Comments on WHO working document QAS/19.793
TITLE OF THE DOCUMENT: **GOOD STORAGE AND DISTRIBUTION PRACTICES**

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*Kindly complete the table **without modifying the format** of the document - thank you.*

World Health Organization

Template for comments

General comment(s) if any:	**Originator of the comments**
We appreciate clarifications when compared with the existing guidance. Although the extended level of detail is welcomed, we wonder if the 'how to do' requirements could be eliminated to allow for 'best practice' standards to be applied by the actors in the supply chain as the technique and automation will evolve.	ISPE
Title of the document seems to be inconsistent with other GDP document titles around the world and does not mention that it applies to medicinal products in the title, e.g. compared with EU's GDP document which is titled "Good Distribution Practice for medicinal products for human use".	ISPE
We recommend limiting the title of this document to GDP where GSP has other meanings throughout the regulatory framework. Good Storage Practices are incorporated in GDP. "Good Distribution Practices for Medicinal Products (Human and Veterinary). We recommend aligning definitions with other WHO guidelines (i.e. WHO guideline on Importation).	ISPE
The draft guidance can benefit from describing where the scope is ending e.g. at the point where the drug is sold by the pharmacy. We suggest adding this clarification **"The draft guide covers Storage Distribution of Finished Medicinal Products from manufacturer to pharmacy hospital and shops) before delivery to patient."** Aligned with other concrete guidance in the draft the terminology of the 'effectiveness' of the Quality System can be specified to be demonstrated by ensuring the conformity with the Quality System elements. The guide could refer more to QRM which is now incorporated in all GxP rules.	ISPE
The document structure contains many chapters, sometimes dealing with the same processes. This could create confusion with "first time users" who have to establish GxP-compliant operations or challenge existing operations. It would be useful to implement an overall structure such as: Quality System, Premises & Equipment, Operations.	ISPE
After reviewing Annex 5 GDP: For warehouses using highly automated and validated systems, it is not always easy to convince auditors a	ISPE

physical isolated quarantine area is not being used. Although further in the text explained 'another effective means like a validated automated system', it might be an improvement to take this up in the description of the definition of Quarantine, e.g. "Quarantine: The status of pharmaceutical products isolated physically or by other effective means (for example by validated automated systems) while a decision is awaited on their release, rejection or reprocessing."	
In general, the document is beneficial if considering an integrated manufacturing-storage-distribution operation. However, the document should also take into account the growing third-party logistics trend including all of the tendencies and "warts" that go along with outsourcing such operations.	ISPE
How are GMP, GDP and GSP differentiated within this document? We do not see GMP used in this document. Should it really be GS&DP from this point forward?	ISPE
Commonly used "should" instead of "must" where certain things are required.	ISPE
The document does not mention alarming critical storage parameters, nor addressing Measurement Uncertainty (MU) in establishing alarm limits. Automated Storage and Retrieval Systems (AS/RS) are not mentioned but are now becoming very common. Suggest that they are mentioned and state that all GSP requirements apply and determine if there are new requirements specific to AS/RS operations.	ISPE
Recommend stating that appropriate alarm limits must be established for critical parameters and that instrument Measurement Uncertainty (MU) be considered in establishing the alarm limits to ensure that the product remains within the required conditions. There are many existing industry guidance documents regarding alarming that should be referenced.	ISPE
The document is light on requirements for pest management, hazardous material storage & handling, and sampling area requirements.	ISPE
It seems that no route risk assessment is suggested. Also, no International multimodal Transportation (Road+Air+Sea) are considered in the document. These points are critical to assess Good Distribution Practices.	ISPE
The document should include a Table of Contents.	ISPE

# section	Line no.	Comment/rationale	Proposed change/suggested text	Classification **L**= low **M**= medium **H**= high	Originator of the comments (for WHO use)
1.1	46	Please mention the purpose for the guidelines in the first paragraph. Quality and integrity of the product for the safety of the patient is the main reason for the guidance.	Proposal: "Storage and distribution are important activities in the supply chain management of medical products **to ensure the quality and integrity of the medicinal product for the safety of the patient."**	M	
1.1	52	We understand and support the intention of this draft to share best practices rather than an intention to implement this guideline in the regulatory framework of an economy. We are wondering how most of the world countries can implement these expectations.	Propose adding at the end of the paragraph: "**It is the intention of this guideline to share best practices. Economies can drive implementation into the regulatory framework, as applicable."**	H	
1	56	Suggest deleting the final sentence in the interest of brevity.	Proposal: ~~The relevant sections should be considered as particular roles that entities play in the storage and distribution of medical products.~~	L	
1.3	59	The term "outlets" is not clear/not commonly used.	Proposal: "This guideline is intended to be applicable to all persons and **entities** ~~outlets~~ involved in any...	L	
1	59 - 62	Section 1.3 states that the guideline is applicable from premises till the person dispensing or providing the product to the patient, whereas Section 1.7 states "This guideline does not deal with dispensing to patients as this is addressed in the World 85 Health Organization (WHO) good pharmacy practice (GPP) guide (xx)." Therefore, the above two points are creating confusion.	We suggest redrafting the wording to clarify the guide applies to the person who deliver the product to patients. This guide does not consider the dispensing process.	M	
1.3	63-64	Clear definitions should be provided for trader, broker, distributor as referenced in lines 63-64 to better distinguish between the different stakeholders and entities involved in the supply chain.	We suggest incorporating in the glossary these definitions: **"Broker: Arranges transactions in relation to the sale or purchase of medicinal products that consists of negotiating independently**	M	

