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	Section No.	**Paragraph #.**	**Line #**	**Current Text**	**Suggested Wording**	**Rationale**
Technical Comments						
1	Introduction	8	3	'Manufacturers distributing their own products should also comply with GDP.'	'Manufacturers distributing their own products must also comply with GDP.'	Changing 'should' to 'must' applies an equal expectation for manufacturers as distributors to comply with GDP.
2	Chapter 1 Quality Management	1.8 (iii)	5	'The quality system should ensure that…. products are delivered to the right recipients within a satisfactory time period;….'	'The quality system should ensure that ……products are delivered to the right recipients within a specified transport time period that has been subjected to transport qualification. Such qualification should be appropriate to the product in question and to the transportation route and conditions;….'	Currently a transport qualification is not referenced. Including the requirement to perform such qualification will ensure a more scientific approach.
3	Chapter 2 Personnel	2.1	3	'The Responsible Person should fulfil his/her responsibilities personally and should be permanently available.'	'The Responsible Person should fulfil his/her responsibilities personally or delegate to a suitably qualified person, and should be permanently contactable.	The term 'permanently' available is applied in several EU guidelines; there is potential for multiple interpretations. It is not always practical for an RP to be available for 24 hours per day and the need for this is questionable. Such a requirement will also impact adversely on the ability of wholesaling operations to utilise the services of contract RPs. Requirements in this area vary between Member States of the EU. Hence, the wording of the document should enable national requirements to be met.
4	Chapter 2 Personnel	2.3	3	'….A degree in Pharmacy is desirable….'	'The qualifications of the RP should meet the conditions provided by the legislation of the Member State concerned and should be appropriate to fulfil the assigned duties. The RP must have appropriate knowledge and	In general, RPs would not hold a Pharmacy qualification and the need for this level of qualification is questionable. Minimum educational requirements should be defined.

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					experience of the relevant EU Directives and Regulations they should have at least one year's practical experience in both or either of the following areas: Handling, storage & distribution of medicinal products Transactions in or selling or procuring medicinal products. In addition the RP should have at least one year's managerial experience in controlling and directing the wholesale distribution of medicinal products on a scale, and of a kind, appropriate to the licence for which he is nominated.'	
5	Chapter 2 Personnel	2.4	1	'The Responsible Person should carry out his/her activities personally in order to ensure the wholesale distributor can demonstrate GDP compliance and that public service obligations are met.'	'The Responsible Person should carry out his/her activities personally in order to ensure the wholesale distributor can demonstrate GDP compliance and that public service obligations are met. The Responsible Person may delegate individual activities to suitably qualified deputies within the organisation, in particular in multi-site organisations.'	It may not be possible or necessary for the Responsible Person to perform all activities personally. It is not clear if a Responsible Person is required to be present in each distribution site or may hold responsibility for multiple distribution sites. It is not clear under what circumstances they can assign deputies. This wording should enable national requirements to be met.
6	Chapter 2 Personnel	2.5	(x)	'delegating his/her duties when absent…'	'delegating his/her duties where appropriate and keeping appropriate records relating to any delegation.'	The condition 'when absent' is removed, to allow the RP to delegate duties at any time.

