented:

4.1. Senior management should be actively involved in the implementation, maintenance and further development of the Quality Management System.
4.2. A clear job description should be in place to define the responsibilities and authorities of the RP and the relationship to other departments and responsible managers (see also attachment to this document).
4.3. The RP should at all times have access to all relevant documents and dossiers to make his/her decisions.

5 Educational Background of the RP

Chapter 2 Article 2.2 demands that the RP "should meet the qualifications and all conditions provided for by the legislation of the Member State concerned". A reference is made to Article 79(b) of Directive 2001/83. However, the Directive does not provide any additional information. In addition, the GDP Guideline states: "a degree in pharmacy is desirable". It should be noted that the degree subject is not critical as long as the relevant competent Authority does not have a specific requirement, then the RP as minimum should have the training and experience detailed in this document.

6 Ongoing Training / Professional Development for the RP

An RP should receive regular training to maintain the competence in GDP (Chapter 2 Article 2.4 of the GDP Guideline). It is recommended that at least 3 to 5 days per year be planned for training purposes. The following table lists topics in which the RP should be trained.

Topic	Reference
Quality Management Techniques and Tools	Chapter 1
Auditing in the GDP environment	Chapter 1 and Chapter 8
Quality Risk Management	Chapter 1, 1.5
Training Management	Chapter 2, 2.4
Hygiene (Personnel and in the facility)	Chapter 2, 2.5
Appropriate GDP Premises and Equipment (incl. Qualification)	Chapter 3, 3.2 and 3.3
Document Management	Chapter 4

Supplier Qualification	Chapter 5, 5.2
Material Management	Chapter 5, 5.4 to 5.8
Recall and Complaint Management	Chapter 6
Management of Outsourced Activities, incl. Contracts	Chapter 7
Falsified Medicinal Products handling	Chapter 3

>>Company Name<<	**Job Description** **Responsible Person for GDP**	Version 01 Page 1 of x

1 Holder of the position: >>Name<<

2 Reporting structure (Supervisor): >>Name<<*

*Remark: The supervisor should be a member of the senior management to guarantee that the RP can address compliance issues and to improve the quality management system.

3 Deputy: >>Name<<

4 Minimum qualification of the holder of the position

- Ideally a minimum of 1-2-year experience in the distribution of medicinal products
- Trained in the requirements laid down in the EU GDP Guideline (2013/C 343/01)

5 Responsibilities of the holder of the position

The RP is responsible for:

- Implementation and maintenance of the Quality Management System including the documentation.
- Authorisation of all quality related activities and their records.
- Implementation and maintenance of the training programme for all quality related tasks of the employees involved in the distribution of medicinal products (including service and administration department).
- Coordination of any recall operation carried out by the organization and/or to assist when one is initiated by the MAH.
- Management of all customer complaints.
- Approval of all suppliers, customer and subcontracted activities related to the distribution of the medicinal products of the company.
- Management of the self-inspection programme to check the compliance with internal policies and the GDP Guidelines plus any National Requirements that must be complied with. This includes the responsibility for introducing corrective and preventive actions.
- In the case where duties are delegated to other persons the holder of the position will need to keep records detailing what was delegated and if appropriate, for how long.
- Authorisation to manage returned, rejected, recalled and falsified medicinal products (including any decision to put returns to saleable stock).
- Supervise the need to implement additional requirements for certain products if the law requires this.
- The RP should be familiar with the requirements for falsified medicinal products ensuring adequately robust procedures are in place to manage any actual or potential falsified medicinal products that are identified in the supply chain. With respect to the ongoing implementation of the Falsified Medicinal Products requirements, the RP should take an active role in the company to develop adequate procedures and processes to manage the new verification procedure and any other requirements that impact on GDP activities.

Created**: >>Date<<**
Approved by: **>>Name<<** **>>Signature<<** (Senior Management)