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			and on behalf of another legal or natural person that do not include physical handling. **Wholesale distributor: Organisation that is involved in all activities consisting of procuring, holding, supplying, importing or exporting medicinal products, apart from supplying medicinal products to the public."**		
2.2	96-97	This statement excludes clinical products to which these practices would equally apply. Further in section 1.7 it is mentioned that this guideline does not deal with dispensing to patients. Therefore, reference to prescription/non-prescription medicines is confusing and should be removed.	Proposal: "Depending on the national and regional legislation, these guidelines may apply equally to **medicinal** products for human and for veterinary use, ~~**The guidelines thus cover products for which a prescription is required by the patient, products which may be provided to a patient without a prescription**~~ biologicals, vaccines and medical devices."	H	
	100	This document excludes the distribution of starting material but does not address its storage.	It should be indicated that this document does include the storage of starting material.	M	
2	101	Suggest adding the reference to the guidance here – distribution of packaging and labels is high risk, and the "other guidelines" should be referenced at the end of the sentence.		M	
3	122	In addition to "Auditing", a definition for "Self-Inspection" should be provided, which is considered as not the same as audit.	We suggest adding in the glossary self-inspection and audit definitions as follows: "**Self-inspections should be conducted in an independent and detailed way by designated competent person(s) from the company. Independent audits by external experts may also**	H	

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			be useful." **"Auditing..."**		
3	154	Further to the definition of "Contract", an additional definition for "Quality or Technical Agreement" should be included, which is a requirement to support subcontractor arrangements between the various parties in the supply chain.	We propose adding text at the end of line 155: "Business agreement for the supply of goods or performance of work at a specified price. **e.g. Quality/Technical Agreement or "QTA" means a separate agreement, executed subsequent to a "contract", between the Parties which shall be incorporated herein by reference, and which sets forth, among other things, the quality control and quality assurance terms for the Product.**"	H	
3	154	A definition for "Contracting Parties" should be provided to explained in order to outline contract giver and contract acceptor concept.	Propose adding a new definition after line 154: "**Contracting Parties: Any entity hired to perform an outsourced activity related to GDP such as manufacture, distribution or storage of the medicinal products.**"	L	
3	155	A contract is also legally enforceable.	Proposal: **"Legally binding** business agreement….".	H	
3	158	There are better definitions for CAPA that maybe worth considering.	We suggest using this definition for CAPA: "**A quality sub-system that collects and analyses information to identify actual and potential product and quality problems, used to define appropriate and effective corrective or preventive actions, then to verify or validate the effectiveness of the corrective and preventive actions".**	M	
3	166	Complaint is in scope as per section 8.	We suggest adding the definition of "Complaint" in the glossary. Proposed text: "**Complaint: Any written, electronic or verbal communication that**	M	

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			alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a drug, combination product, or device after release for distribution."		
3	171	Add the term "Broker" or "Brokering" to the definitions section since it is part of the distribution of product.	Proposal: "…importing, exporting, **brokering** or movement…"	M	
3	174	We recommend adding the term "Device" to the definitions and can be taken from previous WHO documentation. "**Device is in scope per section 2.2**"	Propose add: "**Device: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose.**"	M	
3	193	The term misses the customs aspects.	Proposed alternative wording: **"A person or company that organizes shipments on behalf of the manufacturer to get goods to a market, customer or final point of distribution, including the preparation and management of the associated customs documents".**	H	
3	193-195	The grammar of the sentence seems incorrect at the end.	Proposal: "…any service concerned with clearing and forwarding operations **(including consignment)**…"	L	
3	200	Reference to Good Distribution Practices as a "tool" might be inappropriate.	Suggest replacing "tool" with a stronger term such as "**regulatory guidance"**. Proposal: " …distribution process as well as providing ~~**a tool**~~ **regulatory guidance** to secure the distribution system from … ".	L	

