Comments on: EU draft guidelines on the principles of Good Distribution Practices for Active Substances for Medicinal Products for Human Use

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Consultation Item	Comment / Rationale	Proposal
General Comments	Implementation date should be known. It is our current understanding that this guideline will be finalised by the end of 2013. What will be the timing, implementation period? Or when are companies expected to fully comply with it and will be inspected against this guideline? Duplications between Paragraphs 18. and 19. Paragraph 36. is a continuation of Paragraph 35. Paragraph 45 Self-inspections has actually number 47.	

Paragraph 9	We propose to delete "all" as this would also cover documents not related to API quality as e.g. commercially sensitive information	documentation should be made available on request of competent authorities. Electronic documentation should comply with Chapter 5.4 of Part II of Eudralex, the Rules Governing Medicinal Products in the European Union, Volume 4 (*EU Guidelines to Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use* – hereafter 'EU-GMP'), or its Annex 11 (Guidelines on Computerised Systems).
Paragraph 11	We propose the plural as in an organizations there might be more than one person responsible depending on the respective area	These procedures should be approved, signed and dated by the person(s) responsible for the quality system.
Paragraph 12	We propose to change the last sentence of the paragraph to align it with the respective wording of chapter 6.13 in ICH Q7	Records should be retained for at least 1 year after the expiry date of the batch. For APIs with retest dates, records should be retained for at least 3 years after the batch is completely distributed
Paragraph 13	We propose to change the last two bullet points. The term "authentic" is not defined and therefore it is not clear what the difference might be. Concerning the retest or expiry date it is important to emphasise that the original manufacturer data are requested.	Certificates of Analysis, including those of the original manufacturer - Retest or expiry date stated by the original manufacturer
Paragraph 14	We propose to add "highly sensitizing materials, materials of high pharmacological activity or toxicity" and propose control of access to the premises, to align with the respective requirements in ICH Q7.	Premises and equipment should be suitable and adequate to ensure proper conservation, protection (e.g. narcotics, highly sensitizing materials, materials of high pharmacological activity or toxicity) and distribution of active substances. Monitoring devices, where used, should be calibrated. There should be an adequate system in place in order to prevent unauthorized persons to enter the facilities.
Paragraph 18	We propose a change in the first sentence because validated electronic storage systems are becoming more and more used by manufacturers and distributors. APIs are packaged in a way that a physical separation from other goods is normally not necessary.	Based on a risk assessment active substances should normally be stored apart from other goods, either physically or by an electronic warehouse management system (e.g. bar code system) and under the conditions specified by the manufacturer, if any (e.g. controlled temperature and humidity when necessary).

Paragraph 21	We propose the changes because the principle must be flexible for the company. E.g. how to handle deliveries to countries with specific regulatory requirements on remaining shelf life.	There should be a system to ensure stock rotation (normally 'first expiry (retest date) first out') with regular and periodic checks that the system is operating correctly. Products beyond their expiry date or shelf-life should be separated from usable stock either physically or by an electronic warehouse management system (e.g. bar code system) and not be supplied.
Paragraph 22	We propose changes in line with paragraph 18 and 21	Active substances with broken seals, damaged packaging, or suspected of possible contamination should be withdrawn from saleable stock, and if not immediately destroyed, they should be kept ~~in a~~ clearly separated either physically or by an electronic warehouse management system (e.g. bar code system) so that they cannot be sold in error or contaminate other goods.
Paragraph 23	Needs rephrasing and to be moved to "Deliveries to customers"	
Paragraph 24	We propose the insertion just for clarification. Would this mean that practically the supplier should request to all the customers on a periodical basis a recent copy of their API distribution registration or of their pharmaceutical manufacturing license?	Supplies of active substances within the EU should be made only to registered distributors of active substances according to Article 52a of Directive 2001/83/EU or to authorised manufacturers according to Article 40 of Directive 2001/83/EU.
Paragraph 25	We propose change bullet point d) in order to reflect manufacturers transportation requirements.	d) transport conditions of the manufacturers are followed if specified.
Paragraph 34	We propose to add at the end of the paragraph an additional option.	If the conditions under which returned active substances have been stored or shipped before or during their return or the condition of their containers casts doubt on their quality, they should be destroyed by appropriate means or returned to the manufacturer.
Paragraph 35	We propose the plural as in an organizations there might be more than one person responsible depending on the respective area	d) they have been examined and assessed by ~~a~~ person(s) authorised to do so
Paragraph 38	We propose the changes because the principle must be flexible for the company. E.g. how to handle deliveries to countries with specific regulatory requirements on remaining shelf life	Active substances returned to saleable stock should follow the system in place to ensure stock

	(see also paragraph 21.	rotation (normally 'first expiry (retest date) first out').
Paragraph 41	We propose to add at the end of the last sentence the phrase “upon request” to clearly state that the distributor does not need to inform authorities proactively of a complaint	These should be made available to competent authorities of the Member States on whose territory the products were distributed, upon request.
Paragraph 44	We propose to include the distributor and manufacturer in this information loop since both are actively involved and need to be informed. However, it is unclear which authorities have to be informed by the distributor.	In the event the distributor becomes aware of a serious or potentially life-threatening situation, local, national, and/or international authorities and also the manufacturer of the active substance should be informed and their advice sought
Paragraph 46	We propose to add a sentence at the end of the paragraph to ensure effectiveness of implemented system.	The effectiveness of the arrangements for recalls should be evaluated.