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

No.	LINE NUMBER	CURRENT WORDING	PROPOSED CHANGE	RATIONALE
4.	Lines 84 – 92	–	Add a fourth bullet, or otherwise incorporate the idea that, “Product, process, equipment and facility design provide for adequate control of risks to the patient.”	One could argue that this is already covered by the word “safety” in line 85 and “quality attributes” in line 91, but since so much of the focus of recent guidance documents is related to risk management, it might be good to mention here.
5.	Lines 90-91	...finished product meets all design characteristics and quality attributes...	Delete “design characteristics and”	The term “design characteristics” is superfluous. The product has to meet all quality attributes and not more.
6.	Lines 93-95	For purposes of this guidance, process validation is defined as the collection and evaluation of data, from the process design stage throughout production, which establishes scientific evidence that a process is capable of consistently delivering quality products.	For purposes of this guidance, process validation is defined as the collection and evaluation of data, from the process design stage throughout production and commercial distribution, which establishes scientific evidence that a process is capable of consistently delivering quality products.	In order to truly reflect the product lifecycle (as specified in line 96), the collection and evaluation of data from product in commercial distribution should be included to capture product quality attributes, e.g., stability, breakage, and container-closure integrity, that might be affected in the distribution channels. Adding the term “commercial distribution” to the definition is consistent with the expressed intent of the paragraph beginning at line 539 in the Continued Process Verification section.
7.	Line 95	...quality products.	The term “quality products” should be defined. A suggested definition is “products fit for their intended use, meeting pre-determined specifications and quality attributes.”	Clarification

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13.	Line 235	...critical quality attributes.	The term “critical quality attributes” should be defined. A suggested definition is “physical, chemical, biological or microbiological properties or characteristics that must be controlled (directly or indirectly) to ensure product quality.”	Clarification. Note: The suggested definition is derived from ICH Q8R.
14.	Lines 285 - 286	Documentation should reflect the basis for decisions made about the process.	There should be some paragraph about “legacy” processes validation.	When transferring products from one site to another this information is often not available.
15.	Line 326 and elsewhere.	Performance Qualification	Replace with Process Verification	The term “Performance Qualification (PQ)” has been defined by ISPE, GAMP, incorporated into the V-model and accepted by industry to mean performance of equipment, acting singly or in concert to meet a user requirement. For example, autoclave sterilization is a form of performance qualification to demonstrate the ability to sterilize. PQ also relates to sampling of water, steam, gas, and related systems, it can cover media fills, environmental monitoring, cleaning validation, as well as the operation of equipment together such as on a packaging line. A substitute phrase to be used here could be “process performance qualification,” or “process verification.” Process verification probably comes closest in meaning to that described in the text.