Approaches to Provide Assurance for Biological Measurements

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Workshop on Ultraviolet Disinfection Technologies & Healthcare Associated Infections: Defining Standards and Metrology Needs

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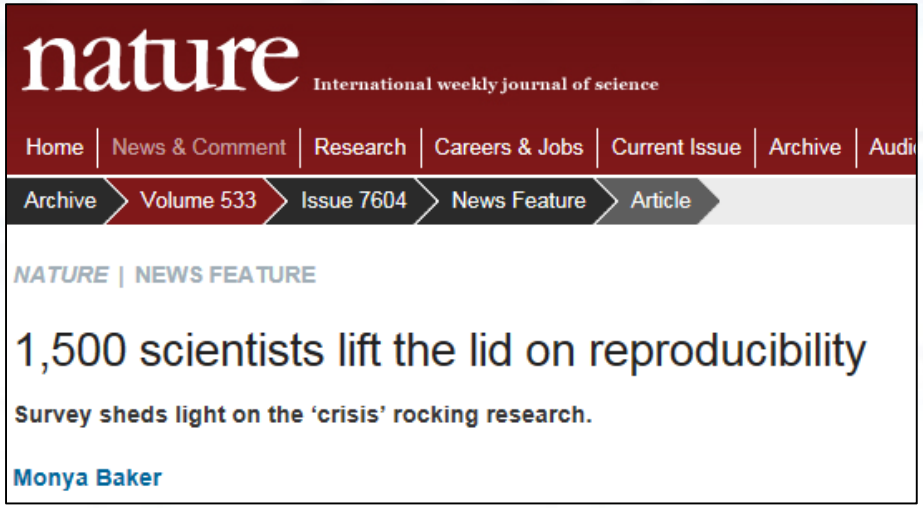
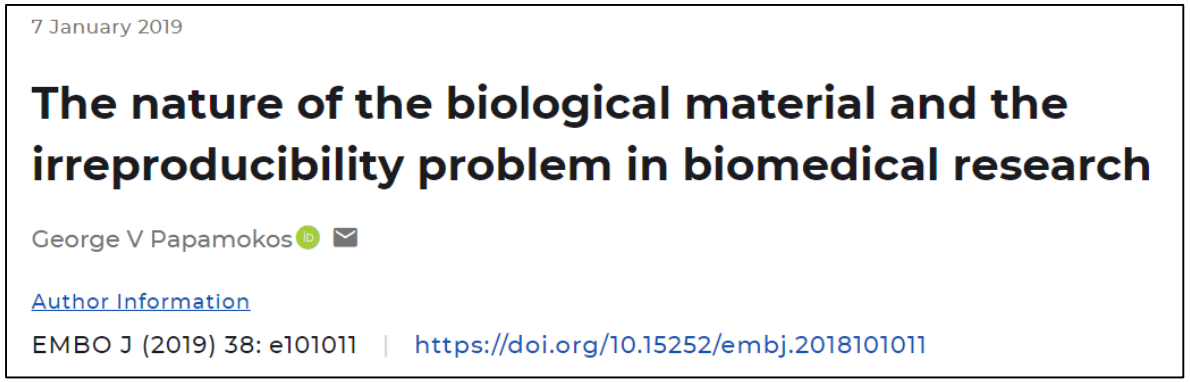
MATERIAL MEASUREMENT LABORATORY

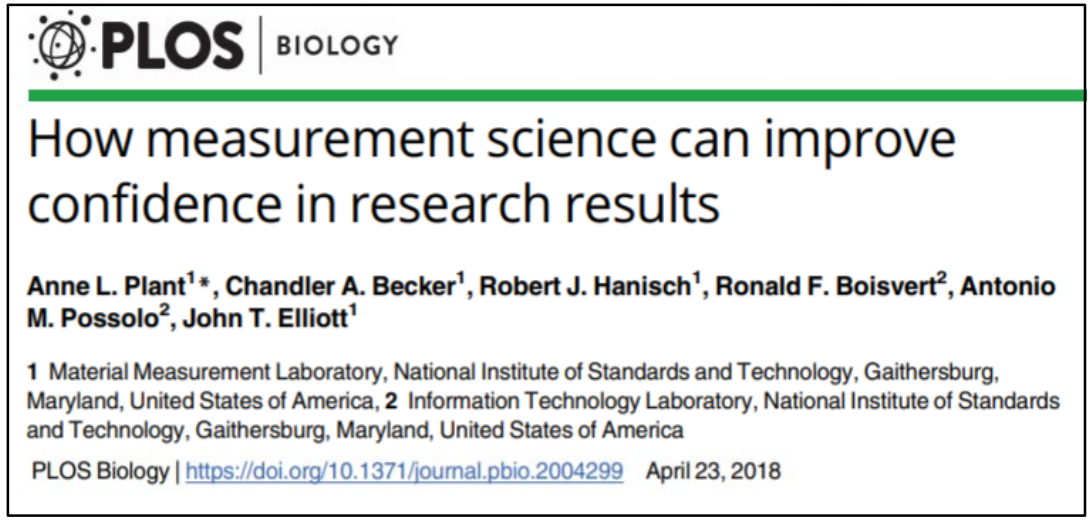
Lack of Confidence in Biomedical Research