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3	218	Is this term necessary?	Suggest clarifying this part with a definition of **Route of transportation and International multimodal activities (Road + Air + Sea) with multiple actors involved.**	L	
3	218 - 221	The term Good Trade and Distribution Practice (GTDP) is not clear in terms of correlation to the term Good Distribution Practice (GDP) as defined in the glossary in lines 197-202. Trade is a commercial/tax term. Its correlation to GDP compliance could be e.g. to supply only to customers who have a wholesale distribution license. Otherwise, a clear definition of this practice and its add-ons as compared to GDP are required.		M	
3	229	Sentence seems to be missing a term.	Proposal: " … any free **trade** zone".	M	
3	248	The term misses the regional restriction.	We suggest modifying as follows: **" … National** Competent Medicines Regulatory Authority.	M	
3	260	Additional definition for the Marketing Authorisation Holder should be provided.	Propose adding text at the end of sentence: "**e.g. is a company, firm or non-profit organisation that has been granted a marketing authorisation. The marketing authorisation allows the holder to market a specific medicinal product in a given country or jurisdiction.**"	M	
3	291	Marketing Authorisation Holder as initiator of a product recall is missing.	Proposal: " … initiated by the **Marketing Authorisation Holder** manufacturer, importer, wholesaler, distributor or a responsible agency".	H	
3	325	Is it worth adding that this information is defined	Proposal: " …of the product. **This information**	M	

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		within the marketing application?	**provided is in the Marketing Authorisation**. The shelf life is used to establish the expiry date of each batch".		
3	330	Procedures come in many forms – including drawings and pictures to ensure the content is not ambiguous. A variation in the form of the definitions would not preclude this approach. Research has shown these forms are more effective.	We propose using the following defintion for SOP: **"A set of step-by-step instructions compiled by an organization to help workers carry out complex routine operations. SOPs aim to achieve efficiency, quality output and uniformity of performance, while reducing miscommunication and failure to comply with industry regulations".**	M	
3	330	SOPs can be also in an electronic form (video SOP). EU GDP also refers to electronic form.	Proposal to include or in electronic form. "An authorized, written/**electronic** procedure…"	L	
3	337	Reference to "falsified & substandard product" should be provided as referenced in section 20 lines 1081.	Propose adding definition on line 337: "**Substandard/Falsified Medicines: Authorized medicinal products that fail to meet either their quality standard or specification or medicinal product that deliberately/fraudulently misrepresent their identity, composition or source.**" As per WHO guideline.	H	
3	339	Would "engaged" include the requirement for a binding contract or should this be specifically added?	Proposal: "A person or entity **that is contracted to provide** ~~**engaged in the activity of providing**~~ products and/or services".	L	
3	341	Recommend changing the term from "Transit" to "Transportation" since the term Transportation is more widely used in the industry. Need to incorporate transit duration which is "storage + transportation"	We propose change the term "Transit" to "Transportation". We suggest clarifying the definition for Transit **"Transit is the combination of staging + product transportation"**	H	

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3	345-346	Definition of "vehicles" should be changed to include wider scope or should stay with removal of aircrafts and boats.	Proposed text for definition of vehicles: "**Any means for which to convey pharmaceutical products such as trucks, vans, buses, minibuses, cars, trailers, aircraft, railway carriages or boats**"	H	
4.1	356	Insufficient guidance is provided for "pest management requirements".	Propose add specific requirements for both premises and operational pest control management.... or point to a common industry best practice for this.	H	
4.2	361	The document can benefit from clarifying the scope of distribution by expressing clearly where the provision of this guideline ends.	Proposal: "GSP and GDP are applicable to: products moving forward in the distribution chain from the manufacture **to the pharmacy**;"	H	
4	361	Scope is too narrow to cover all operations from a manufacturer's point of view.	Proposal: "products moving forward in the distribution chain from the manufacturer **via involved partners in the supply chain down to patient level. GDP includes end to end supply chain including storage, transportation and distribution".**	M	
4.2	364	Reference to "donations of products" is misleading. Would donations of products be automatically included under line 361: products moving forward in the distribution chain from the manufacturers? What about clinical supply?	Recommend including this in the Scope or Introduction of this document.	L	
5	366	Add a requirement concerning selection/qualification of all involved entities handling the product in addition to the current requirements in sections 12.1 and 18.4.		M	
5.1	370	5.1 relates to selection and qualification of entities; we suggest clarifying this point.	We suggest adding selection and qualification activities for this point: " **Selection and Qualification** of entities involved in		

