

Regulatory Commenting Guidelines for Subject Matter Experts

1. If the guidance is a revision to a current guidance, focus comments on the new items in the regulation/ guidance rather than on the existing sections that remain unchanged (applies to documents which have been previously released by the agency). This is generally most relevant for EMA publications.
2. Comments need to be meaningful and specific. For example, a comment of “This is stupid” does not meet the criteria and will generally be eliminated from consideration.
3. Meaningful comments need to include sound justification for the proposed change as well as specific language that could be substituted for what the regulators propose. Comments that do not include a valid justification and proposed change will likely be omitted.
4. If the incorrect grammar in a document could result in a misinterpretation of the requirements, then please correct it. If not, and if there are many grammatical errors, a single suggestion that the “...grammar should be reviewed and edited as necessary prior to issuance of the final document” is an appropriate comment to be made one time.
5. Identify the line, section, or page number on which you are commenting, per the commenting form.
6. Write clearly and simply.
7. When making reference to other regulations/guidance, be specific and provide the official title and publication date where relevant either within the text or as a footnote.
8. Avoid comparing the document under consideration to a similar one published by another regulatory authority. While this is important to do internally within a company, it’s generally not met with any favor by the regulatory authorities.
9. Check and correct grammar, punctuation and spelling before submitting for review. Your comments should be publication-ready when you are done.

Last updated January 2013



Regulatory Comment Form

Proposed Regulation/Guidance Document: ***Guidelines on the Principles of Good Distribution Practice for Active Substances for Medicinal Products for Human Use; Ref. Ares (2013)148102 - 05/02/2013***

Comments Submitted by: ISPE – International Society for Pharmaceutical Engineering

General Comments

The need to maintain a quality system is indicated but there is no reference to management review of the quality system.
Risk Management principles as part of a quality system are referred to (e.g. in item 3) but not explained.
That the quality system should extend to all outsourced activities is implied but not explicitly stated.
In respect of the above the text should be more harmonised with the recently approved EU-GDP for medicinal products.

Proposed Regulation/Guidance Document: *Guidelines on the Principles of Good Distribution Practice for Active Substances for Medicinal Products for Human Use; Ref. Ares (2013)148102 - 05/02/2013*

No.	SECTION	COMMENT / RATIONALE	PROPOSED CHANGE (IF ANY)
2	Personnel Point 7	More appropriate terminology	Replace the word “guarantee” with “ensure”: “Key personnel involved in the warehousing of active substances should have the appropriate ability and experience to guarantee ensure that active substances are properly stored and handled.”
4	Records Point 12	The retention period of “5 years at least” for records in Point 12 should be clarified to avoid misinterpretation.	Change “Records should be clear and readily available. They should be retained for a period of five years at least.” to: “Records should be clear and readily available. They should be retained for a period of five years at least from the last date of distribution or expiration of the active substance batch, whichever is later. ”
5	Records Point 13	It would be desirable to include any deviations / exceptions noted during transportation and receipt of batches in the records under Point 13.	Under “Documents that should be retained and available include:” at the end of the list insert “ Deviations/Exceptions from the prescribed quality system. ”
6	Storage Point 18	Please clarify what is meant by other goods. Should this refer to “other non-pharmaceutical goods”?	“Active substances should normally be stored apart from other non-pharmaceutical goods...”
17	Self-inspections	The sequential number for this item is incorrect.	