4th PQRI Workshop on ICH Q3D Elemental Impurities Requirements 2020

Breakout Session 1:

Implementation Problems and Future Needs

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Implementation Problems and Future Needs

- What has been the experience of the participants with implementing the ICH Q3D requirements in their companies?
- What questions have sponsors been getting from regulators on current submissions containing elemental impurity information?
- Are drug application sponsors seeing differences in the level, location and type of information required by regulators in different regions, needed to support their elemental impurity risk assessments?
- What are your experiences or challenges in using the finished product approach or the component assessment approach?
- What has worked well? What has not worked well?

Implementation Problems and Future Needs

- How much data/information is needed to perform a scientifically valid risk assessment? How much of the data do you include in your filing (vs maintaining in a company report)?
- Have regulators defined the number of batches required for testing to support the risk assessment? Are the number of batches between regions to the same?
- How often has the risk assessment indicated that the EI level was greater than 30% of the PDE and what kind of control strategies did you then implement?
- How are you handling change control for Risk Assessment Reports?

Implementation Problems and Future Needs

- How successful have you been in acquiring useful elemental impurity information from your supplier? Are you getting cooperation from your suppliers for change control?
- What experience have you had in using supplier information vs testing performed by the user in developing your risk assessment?
- Have companies tried to implement specifications with their excipient suppliers, and if so, based on what?
- How successful have you been in using this data and any established supplier specifications to support elemental impurity strategy in your regulatory filings?