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			the storage and distribution …".		
5.2	375	It should be added that it is the Senior Management of the entity (which is licensed).	Proposal: "Senior Management **of the entity** has the …"	L	
5.2	376	We agree that a QMS should be effective. The guideline can benefit from being more descriptive how the effectiveness can be demonstrated.	Proposal: "The ~~**effectiveness,**~~ roles, responsibilities and authorities should be defined, communicated and implemented throughout the organization. **The effectiveness can be demonstrated by ensuring the compliance of the Quality System Elements as described in Art 5.3.**"	H	
5.3	382-383	We have suggested using only GDP for storage and distribution activities. The wording "as far as possible" indicates gaps in the supply chain and each entity need to ensure the quality of the product is maintained when within control.	Proposal to remove "GSP" and "as far as possible". Proposal: "~~GSP and~~ GDP is adopted and managed through satisfactory arrangements to ensure~~**, as far as possible,**~~ that the medicinal..."	M	
5.3	385	Reference to "appropriately procured" seems a bit too vague. Therefore, proposal to replace with in "compliance with legislation" to underline the fact that each stakeholder in the supply chain must be licensed or qualified.	Proposal: " … products are appropriately procured **in compliance with the legislation**,…"	H	
5.3	385	Terminology	Proposal: "products are appropriately procured, stored, distributed and delivered to the **appropriate** ~~**right**~~ recipients;	L	
	386	Need to mention that this must be documented.	Proposal: "… recipients, **and that this is verified and documented throughput the product lifecycle."**	L	
5.3	389	The appropriate definition of risk vs. hazard should be applied.	Proposal: "all **hazards and risks** ~~**risks**~~ are identified, and where necessary, effective controls are	M	

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			implemented;"		
5	5.3	The content here is addressed in more detail in sections that follow.	Suggest deleting section 5.3.	M	
5.3	391	Quality audit and self-inspections are not synonyms.	There is a procedure for self-inspection and /or quality audit	H	
5.3	391	Define the terms "quality audit" and "self-inspection" in the Glossary to avoid misunderstanding of definitions.		M	
5.3	396	Include execution of Quality Management Reviews in the quality system elements	Propose add: "there is a system for quality management review (QMR)"	L	
5	400	Suggest rewording some of the content of 5.5 and 5.6 for clarity	Proposal: "**5.5 There should be an appropriate organizational structure that is authorized and dated.** **5.6 The duties and responsibilities for all staff members should be clearly defined in their job descriptions, which are approved and dated".**	M	
7.1	428	Emerging regulation should be added to management review in line with EU GDPs.	Propose to add another bullet after line 428: "**• monitoring of emerging (new) regulations**"	H	
7.2	430	Wording is not clear.	Proposal: **"Management Review meetings should be documented, and** records should be Maintained".	M	
8	433	The process for retrieval of the complaints samples is not stated.	Proposal: "A process should be defined for the retrieval of complaints, related samples and their appropriate storage and segregation".	M	
8	441	The document should include some flexibility.	Suggest adding "where applicable" at the end of the	M	

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			sentence.		
8	449	Other quality problems incurred prior to storage should not be in scope of the guidance.	Proposal: 'Product quality problems **triggered by storage and transportation** or suspected cases ….".	L	
8	450	Distributors should not directly interact with authorities in such cases in order to avoid unnecessary rumours and confusion. Manufacturers quality system process will give guidance on proper escalation.	Propose amend to: **"The information should be shared with the manufacturer or the product owner in order to notify the appropriate national and/or regional regulatory authorities".**	H	
9.3	462	It is important to mention (as part of the first bullet point) if there is any data to suggest the condition of product while at the consignee. A return could be refrigerated product shipped in temperature-controlled packaging, opened to ambient at the consignee, and then returned in temperature-controlled packaging. 1/ was the packaging opened by the consignee? 2/ if yes, for how long and under what conditions?	Proposal: "A risk-based process should be followed when deciding on the fate of the returned goods. This should include, but not be limited to, the nature of the product, storage conditions, condition of the product history, time-lapse since distribution, manner and condition of transport while being returned, **availability of evidence that labelled storage conditions were maintained while with the consignee".**	H	
9	467	Include the "remaining shelf life" as a factor to consider.		M	
9.3	472	Add a statement to check returned goods for possible counterfeit activities.	Proposal: **"Check returned goods for any signs of counterfeit material".**	M	
9.4	473	Include the word "accepted" along with rejected.	Proposal: "Where products are **accepted** or rejected, authorized procedures should be followed, including safe transport".	L	

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9	481	It would be useful to define a time such as the time period mentioned in section 18.31.		M	
10	489	Adding more detail would ensure consistent interpretation of the current requirements.	Proposal: "…. checked annually **through a mock recall,** updating the procedure if necessary".	M	
10.4	495	Since the recall must be agreed and legally approved with the authority it should be specified that national and regional authorities must be informed prior execution or in urgent cases within defined timelines.	Propose add at end of sentence**:** **"prior to execution or within defined timelines".**	L	
11	513	It would be helpful for the readers to put a self-inspection document in place along with the checklist. This would help to ensure consistency in the self-inspection process at the facility	Propose add: **"A self-inspection document in the form of an SOP/protocol must be in place as per the GDP/GLP/~~GSP~~ guidelines".**	M	
11	513	Section 11 should also include auditing. Proposal to align section with "GUIDELINES ON IMPORT PROCEDURES FOR PHARMACEUTICAL PRODUCTS".	Proposed text to add on line 527 as a separate section: "**Self-inspections should be conducted on a routine basis to verify the correct functionality of the quality system standard operating procedures in place at the entry port. Corrective and preventive actions measures should be implemented for any potential deficiencies identified. Audits by third parties are further recommended. Audits and self-inspection records should document compliance of personnel to both the standard operating procedures adopted and the equipment used in screening technologies (i.e. measuring and monitoring devices, instrument for sampling, testing, etc.) .**"	H	
11	519	Self-inspections must be performed on a risk	Proposal: "Self-inspections should be conducted	L	

