

NIST Workshop: Strategies to Achieve Measurement Assurance for Cell Therapy Products

May 11-12, 2015, NIST Campus, Gaithersburg, MD, Bldg. 101, Green Auditorium

Goal: Examine approaches for improving confidence in the measurements that are necessary for bringing cell therapy products to market.

Scope: Challenges in achieving reproducibility, accuracy and comparability in biological assays have been identified as major roadblocks to development, manufacturing and regulatory approval of cell therapy products (CTPs). Improving confidence in measurements for CTPs involves understanding and controlling sources of variability, development of appropriate reference materials to enable traceability and providing objective evidence to validate results. The workshop will focus on strategies to achieve measurement assurance for assays that may contribute to characterizing critical quality attributes and/or potency, and will include breakout sessions focused on specific measurements.

Organizing Committee: Fouad Atouf (USP), John Elliott (NIST), Kyle Kolaja (CDI), Sheng Lin-Gibson (NIST), Michael McCaman (Lonza), Steven Oh (FDA), Anne Plant (NIST), Darwin Prockop (Texas A&M), Pam Robey (NIH), Jon Rowley (Rooster), Carl Simon (NIST)

Content: The first morning will cover strategies for achieving confidence in measurements, such as traceability, reference materials, validation, uncertainty analysis & inter-laboratory testing. In the afternoon, we will breakout into sessions focused on specific measurements, such as cell counting, viability and functional tests. On the second morning, report-outs will lead discussion on the key steps that were identified for improving the confidence in the cell measurements that were examined.

Link: <http://www.nist.gov/mml/bbd/biomaterials/measurement-assurance-for-cell-therapy-products.cfm>

Monday, May 11

7:30: Coffee & pastries; NIST cafeteria also has a full breakfast bar for purchase

9:00 – 9:10: Anne Plant (Chief, Biosystems & Biomaterials Division), Opening Comments

9:10 – 9:15: Laurie Locascio (Director, Material Measurement Lab), Welcome to NIST

9:15 – 9:45: Marc Salit (NIST), “Systematic Elements of Metrology, & How They Work”

9:45 – 10:15: John Elliott (NIST), “Protocol Design & Inter-Laboratory Testing”

10:15 – 10:45: Chris Wiwi (Celgene), “Analytical Considerations for Cell Therapy Manufacturing”

10:45 – 11:05: Coffee Break

11:05 – 11:35: Mahendra Rao (Q-Therapeutics), “Developing & Using Reference Materials for Stem Cells”

11:35 – 12:05: Ivan Rich (Hemogenix), “Validating a Cell Viability Assay”

12:05 – 12:30: John Elliott, Charge for breakout sessions: Discuss how to improve confidence in the assigned measurement. Generate a draft summary of challenges and opportunities that may include: sources of variability, cause & effect diagram, flowchart of a robust assay protocol, sensitivity testing, needs for reference materials, positive & negative controls, inter-laboratory testing.

12:30 – 1:30: Lunch (for purchase at NIST Cafeteria)

1:30 – 1:45: Continue charge for breakout sessions (Green Auditorium)

1:45 – 4:30: Parallel Breakout Sessions:

- Breakout #1 (Lecture Room E): Cell Counting; Moderators: Janet Davis (Janssen) & Sumona Sarkar (NIST)
- Breakout #2 (Lecture Room D): Cell Viability; Moderators: Ivan Rich (Hemogenix) & John Elliott (NIST)
- Breakout #3 (Lecture Room A): Functional Cell Assay (In Vitro Angiogenesis); Moderators: Claudia Zylberberg (Akron Biotech), Yael Porat (BioGenCell), Juliana Woda (Juventas), Eytan Abraham (Lonza), Michael Halter (NIST), Carl Simon (NIST), Sandro Matosevic (Akron Biotech)

4:30 – 5:00: Reconvene (Green Auditorium): First impressions from breakout sections

5:00: Break for the day

5:30: Shuttle back to Holiday Inn (for those not going to Brasserie Beck)

6:00: Dinner, Brasserie Beck: <http://brasseriebeck.com/>, located in Kentlands near Lowe's, 311 Kentlands Blvd, Gaithersburg, 301-569-4247; US government cannot provide meals due to federal regulations.

For people without a car: meet on the bldg. 101 steps at 5:45 & we will drive you to dinner & back to the hotel.