Estimated over $28B spent annually in U.S. on preclinical research that is irreproducible[1]

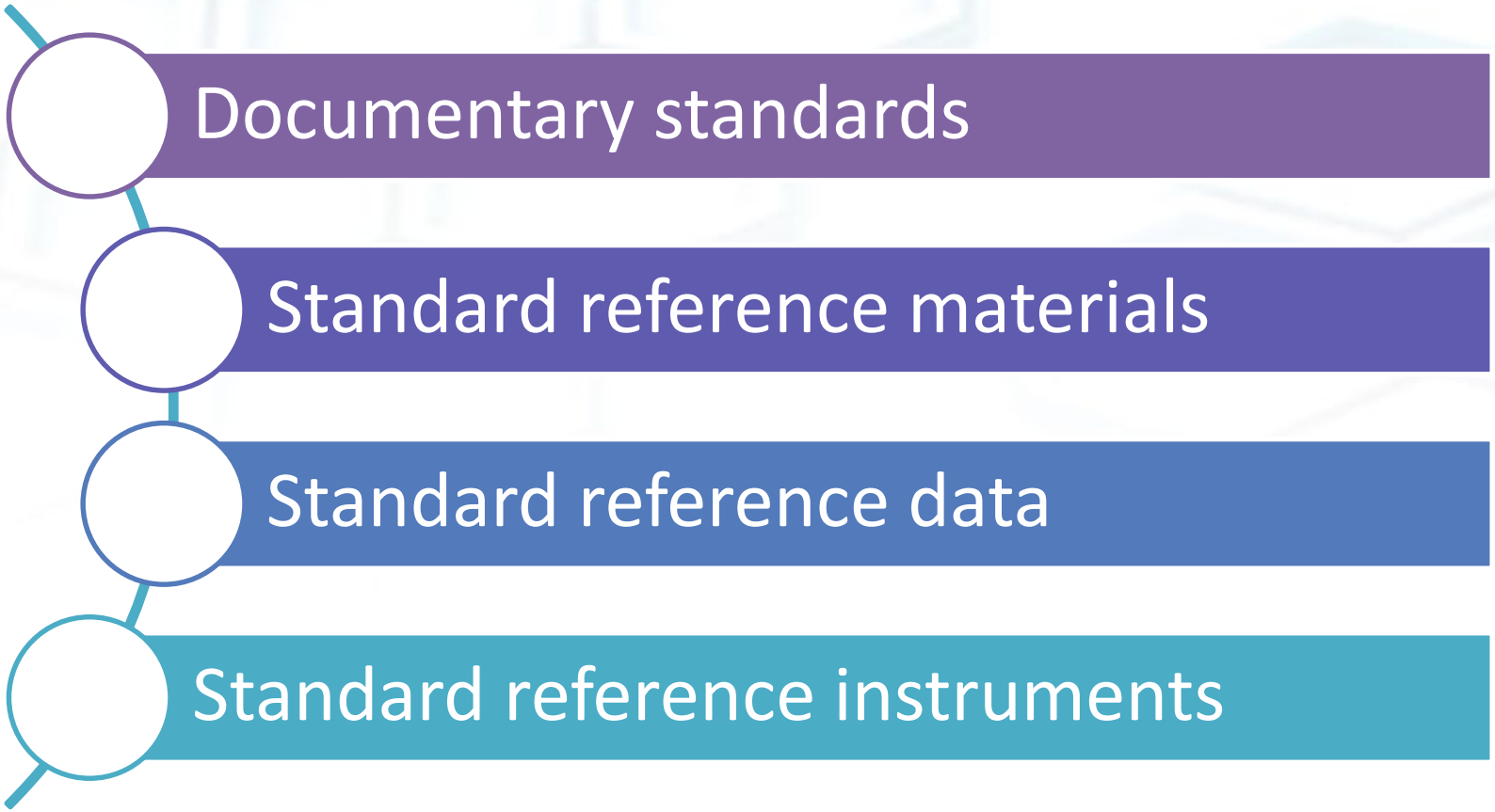
https://www.nih.gov/research-training/rigor-reproducibility





