

Strategies to achieve measurement assurance for cell therapy products

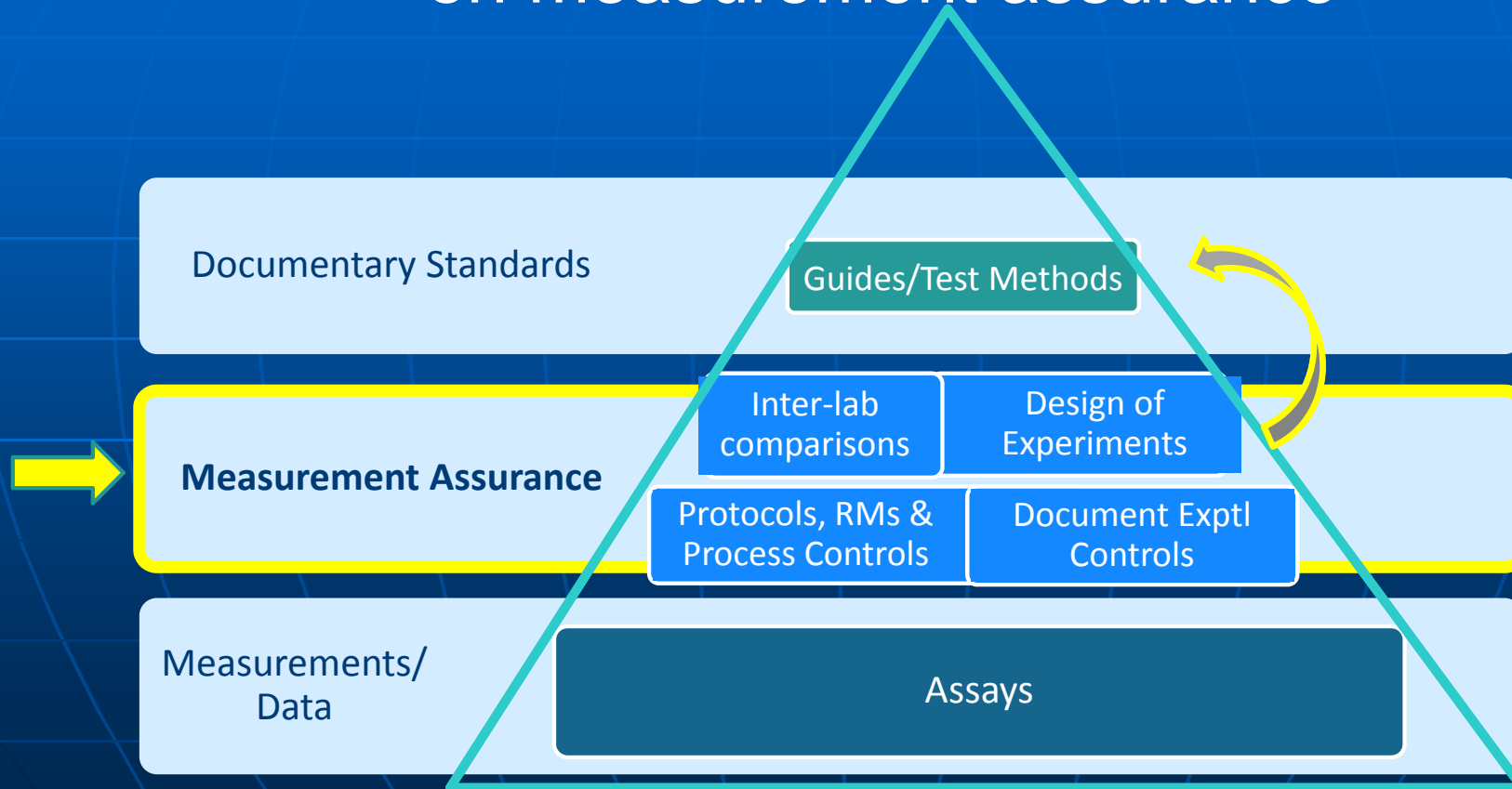
What is measurement assurance?



