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

Comments on WHO Working Document QAS/……..
Title of the document :WHO Good xxxxxxx practices for yyyyyyyyy

World Health Organization

Example for comments

Comments submitted by : xxxxxx
Telephone number : xxxxx
Address : xxxx
Email : x
Date : xxxxxxx

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

		General comment(s) if any :			**Originator of the comments**
# section	**# Pararaph If more than one**	**Comment / Rationale**	**Proposed change / suggested text**	**Classification** **L**= low **M**= medium **H**= high	**Originator of the comments (for WHO use)**
4.11	3	Manufacture of Sterile Preparations	There is a typo under point (b) – “lee” should be revised to “less”.	L	
10.7		Clause states the clothing required for each grade of the working area and the first sentence added to 3rd paragraph Grades A/B (personnel should be excluded from Grade A) is related to a practice. New filling lines allow to comply with the exclusion of personnel from grade A.	Delete ¨personnel should be excluded from Grade A areas¨ in this clause and include a new one using a wording similar to US Food and Drug Administration’s 2004 Aseptic Processing Guidance ¨ As operator activities increase in an aseptic processing operation, the risk to finished product sterility also increases.	H	
		Box will increase automatically as you type			
		Please add rows as necessary (with "copy and paste" empty rows)			