

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

Breakout Session III: Acceptable Risk Assessment Strategies & Outstanding Analytical Challenges

Facilitators:

Nancy Lewen

Tim Shelbourn

Josh Foote



Acceptable Risk Assessment Strategies & Outstanding Analytical Challenges

- 1. What questions have sponsors received from regulators regarding their risk assessment strategies?**

Acceptable Risk Assessment Strategies & Outstanding Analytical Challenges

2. If testing performed, what was done?

Acceptable Risk Assessment Strategies & Outstanding Analytical Challenges

3. Does risk assessment strategy leverage the ICH Q3D 30% threshold?

—

Acceptable Risk Assessment Strategies & Outstanding Analytical Challenges

4. What analytical challenges have been encountered?

Acceptable Risk Assessment Strategies & Outstanding Analytical Challenges

5. Are there remaining concerns regarding risk assessment strategies or analytical challenges?

—

Open Ended – solicit discussion