PQRI/USP Workshop on ICH Q3D Elemental Impurities Requirements – Recent Experience and Plans for Full Implementation in 2018

Breakout Session II:

Industry Experience with Previous Submissions on New Drugs and Concerns about Implementation for Existing Drugs

Facilitators:

Katherine Ulman

Dave Fillar

Mark Schweitzer

PQRI Product Quality Research Institute

usp™

Industry Experience with Previous Submissions on New Drugs and Concerns about Implementation for Existing Drugs

1. **What questions have sponsors received from regulators on current submissions containing EI information?**

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2. What have sponsors included in filings? At what level of detail?
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3. What supporting information do sponsors have available on-site?

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4. Where is information being provided in filings? Is filing location consistent for all regions?

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When provided in multiple section, are hyperlinks included?

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5. What concerns are there for implementation of existing drugs?

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Open Ended – solicit discussion