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		assessment basis and their schedule needs to be approved	periodically **based on risk assessment** following an **approved** annual schedule".		
11	522	Involving external bodies for self-inspections (or even contracted audits) needs appropriate expertise of the subject.	Proposal: "Audits by independent third parties **with proven subject matter expertise** may be beneficial".	L	
11	537	For premises drawings should be approved	Proposal: " …. products. **Building premises and flows avoiding as much as possible crossing should be approved and dated".**		
12.2	539	Add the requirement for sufficient space for ensuring effective operations and avoiding damage	Proposal: "There should be sufficient space, lighting and ventilation to ensure required segregation, appropriate storage conditions and cleanliness **allowing for effective operations and avoiding damage".**	L	
12	546 and 589	Needs clear definitions	Propose add definitions for "Temperature and / or relative humidity".	M	
12	553	Cleaning operation and pest control should be recorded	Propose: " Premises should be kept clean. **Cleaning and pest control operational should be recorded and monitored for traceability purpose".**	H	
12.10	562	The Receiving area must be segregated from Shipping / staging area and clearly identified to avoid mix-ups	Propose add: **"The Receiving area must be segregated from Shipping / staging area and clearly identified to avoid mix-ups".**	H	
12.10	562	The Receiving area (transient storage) must be maintained at an acceptable temperature while receiving is completed.	Propose add: **"The Receiving area (transient storage) should be maintained at an acceptable temperature appropriate to the product storage requirements".**	H	

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12	566	The document should also include the date of incoming delivery for the records	Proposal include: **"Date of Incoming Delivery"**	H	
12.13	577	The requirement should be that every container is clean and free from dust.	Propose to replace text in section 12.13 with "**Containers used in receiving area should be clean and free from dust and odour ~~Receiving areas should be of sufficient size to allow cleaning of incoming containers~~. Receiving area should provide enough space or equipment to remove dust before storage.**"	H	
12	591	The physical quarantine area should be properly labelled to avoid cross-contamination with rest of the materials and products	Proposal: "The **physical** quarantine area should be properly labelled to segregate from rest of the materials and products. **Electronic quarantine with qualified IT systems is acceptable as well"**.	M	
12	594	The area for storing rejected materials and products should be properly labelled to avoid cross-contamination with rest of the materials and products. GMP requires these products to be locked.	Proposal: "The area for storing rejected materials and products should be properly labelled to segregate **them under locked conditions** from **other** materials and products".	M	
12.18	595	The type of required segregation is not specified.	Proposal: "They should be stored separately **(locked)** from other materials and products **using appropriate segregation SOP's while awaiting destruction or return to the supplier".**	L	
12.22	612	Wording to acceptable temperature limits is too vague.	Proposal: "Storage areas should be maintained within **specified ~~acceptable~~** temperature limits."	H	
	614, 682/683, 890, 956	Need to include alarming along with controlling, monitoring, and recording in these requirements.	Propose add: … **"controlled, monitored, alarmed and recorded."** with calibrated equipment.	H	

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12	617	"Suitable pallets" does not define the expectations	Propose amend: **"Aluminium or plastic pallets or wooden (approved) treated pallets for finished products** should be used … ".	M	
	618	Wooden pallets are a problem with pest control.	Recommend the use of wooden **approved treated** pallets where product is to be stored or handled.	H	
12	624	Safe is not a prescriptive term to use in this context.	Propose amend to: "The pest control agents should be used **in a manner where there is minimal risk of contamination"**	M	
12.27	634	Computerized systems for storage often work with "chaotic storage". It should be also validated that the system can handle a total power-outage and ensuring to find the required product.	Proposal: "… validated **to demonstrate security of access, to find the storage location and handle the FEFO even in the case of a total power-outage or computer outage".**		
	636	Requirements for sampling areas not given. Sampling of finished products	Propose add: **"Sampling must take place in a separate sampling area with appropriate conditions (T°, HR)".**	H	
12.29	641	It is unclear why dedicated storage areas for narcotics or hazardous materials are required from a GDP perspective, as long as appropriate access restrictions and security measures are in place.	Propose amend: "Certain materials and products such as highly active and radioactive materials, narcotics and other hazardous, sensitive and/or dangerous materials and products, as well as substances presenting special risks of abuse, fire or explosion (e.g. combustible liquids and solids and pressurized gases), should be stored in an ~~**dedicated**~~ appropriate area that is subject to appropriate ~~**additional**~~ safety and security measures".	M	
12	655	Is use of a warehouse management system OK or should the material be under lock and key to prevent any use?	Proposal: " … Under a ~~quarantine~~ **locked rejected area** system designed to prevent their use until a final decision is taken on their … ".	H	

