Comments on Guideline for Industry

Title of the document: Consultation on EU GMP Guidelines, revised Annex 17 on the Real Time Release Testing

Comments submitted by: Vertex Pharmaceuticals
Address: 50 Northern Ave, Boston, MA 02210 USA
Contact: Tom Hansen, Global Regulatory Affairs
Email: tom_hansen@vrtx.com
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# section	# Lines	Wording from Document / Rationale to change	Proposed change / *suggested text*	Classification L= low M= medium H= high	Originator of the comments
3.1	24	"**Interaction with the relevant regulatory authority……RTRT control procedure applied to site."** / These 2 sentences regarding regulatory agency interaction are not relevant to this guideline as the scope of guideline focuses on application of RTRT in manufacturing after authorisation.	**Delete**	M	Vertex
3.3	43	**"A RTRT master plan should be prepared which should be integrated and controlled through the pharmaceutical quality system."** / Implies that the RTRT must be a stand-alone document	**Clarify that the RTRT master plan may refer to other documents** / *"A RTRT master plan should be prepared which should be integrated and controlled through the pharmaceutical quality system. The RTRT master plan may be a separate file or a file referring to other files."*	M	Vertex
3.3, 3.6	47, 70 - 82	**"iii. Control Strategy"** / Control strategy should not be part of the RTRT master plan. Rather, RTRT should be part of the control strategy.	**Delete line 47, and move lines 70 – 82 to the end of section 3 (after line 112).**	H	Vertex

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3.6	76	**"The control strategy should … include Operating Characteristic curve or the Acceptable Quality Level (AQL) and Unacceptable Quality Level (UQL) associated with the plan."** / Control approach is not applicable to all implementations of RTRT, in particular where large N is not a factor.	**Include "where applicable" /** "The control strategy should also describe the sampling plan, acceptance/rejection criteria, and include *where applicable* Operating Characteristic curve or the Acceptable Quality Level (AQL) and Unacceptable Quality Level (UQL) associated with the plan."	H	Vertex
3.11	112	**"End testing for release purpose can be acceptable … due to analytical equipment failure (see 3.3)**" / This is in conflict with CHMP Guideline on RTRT: EMA/CHMP/QWP/811210/2009-Rev1.	**Add a statement to the end of this section, copied from the CHMP guideline on RTRT.** / *"In the event that the test results of RTRT fail or are trending toward failure, RTRT may not be substituted by end-product testing. Any failure should be investigated and trending should be followed up appropriately. Batch release decisions will need to be made based on the results of these investigations, and must comply with the content of the marketing authorization and current GMP requirements."*	H	Vertex