Shire

To: European Commission
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Shire's Response to Volume 4, EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary US
Annex 15: Qualification and Validation

Shire welcomes the opportunity to submit the following questions and comments, in response to the consultative document on Qualification and Validation.

1) In reference to Section 1.5 part d, which states that the VMP should be a summary document and contain template formats to be used in protocols and reports. Instead of requiring a "template", which is quite specific and seems to imply a cut and paste document, we suggest that a list of key elements is required, to clarify what the agency is expecting.

2) In section 4.14 "documented in the VMP" is not previously described. The only mention of the VMP is only related to the site validation programme and not to process validation.

3) In reference to section 4.7, which states that normally batches manufactured for process validation should be the same size as the intended commercial scale batches, please clarify that this covers both manufacturing and packaging processes.

4) In reference to section 4.8, which states that facilities, systems, utilities and equipment used for process validation should be qualified and test methods should be validated, we recommend that it is reworded to state that they should be "appropriately validated or qualified for their intended use (e.g. consider compendia and in-process test methods).

5) In reference to section 4.20, while it is good to have the listed subsections, we recommend that they are not mandatory and that this section is reworded to state that they may be included rather that "should" be included.

6) In reference to section 4.20, parts e and f should be one point.

7) In reference to sections 9.3 and 9.12, we would like to request clarification regarding expectations for how these principles could apply to a cleaning verification program, either lieu of a full cleaning validation program, or in the time period while validation information is being collected.

Sincerely,

Joseph Zarkoski
Head of Regulatory Compliance, QA