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12.35	664	Delete as this is a repeat of 12.26 (line 627)		L	
12.40	688	Delete as this is a repeat of 12.39 (line 682)		L	
12.38	676	Wording is still not clear in stating the requirement to qualify the premises and equipment used to store pharmaceutical products and only exemptions may be allowed (e.g. pre-qualified equipment). It's also not clear in WHO TRS 961, Annex 9 that at minimum a periodic review is necessary, or re-qualification in case of major changes. The requirement for temperature mapping in the current WHO TRS957, Annex 5 is often (mis-)understood as a sufficient qualification.	Propose amend: **"All premises and equipment intended for the storage of pharmaceutical products need to be qualified to demonstrate their fitness prior to the first use. Periodic review/re-qualification needs to be executed and documented. (Ref: WHO Technical Report Series No. 961, Annex 9, Model guidance for the storage and transport of time- and temperature–sensitive pharmaceutical products)".**	H	
12.38	677	Showing temperature uniformity across a storage facility is impractical. Better to refer to temperature distribution within the acceptable range. E.g., chambers of high volume (such as a warehouse) with have stratification regardless of the controls. Many have outer walls and integrated docks which make uniformity impossible.	Proposal: "Where required, mapping studies for temperature and relative humidity, as appropriate, should be done to show **appropriate temperature distribution and control** across the storage facility within defined T° range".	H	
12	679	Missing words	Proposal: " … for example, to **product storage** areas …".	M	
12.38	679	Application of this requirement should be specific only to chambers where product is stored.	Proposal: "This applies, for example, to areas, refrigerators and freezers **where products with prescribed temperature storage conditions are stored**".	M	
12	684	The requirement is not clear. 12.40 is a repeat of 12.39.	Propose adding at end of sentence: " … reviewed **for any trends indicating that the system performance**	M	

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			had dropped”.		
12	686	The time records are kept for should be defined –	Proposal: “ … kept for a suitable period of time and as required by national legislation **following a company SOP”**.	M	
12.40	688-692	Section is a duplicate of 12.39	Delete	L	
13.3	704, 841	Term “issued” could be changed to “dispatch” to align with sections 12 and 18	Proposal: “Damaged containers should not be ~~**issued**~~ **dispatched** unless the quality of the material has been shown to be unaffected”.	L	
13	709	Could be written in simpler English	We suggest rewording as follows: **“Stock should be routinely checked for product near its expiry date, product requiring retesting, and obsolete stock”.**	M	
14.2	716	Computerised systems should be validated. The word “capable” is too vague.	Proposal: “Computerised systems should be **validated and** capable of achieving the **expected** ~~**desired**~~ output and results.”	L	
14.5	726-727	Add computerised GXP systems.	Propose: “Where **computerised** GXP systems are used, these should meet the requirements of 21 CFR 211 Part 11, EU chapter 11 and WHO guidelines on computerized systems.”	M	
14	729	Provide a reference to help the reader understand ALCOA principles.	We suggest adding a definition for “**ALCOA” in the glossary**.	H	
14	729	ALCOA principles should be mentioned in the general section, not only applying to section 14 for computerized systems and equipment, but also to data generated during the qualification or operational		H	

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		activities			
15	734	The sentence as written is confusing - many will try to use a risk assessment – suggest using language aligned with other guidance and adding a reference to something like the ISPE C&Q Guide	Propose add: **"A science and risk-based approach to qualification / validation should be used".**	H	
15.2	737	Computerised systems are missing and should be added.	Proposal: "Premises, utilities, equipment and instruments, processes and procedures, **and computerised systems** should be considered."	M	
15	737	As written the key quality system and its role are not highlighted	Propose add: **"The change management system should be used to evaluate changes and record the rationale for the scope of commissioning and qualification required for the change if it is approved for implementation".**	M	
16	747	Additional requirement	Propose add: "**The organizational structure should be set out in a authorized and dated organizational chart"**.	L	
16.1	749	16.1 This appears ambiguous, subjective and unenforceable as written. What number and composition of personnel is adequate? To do what? Re-assess and write in a more prescriptive fashion by specifying what the purpose is and circumstances under which one could determine the number of personnel is sufficient. Industry and an Inspector/Investigator must have sufficient details to judge whether or not the company is meeting its obligation in this regard, else it is a meaningless requirement and too open to interpretation.	Proposed alternate wording: **"Management should ensure adequate numbers of qualified and trained operations, quality, or other personnel to be able to manage workload and execute procedures in a timely fashion while maintaining attention to detail. There should be no bias or compromise required to meet financial, scheduling, or other such commitments".**	H	SD