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7	Chapter 2 Personnel	2.16	1	'The storage of food, drink and smoking materials or medication for personal use in the storage areas should be prohibited.'	'The storage of food, drink, smoking materials or medication for personal use in the storage areas is prohibited. It is also prohibited to eat, drink and smoke in storage areas.'	The wording should be amended to state explicitly that it is prohibited to eat, drink and smoke in storage areas.
8	Chapter 4 Documentation	4.10	3	'Records should include...; and batch number where required.'	'Records should include… and lot number/batch number.'	Recording of the Batch Number and/or lot number should be stated as a requirement to ensure traceability and prompt recall.
9	Chapter 6 Complaints, Returns, suspected falsified medicinal Products and Medicinal Product Recalls	6.9	1	'Medicinal products which have left the premises of the distributor should only be returned to saleable stock if:…'	'Medicinal products which have left the premises of the distributor should only be returned to saleable stock following completion of a documented Risk Assessment that takes into account the following minimum considerations; product type, customer and premises. Medicinal products should only be returned to saleable stock if: ...'	A risk based approach is preferred as it reflects a scientific evaluation of the appropriateness of returning product to saleable stock.
10	Chapter 6 Complaints, Returns, suspected falsified medicinal Products and Medicinal Product Recalls	6.9	v)	'the distributor has reasonable evidence that the product was supplied to that customer and the batch number of the dispatched product is known,….'	'the distributor has reasonable evidence that the product was supplied to that customer and the batch/lot number of the dispatched product is recorded, that a copy of the original…'	It should be a requirement that the batch/lot number is always recorded. In instances where the distributor does not record the batch number, product returns from a customer should not be considered acceptable.
11	Chapter 9 Transportation	9.2	N/A	'If a deviation has occurred during transportation, this should be reported to the distributor and recipient of the affected medicinal	'If a deviation has occurred during transportation, this should be documented and managed in accordance with the Quality Management System. All such	The current wording does not include a requirement to document the details of the deviation as part of the process for handling and reporting such events.

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				products.'	deviations should be reported to the distributor and recipient of the affected medicinal products.'	
12	Chapter 9 Transportation	9.13	2	'…reloading e.g. at terminals and hubs, these premises should be audited and approved prior to deployment…'	'…reloading e.g. at terminals and hubs, these premises should be qualified using a risk based approach and where possible audited and approved prior to deployment…'	An audit of each hub may not be necessary. It is suggested that a risk based approach is adopted as this reflects a scientific approach.
Requests for Clarification						
13	Chapter 3 Premises and Equipment	3.3	1	'…areas designated for the storage of products awaiting further decisions as to their fate. These include … and recalled product.'	'… areas designated for the storage of potentially defective products awaiting further decisions as to their fate. These include any product suspected of falsification, returned, rejected, quarantined or recalled product and product awaiting disposal. Where products are not stored and managed under a validated computer software system there should be suitable segregated areas designated for their storage at different stages of processing (e.g. quarantine, released). Any system replacing physical quarantine should be validated to provide equivalent security and access controls. Products in segregated areas should be	It is proposed to differentiate between product Quality status and product Release status. Where material control is achieved by validated computer software there should be no requirement for physical segregation. However, defective product (high risk) should be physically segregated and stored in areas with limited access. Where products are not stored and managed under a validated computer software system there should be segregated areas designated for the storage of products awaiting further decisions as to their fate. Any validated system replacing physical quarantine should provide equivalent security and be validated to demonstrate security of access; as with material not controlled by a validated system defective product (high risk) should be segregated with limited access to this area(s). The validated Inventory IT system should be sufficient

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					appropriately labelled with their status, e.g. rejected, quarantine or released.'	to control the location of product at various stages of release (low risk).
14	Chapter 3 Premises and Equipment	3.4	1	'Medicinal products not intended for the Union market should be kept in segregated areas.'	Either remove this paragraph or clarify the reason for the segregation.	It is not clear why medicinal products not intended for the EU should be kept in segregated areas. If a product is in a high risk category, it should be segregated. All other products can rely on the validated IT Inventory system to control the location.
15	Chapter 3 Premises and Equipment -Computerised System	3.20	1	'Before a computerised system is brought into use, it should be confirmed as being capable of achieving the desired results.'	'Before a computerised system is brought into use, it should be demonstrated through appropriate validation or verification studies, that the system is capable of achieving the desired results accurately, consistently and reproducibly.	Validation or appropriate verification of computerised systems should be documented prior to use. GDP expectations for the validation of computerised systems should be clear.
16	Chapter 6 Complaints, Returns, suspected falsified medicinal Products and Medicinal Product Recalls	6.9	iv)	'medicinal products which have left the premises of the distributor should only be returned if:…..they have been examined and assessed by a sufficiently trained and competent person authorised to do so;….'	'if:…. they have been visually inspected, assessed or retested as necessary by a sufficiently trained and competent person authorised to do so. Quality risk management should be integrated into the assessment and documented appropriately;'	The suggested wording brings greater clarity to the expectations for examination of returned product. The risk assessment will conclude if examination is sufficient, or if retesting is required.
17	Chapter 9 Transportation	9.3	N/A	'In cases where the recipient notices the deviation,…'	'In cases where a deviation has occurred, it should be documented appropriately by the recipient and reported to the distributor. Where necessary, the manufacturer ….'	The suggested wording strengthens the expectation for the recipient to manage deviations appropriately.

