Session 3: Needs and Approaches for overcoming gaps in obtaining sufficient measurement assurance for cell counting

Regulatory considerations for cell counting
Steven Bauer / FDA

Measurement assurance strategies
John Elliott / NIST

Round Table Discussion
• Common methods/best practices
• Reference materials
• In process controls for the measurement process
• Other strategies for measurement assurance
• Documentary standards
Round Table Discussion

Moderator: Sumona Sarkar, NIST
Some Considerations

What are the gaps in the existing resources for cell counting?

What are the best practices for establishing validated cell counting methods?

How can we improve our confidence in cell count measurements?

How can we assure comparability of cell counting measurements?

Are there pre-competitive activities the community can engage in to assure the quality of cell counting measurements?
What are common practices across cell counting

Identifying appropriate control materials

Sources of variability

Method Comparability

Gating Practices

Dealing with sample artifacts (bubbles, debris etc.)

Collaboration to draft consensus practices

What set of cell types for instrument validation

Improving variability in cell counts

Method Transfer

Influence of Count on Bioassays

Sample Stability during Counting

Method acceptance criteria

Control Experiments prior to a run

Approaches for limiting user variability

Influence of Count on Bioassays

Counting irregular cells

Good Study Designs

Standard for live/dead assessment and counting

Instrument-instrument variability

Accuracy/True Counts

Counting irregular cells

Sources of variability

Influence of Count on Bioassays
Additional Information
Workshop Goals

• Raise awareness of the importance and challenges associated with cell counting measurements

• Develop and document best practices for cell counting

• Discuss options to address measurement challenges through collaborative studies (NIIMBL)

• Workshop outcomes to support the development of international standards and more specific measurement challenges
## Workshop Participants: Resources

- Accurate measurement of peripheral blood mononuclear cell concentration using image cytometry to eliminate RBC-induced counting error
- Morphological observation and analysis using automated image cytometry for the comparison of trypan blue and fluorescence-based viability detection method
- A high-throughput AO/PI-based cell concentration and viability detection method using the Celigo image cytometry
- Cell Gene Therapy Insights 2016;2(6),663-673.
- USP 1034 Analysis of Biological Assays
- ICH Validation of Analytical Procedures: Text and Methodology Q2(R1)
- ICH Guidance for Industry Q2B Validation of Analytical Procedures: Methodology
Workshop Participants

What Types of Follow-on Activities/Projects would be valuable from this workshop?

- Case studies that exemplify cell counting method evaluation
- Protocols/Best Practices Documents
- White Paper
- Establishing written consensus standards
- Collaborative/Inter-lab studies
Q5 List 3-5 factors associated with the cell sample that have played a part in selecting your cell counting method (e.g. cell source, aggregation, sample stability etc.)

Answered: 19   Skipped: 0
Q6 List 3-5 other factors you consider when selecting your cell counting method (e.g. Cost, Ease of use, measurement confidence etc.)

Answered: 19   Skipped: 0