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	752	Does not mention that training records must be kept.	Propose add at end of sentence: **" … and records maintained for such qualifications"**	M	
	775	For better clarity it should be easier to merge 16.8/16.9	Proposal: "Personnel should be trained in, and observe high levels of, personal hygiene and sanitation. **Records of all training, attendance and assessments should be kept".**		
16	778	"Assessments" should be used – plural.		L	
16.10	783	Include equipment's also along with garments i.e Personnel protective equipment's for better clarity.	Proposal: " … with protective garments and **personnel protective equipment's (PPEs)** as necessary"	M	
	785	Hygiene could be more developed.	Propose add: "**Personnel should not be allowed to drink, eat, smoke in storage and transit areas, for hygiene and safety reasons"**		
17.1	801	"Contracts and data" should be added. Contracts are also specified in this document and data refer to electronic form.	Proposal: "Documentation includes all procedures, records, **contracts and data** whether in paper or electronic form. **Documents should be dated and approved"**	H	
17	812	Use a consistent approach with line 729.		M	
17.10	833	Batch number is missing in the listing. Section 17.11 is more detailed and complete and contains the same information as 17.10.	Proposal to keep 17.11 and delete 17.10.	H	
17.10	833	17.10 Not all records are product-specific E.g., facility qualification documents, PM records, etc.	Proposal: "**Product-specific transaction** records should contain at least the following information:	17.10	833
17.10	833	There are a lot of different kinds of reports, for some	Proposal: "Records should contain ~~at least~~ the	L	

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		of them, not all bullet points can be considered. For example report for multiproducts or generic records: the name of the product can't be specified	following information, if applicable: **Product name,/ Company / API".**		
18.2	855	Procurement is missing.	Proposal: "**Procurement,** storage and distribution…"	H	
18	868	English could be improved	Proposal: **"Materiel receipt"** – to replace "receiving"	L	
18.6	869	Should be labelled and locked to prevent any use.	Proposal: " …Should be **labelled**, separated, ~~quarantined~~ **locked**, and investigated.	H	
18	874	Suggest integrating the content of this section with 12.19 – for brevity		M	
18	910	There is no clear statement about the need to qualify means of shipment (active/passive containers, trucks, etc).	Propose add: "**All transportation equipment intended for the storage of pharmaceutical products need to be qualified to demonstrate their fitness prior to the first use. Periodic review/re-qualification needs to be executed and documented".**	H	
	910-912	"Distribution and Transport" needs to meet all GDP requirements.	Suggest state that all previous requirements for G**D**P also apply to "Distribution and Transport".(Temp & RH mapping, monitoring, recording, documentation, etc.)	M	
18.18	913	Recommend removing "There should be no risk" from line 913 since elimination of all risk is not able to be done.	Propose replace last sentence with: "**The risk to the quality of the material or product should be minimised to the acceptable level ~~There should be no risk to the quality of the material or product~~** during transport and distribution."	H	
18	922	Suggest editing this line.	Proposal: " …. should be provided when requested, or	M	

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			when provision is a local legal requirement".		
18	926	Suggest simplification to remove terms that are not defined – and may not improve security or traceability.	Propose add: **"The role and responsibilities of employees working in distribution areas should be set out in written job descriptions along with any arrangements for deputising".**	M	
18.27	942	These should be removed from service.	Propose last sentence read: "These should be removed from service".	M	
18	948	Suggest combining 18.29 with 18.30 to improve readability.		M	
18	956	Would the retention time be the same for a fixed asset – if yes, please say so, and the review requirements would be the same for similar systems.		H	
18	961	Accuracy and the impact of it is not explained.	Propose add: "Instruments should be accurate to +/ x degrees, if not the operating limits should be adjusted to allow for any potential error. (+/_ x degrees accuracy allows for rounding of any instrument readings.) Measure accuracy have to comply with the t° range and expectations".	H	
18.35	972	Adding the packaging materials used inside the tertiary shippers (here referred to as "containers").	Proposal: "Shipment containers**, stuffing packaging materials as well as fixation aids** should have no adverse effect on the quality of the products and should offer adequate protection to materials and products. Containers should be labelled indicating, e.g. handling and storage conditions, precautions, contents and source, safety symbols as appropriate".	L	
18	972	Typically, shippers are qualified to maintain the		H	