Tuesday, May 12

7:30: Coffee & pastries; NIST cafeteria also has a full breakfast bar for purchase

9:00 – 9:10: Sheng Lin-Gibson (Deputy Chief, Biosystems & Biomaterials Division), Opening remarks

9:10 – 10:40: Reports from breakout sessions

- 9:10 – 9:40: Breakout #1 Report: Cell Counting
- 9:40 – 10:10: Breakout #2 Report: Cell Viability
- 10:10 – 10:40: Breakout #3 Report: Functional Cell Assay (In vitro Angiogenesis)

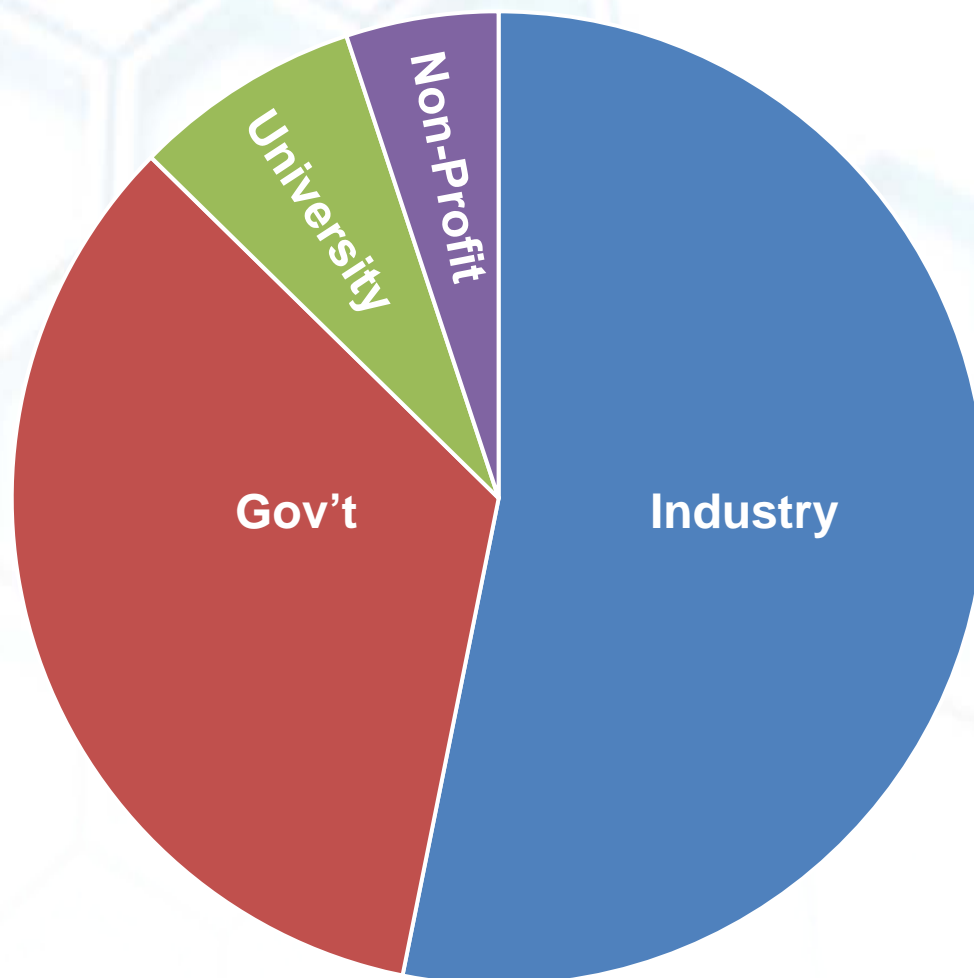
10:40 – 11:00: Coffee Break

11:00 – 12:00: Panel discussion; Moderator: Carl Simon

Michael Mendocino (Mesoblast), Pam Robey (NIH), Chris Wiwi (CelGene), Steven Oh (FDA), Mahendra Rao (Q-Therapeutics), John Elliott (NIST), Jessica Carmen (ARM), Ivan Rich (Hemogenix)

12:00 – 12:15: Concluding remarks

80 Workshop Participants



NIST
NIH
Army
FDA
Janssen
Lonza
J&J
CDI
Biospherix
Medimmune
Akron Biotech
Cook

USP
Maxcyte
Thermofisher
GE
Chemometec
AABB
Wake Forest
Fortus Medical
Athersys
RoosteBio
Cleveland Clinic
Asterias

Mesoblast
Terumo BCT
Ga Tech
Sistemic
Hemogenix
Loughborough Univ.
Biologics Consulting Grp
PCT
NCSU
Neural Stem Cell Institute
Juventas
Novartis

Choice of Breakout Session Topics

- Breakout session topics selected based on an un-scientific poll of 23 people, each person responded with 3 to 5 assays they think are important & need improvement
- The focus is less on the assay & more on the measurement assurance process, & these concepts are generalizable