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18	Chapter 9 Transportation of products requiring special conditions	9.18	2	'Transportation of medicinal products comprising highly active and radioactive materials should be transported in safe, dedicated and secure containers and vehicles...'	'Transportation of medicinal products comprising highly active…, dedicated (where necessary) and secure containers and vehicles.'	It can be difficult and unnecessary to have dedicated vehicles for the transportation of all highly active materials. The suggested wording introduces appropriate flexibility to this requirement.
19	N/A	N/A	N/A	The current text does not state if the guideline applies to material used in clinical trials.	State if the guidelines are applicable to clinical trial materials.	A statement of applicability of the guidelines to clinical trial materials will provide greater clarity for the Industry.
Request for Addition of Information						
20	Chapter 2 Personnel	2.5	to be created	There is no section on personnel gowning requirements.	'2.5 His/her responsibilities include, but are not limited to: xiii) Ensuring appropriate clothing is worn by personnel involved in the distribution of pharmaceutical products. Such clothing should be suitable to the activities that personnel perform.	Visitors/contractors should wear appropriate protective/safety clothing where necessary. A qualifying clause should be included to clarify that the onus is on the Responsible Person to ensure appropriate Personnel Protective Equipment and Personnel Protective Clothing are worn where necessary by personnel involved in the distribution of pharmaceutical products suitable to the activities they perform.
21	Chapter 3 Premises and Equipment	N/A	N/A	There is no section under Premises and Equipment for control of the movement of visitors	Create a new heading under 3.29 and create a new point, point 3.30) ***'Visitors*** 3.30 Visitors to the facility should be accompanied by authorised personnel. Adequate protective clothing should be provided to visitors during the visit	This wording will further ensure product and visitor protection.

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					to minimise risk of product contamination.'	
22	Chapter 3 Premises and Equipment -Temperature and Environmental Control	3.14	5	'The mapping exercise should be repeated…or whenever significant modifications are made to the facility or the temperature controlling equipment.'	Include an Annex detailing expectations for thermal mapping.	The expectations for environmental controls should be clearly defined.
23	Chapter 3 Premises and Equipment -Equipment	N/A	N/A	Text is not included currently relating to equipment and vehicle inspections.	Create a new heading under in ***Equipment*** after 3.19 and renumber subsequent points as applicable. '3.20 Vehicle inspections should be carried out prior to loading and upon arrival of goods, to ensure the integrity of the medicinal products is not compromised. Such inspections should be documented. The transport qualification should incorporate a review of this area and controls required to ensure continued compliance.' (Note: Subsequent sections of the guidelines will require renumbering as a result of inclusion of this additional paragraph.)	Equipment and Vehicle Inspections are not referenced. Addition of this section will ensure continued monitoring of the carrier.
24	Chapter 7 Contract Operations	N/A	N/A	***'Principle*** When outsourcing activities a written contract should be	***'Principle*** When outsourcing activities a written contract should be drawn up in	There is no requirement in this guideline to create procedures to define the generation of a written

