

Roundtable Session 1 – Table 5 – How Are You Monitoring the Health of Your Bioassay Methods?

Facilitator: Tara Stauffer, *Bristol-Myers Squibb Company*

Scribe: Simone Tomaschek, *Roche Diagnostics GmbH*

How are you monitoring the health of your Bioassays methods?

1. What constitutes Bioassays Method “health”?
 - EC50
 - Internal control
 - Reference Material
 1. Primary & Secondary
 - Raw signal
 - Parameters A,B,C,D
 - DS & DP Trending
 - Failure Road
2. How does the approach change based on the phase of development?
 - Separate assay control
 1. E.g. Tox Batch
3. Potential use cases of Bioassays method monitoring that may be utilized to evaluate product quality?
 - Prove impact if it is really product quality trend US. Method trend
4. Challenges for monitoring?
 - Semi-automated trending
 - Different labs trending the same things
 - Across sites monitored on an annual basis
 - Pipetting training new analysis
 - G6 wells – all the same dilution
 - EC50 (no serial dilution)
 - Heat map
 - Observe, be observed, 3 valid assays
5. How are AI & other digital tools influence practices?
 - Automated export