Knowing the level of confidence you have in the data that you are using to make a decision.

Having the data that provide credibility of the measurement result.

The process of developing a standard is founded on measurement assurance

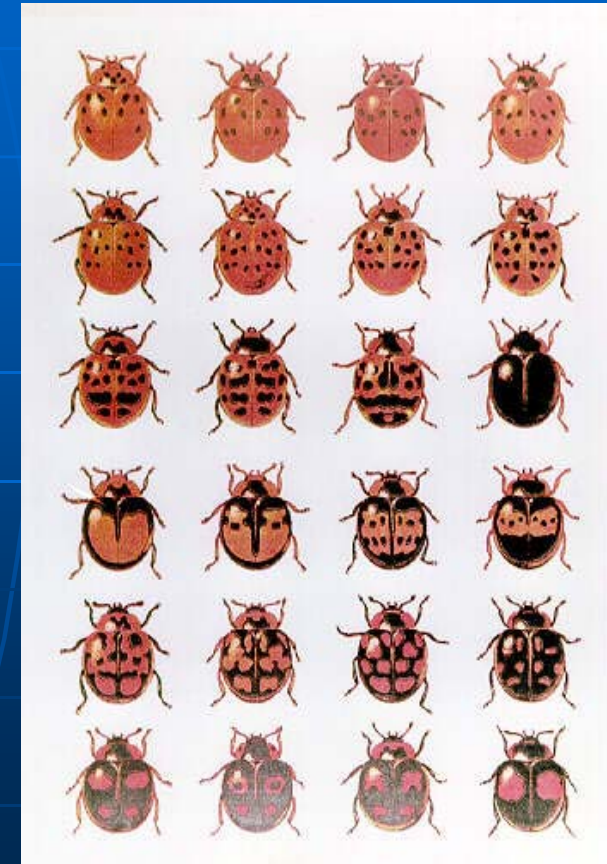


Measurement assurance in this field is not always straightforward.

- What is the measurand?
- Is your assay measuring what you intend?
- Are there assay variables (personnel, reagents, unknown factors) that are influencing the assay result?
- Can other labs get the same response?
- Will help to distinguish biological variability
 - but only if the dispersion around the measurement is less than the dispersion around the biological response.

Is an assay biologically meaningful?

**Not a
discussion
for today**



What is our desired outcome today:

- Explore how the concepts of measurement assurance can be applied to regenerative medicine.
- Discuss how to use metrology tools to assess a measurement process.
- Share best practices.

Some tools for achieving measurement assurance:*

- Ishikawa (cause/effect) diagram to identify sources of variability
- Design of Experiment
- Process Controls
- Charting
- Validation specifications
- Interlaboratory comparisons
- Reference Materials for traceability

* There are many different ways of realizing confidence in measurements.

Break-outs sessions: Discussion points

Identify sources of uncertainty in each type of assay.

Consider how to determine the most important sources.

Assess how those sources could be mitigated.

?Compare assays to one another?

How to test if all important sources of uncertainty are identified?

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Monday Morning Talks

- Laurie Locascio (Director, NIST Material Measurement Lab), Welcome to NIST
- Marc Salit (NIST), "Systematic Elements of Metrology, & How They Work"
- John Elliott (NIST), "Protocol Design & Inter-Laboratory Testing"
- Chris Wiwi (Celgene), "Analytical Considerations for Cell Therapy Manufacturing"
- Coffee Break
- Mahendra Rao (Q-Therapeutics), "Developing & Using Reference Materials for Stem Cells"
- Ivan Rich

- Lunch
- Charge to the Breakout Sessions

Monday Afternoon Breakout Sessions

- Breakout #1: Cell Counting
- Breakout #2: Cell Viability
- Breakout #3: Functional Cell Assay
- Preliminary reports from breakouts

Tuesday Morning

- Full reports from breakouts
- Panel discussion