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				drawn up.'	accordance with documented procedures.'	contract between acceptor and giver.
25	Chapter 7 Contract Operations	7.2	N/A	An audit of the contract acceptor should be performed……	Audit of the contract acceptors should be performed based on documented risk assessment	Wholesalers may use many subcontractors to perform required task, it is not always possible to audit every contractor, a risk based approach to audit will ensure all critical contractors are audited.
26	Chapter 9 Transportation	9.6	N/A	There is no description or requirement for pest control for vehicles.	Create as a new point under 9.6 and renumber as appropriate. 'Vehicles, containers and equipment should be kept free from rodents, vermin, birds and other pests. There should be written programmes and records for such pest control. The cleaning and fumigation agents used should not have any adverse effect on product quality.'	Pest control for vehicles is a requirement in WHO guidelines and some national guidelines; therefore it is proposed that similar wording to the WHO Guide is used in this guideline.
27	Chapter 9 Transportation-Transportation	N/A	N/A	Current text does not identify the need for written procedures for handling accidents during transportation that result in product damage.	Create a new point under Transportation after 9.13, and renumber as applicable. 'There should be written procedures for handling accidents during transportation that result in damaged product.'	There is no requirement to document the controls in place to ensure appropriate steps are taken in the case of accident during transit. In case of possible accident there should be a written procedure in place to handle damaged containers with hazardous products.
28	Chapter 9 Transportation-Temperature Control during Transport	N/A	N/A	Current text does not identify requirements for the use of dry ice containers or for training personnel in the use of such containers.	Create a new point under 9.21 and renumber subsequent points as applicable. 'If dry ice is used in insulated boxes, it should be located such that the	The additional text will clarify expectations for the use of dry ice containers and for personnel training in the use of such containers.

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					product does not come in direct contact with the dry ice. Staff must be trained on the procedures for assembly of the insulated boxes in combination with dry ice.'	
29	Chapter 9, Transportation	9.13		….requires unloading and reloading e.g. at terminals and hubs, these premises should be audited…	Clarify the need for audit of hubs.	Section 9.12 requires for hub to hold wholesaler's distribution authorisation if used for holding medicinal products for longer than 24 hours. Section 9.13 requires hubs to be audited and approved if used for loading and unloading goods and adequate temperature monitoring to be in place. There are over 1000 hubs across Europe used for unloading and loading medicinal products to ensure goods are transported to the correct destination. It is unreasonable to expect all these facilities to be audited and approved by all users. We suggest a risk based approach to approval and possibly document based audit may be sufficient.
Editorial Comments						
30	Chapter 4 Documentation	4.8	1	Typo ' 4.8 Records'	(Create new heading for Records and renumber as applicable) **'Records** 4.8 Records must be kept … 4.9 Records should include … 4.10 Records should be …'	To correct the layout of this section so ***Record***s is changed a topic heading.
31	Chapter 5 Operations	5.29	3	'…The batch number should be recorded, where required.'	'… The batch number/ lot number should be recorded.'	Removing "where required" and including the lot number/batch number will ensure it is recorded at all times.
32	Chapter 5 Operations	5.32	4	'… batch number at least for products bearing the safety features, where	'… batch/lot number at least for products bearing the safety features;'	Removing "where required" and include the lot number/batch number will ensure it is recorded at all times.

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				required;'		
33	Chapter 6 Complaints, Returns, suspected falsified medicinal Products and Medicinal Product Recalls	6.9	ii)	'medicinal product returns from a customer not holding a wholesale distribution authorisation should only be returned to saleable stock if they were returned within 5 days of original dispatch;….'	Consider removing	The basis for the 5 day rule is not clear. Consider removing this clause completely since the suggested wording for 6.9 will capture any risk to the product.
34	Chapter 6 Complaints, Returns, suspected falsified medicinal Products and Medicinal Product Recalls	6.9	v)	Spelling errors in line 1 'Th' 'upplied'	Correct spelling to 'the' Correct spelling to 'supplied'	To correct typographical errors.
35	Chapter 9 Transportation-Temperature Control during Transport	9.19	4	'…provided with a temperature data…'	'…provided with temperature data …'	Remove 'a' to correct typographical error.