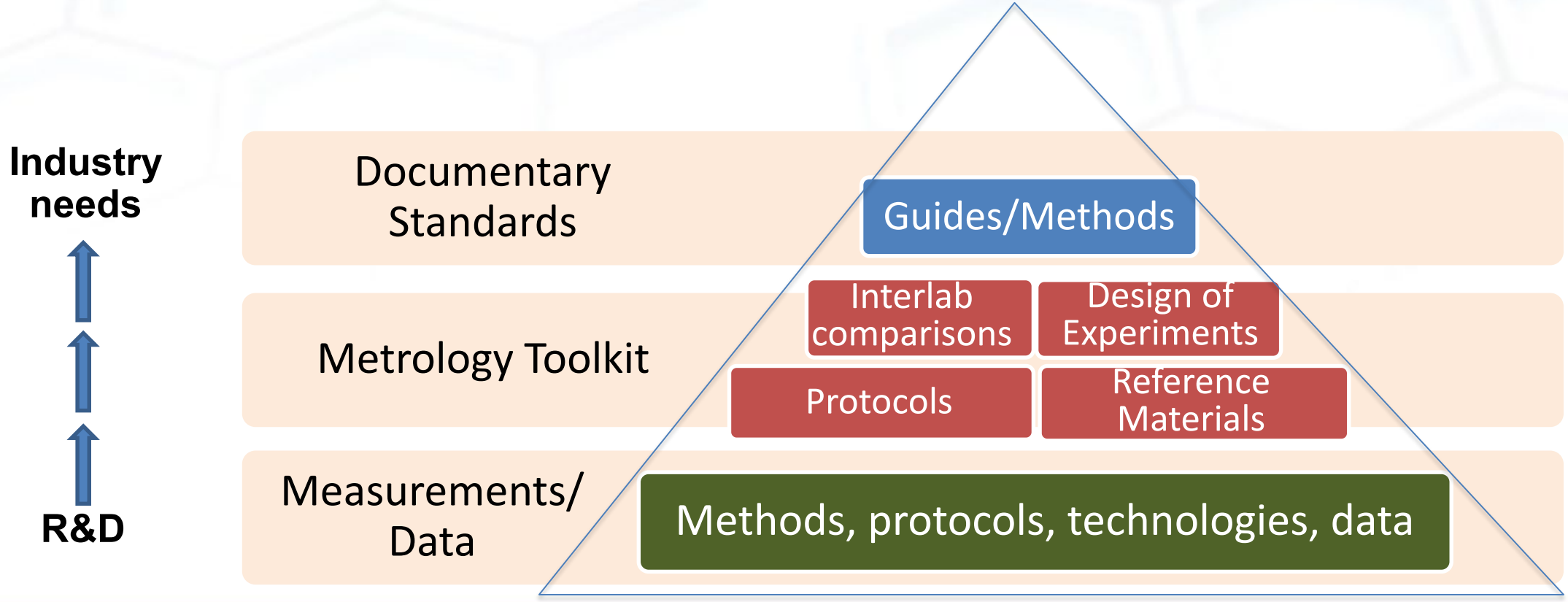
1 Freedman et al. "The Economics of Reproducibility in Preclinical Research," 2015, PLoS Biol 13(6): e1002165.

Standards


Documentary standards
Standard reference materials
Standard reference data
Standard reference instruments