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		specified conditions – and may also be monitored – there is no guidance on this aspect of the supply chain.			
18.36	977	18.36 should also mention Liquid Nitrogen if mentioning dry ice.	Proposal: "Special care should be taken when using dry ice or **liquid nitrogen** in shipment containers due to safety issues and possible adverse effects on the quality of products".	H	
18.38	986	The paragraph allows products to be sold and/or distributed to persons or entities that are authorized to acquire such products. How can individual persons receive an authorization for this? In the future maybe yes, but currently not supported.		M	
18.41	995	As some institutions may have multiple branches or the ordering is managed by a central purchasing group, should the address be complete delivery address instead of just complete business address?	Proposal: "Records for the dispatch of products should be prepared and should include information such as, but not limited to, date of dispatch; complete business name and **shipping** address (no acronyms), type of entity responsible for the transportation, telephone number, names of contact persons; status of the addressee (e.g. retail pharmacy, hospital or community clinic); a description of the products including, e.g. name, dosage form and strength (if applicable); quantity of the products, i.e. number of containers and quantity per container (if applicable); applicable transport and storage conditions; a unique number to allow identification of the delivery order; and assigned batch number and expiry date (where not possible at dispatch, this information should at least be kept at receipt to facilitate traceability)".	L	

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18	988	The text does not align with the example.	Type and status (approved) of the addressee	M	
18	1003	Clarify the goal of the requirement, consider combining 18.41 and 18.42	Propose add at the end of the last sentence of 18.42: " … **"for any potential recall".**	M	
18	1011	It's not clear how this requirement reduces security risks - perhaps the procedural requirement is to keep the doors locked?		M	
18.43	1013	Add external environment impact on temperature-controlled products during unloading/loading.	Proposal: "...to avoid damage **and reduce security risks and reduce impact of external environment on temperature-controlled products/materials transported in vehicles.**"	H	
18.44	1016	Should a time frame be presented?	Proposal: **"X weeks prior to expiration . X to be defined in company's SOP'S"**	M	
18.46	1029	Example text is not required in this statement. Additionally, some may not be familiar with the term thermolabile.	Proposal: "appropriate environmental conditions are maintained **as per the storage conditions on the label for the product or material** e.g. using cold chain for thermolabile products."	M	
18	1032	The distributor should contact the manufacturer to determine the best course of action.	Proposal: " … be reported to the distributor ~~**and**~~ , recipient, **and manufacturer**".	M	
	1040	We suggest adding some requirement for specific transportation with additional risks.	Proposal: " … secured containers and **secured** vehicles, **routes, and authorised persons"**.		
18.41	1047	Impact on product quality not explicitly mentioned.	Proposal: "Damage to containers and any other event or problem that occurs during transit must be recorded and reported to the relevant department, entity or	M	

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			authority, and investigated **by a deviation handling procedure (which will also assess the impact on product quality)**".		
19.3	1069	To add the responsibility of the contract giver to check also the adequate resources.	Proposal: "The contract giver should assess the competence, **including adequate resources,** of the contract acceptor before…".	L	
20.3	1090	In section 12.27 a computer-based segregation is allowed. This always leads to discussions with auditors who expect a physical segregation. It should be clearly specified, that a physical segregation is expected for substandard and falsified products and maybe also for products in quarantine, but otherwise allow the segregation by computerized systems.		M	
	1122	Which references will be added? It's difficult to propose further reading references without knowing this.		L	
ANNEXURE 1 Table 1	1138	"Store at controlled room temperature" "20 to 25°C" is a more restrictive requirement comparing to Pharmacopoeia limits "15 to 25°C" and could have a high impact on setting up the set points for the warehouse's storage facilities. Could there be references added to the note 1 "These limits are recommended values, based on pharmacopoeia limits and guidelines"?	Propose: "Store at controlled room temperature 15 to 25°C. **Temperature range to be in accordance with National rules".**	H	
Annex 1.	1138	Remove defined temperature range of 15 –30°C for ambient conditions. This requirement is impossible to be met, especially in hot extreme weather in developing	Propose: "Storage in dry, well-ventilated premises ~~**at temperatures of 15-30°C**~~. Extraneous odours, other indications of contamination, and intense light must	H **(very Critical)**	

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		countries. Ambient temperatures cannot be defined to narrow rage as they differ across the world in different seasons. Chilled is not the same as refrigerated. It is normally wider range than 2-8 deg C. Store in freezer range is too narrow as there are products requiring much lower temp ranges. CRT should not be narrowed to 20-25 deg C. It should be 15-25 or 15-30 deg C.	be excluded.”		
Table 1	1138	Dry place per USP is does not exceed an average of 40% RH.	**Suggest aligning with ICH or National rules**	M	
	1138	Ambient conditions is similar but not the same as USP CRT – should there be alignment?	**Suggest aligning with ICH or National rules**	M	
	1138	Light sensitivity should also consider the wavelength – some products are UV sensitive.	Consider adding a footnote	M	
	1138	Is there a reference to support the definition of chilled used here?		M	