Measurement Assurance

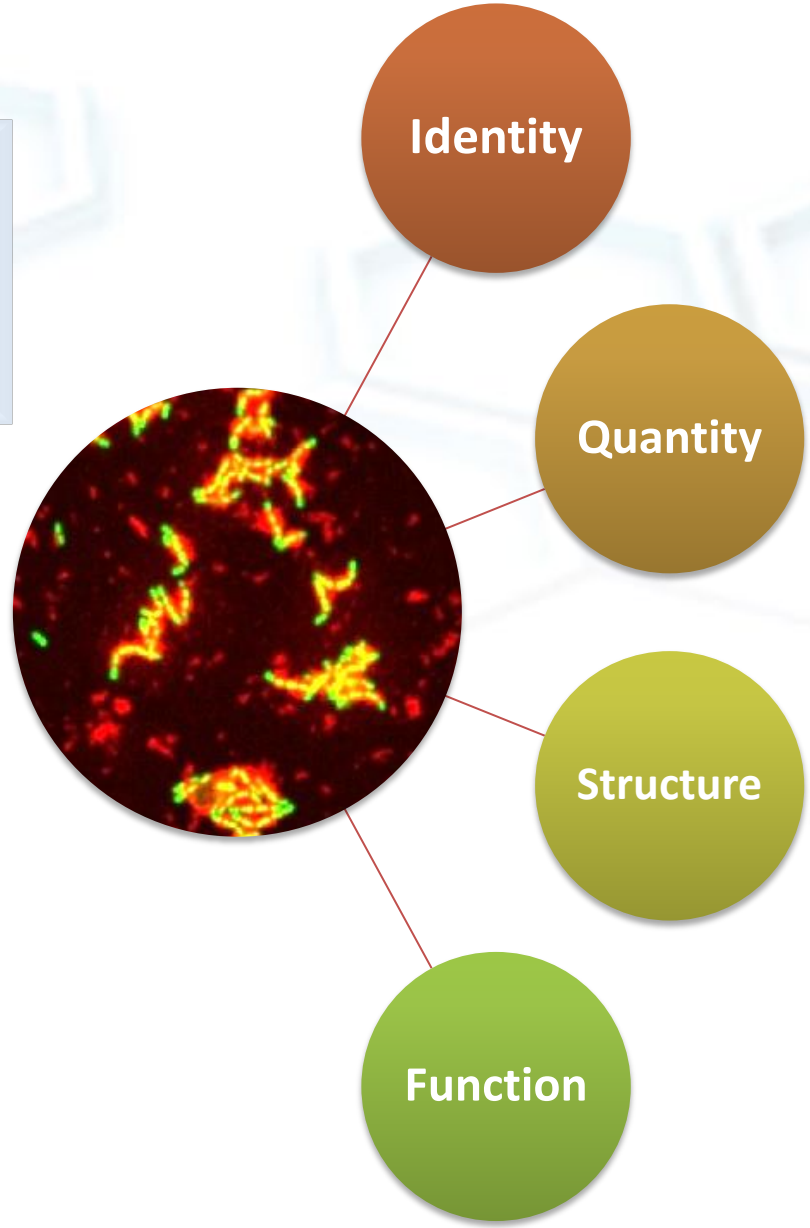
- Provides a known level of confidence to inform decision making
- Is based on supporting data and metadata to provide credibility
- Leads to accelerated technology development and translation



Microbial Metrology

Developing measurement science, technology, and standards to increase confidence in measurements of microbes and their complex communities and to promote responsible biotechnology innovations

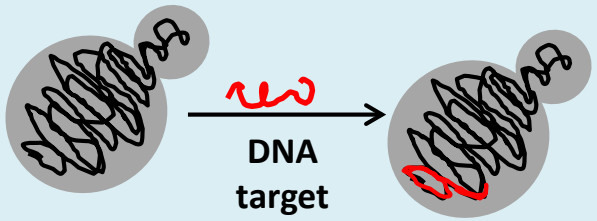
Planktonic cells
Microbiome Communities
Biofilms



Candidate RM 8230: Living Cells Characterized for Total Cell Count and CFUs

Sandra Da Silva

Saccharomyces cerevisiae NE095



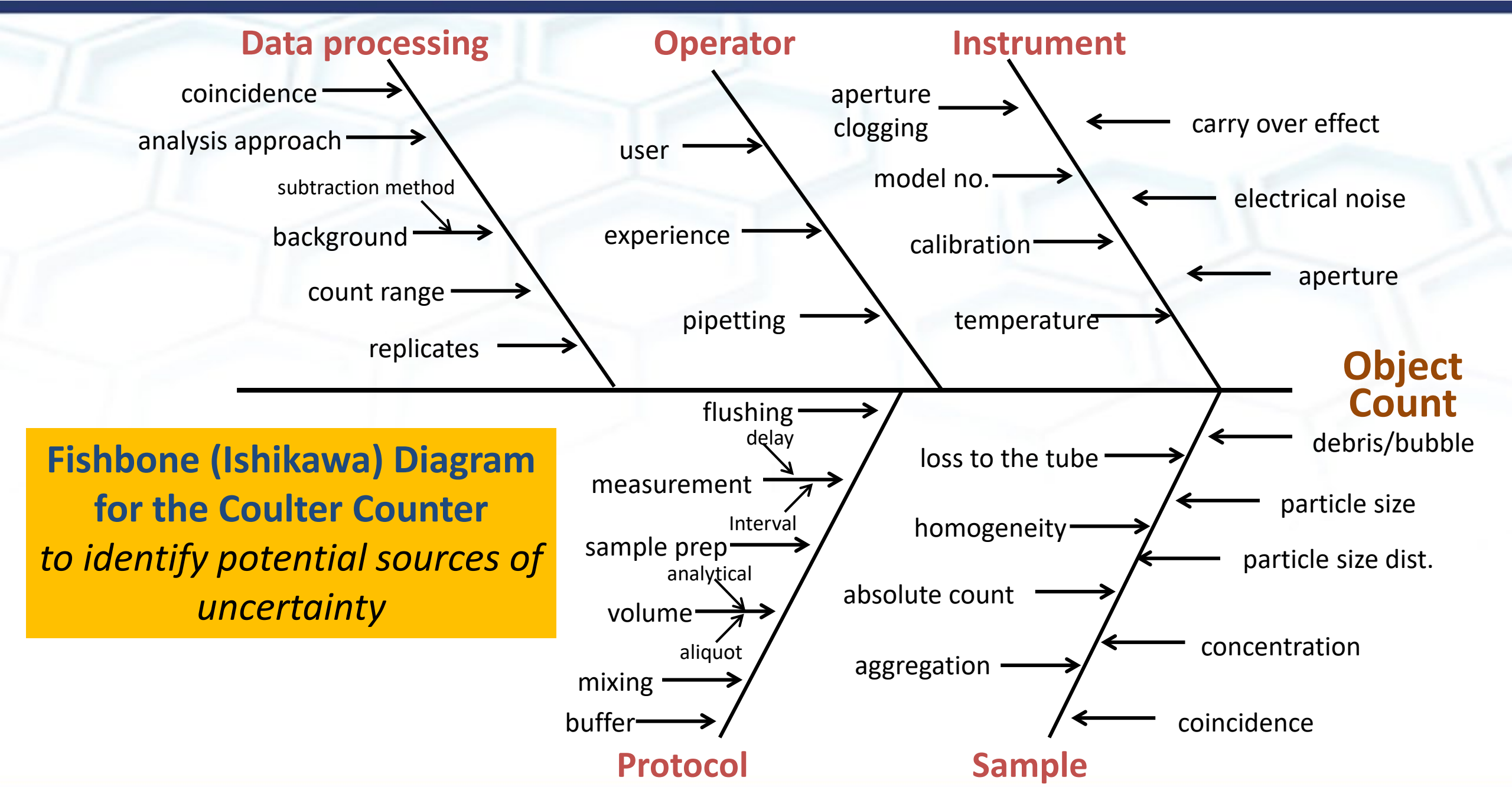
Homogeneous, Stable, Fit for Purpose

Measurand	# per vial x 10^7
Total cells (Coulter)	**3.81 ± 0.51 (13.3 %)**
CFUs (Plating)	0.095 ± 0.018 (18.9 %)

Antimicrobial testing
Probiotics
Live biotherapeutic products
Food contamination
NGS pathogen detection
Biothreat detection

"Ground truth" material to

- assess accuracy of total cell count methods
- enable comparison of methods
- evaluate efficiency of antimicrobial approaches
- increase confidence in results

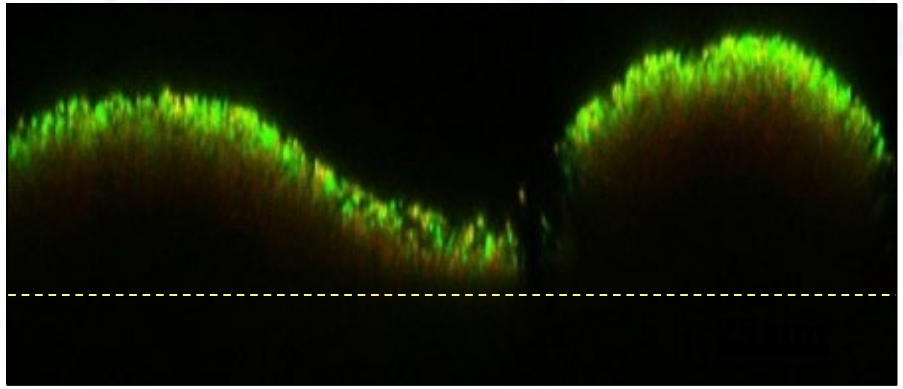


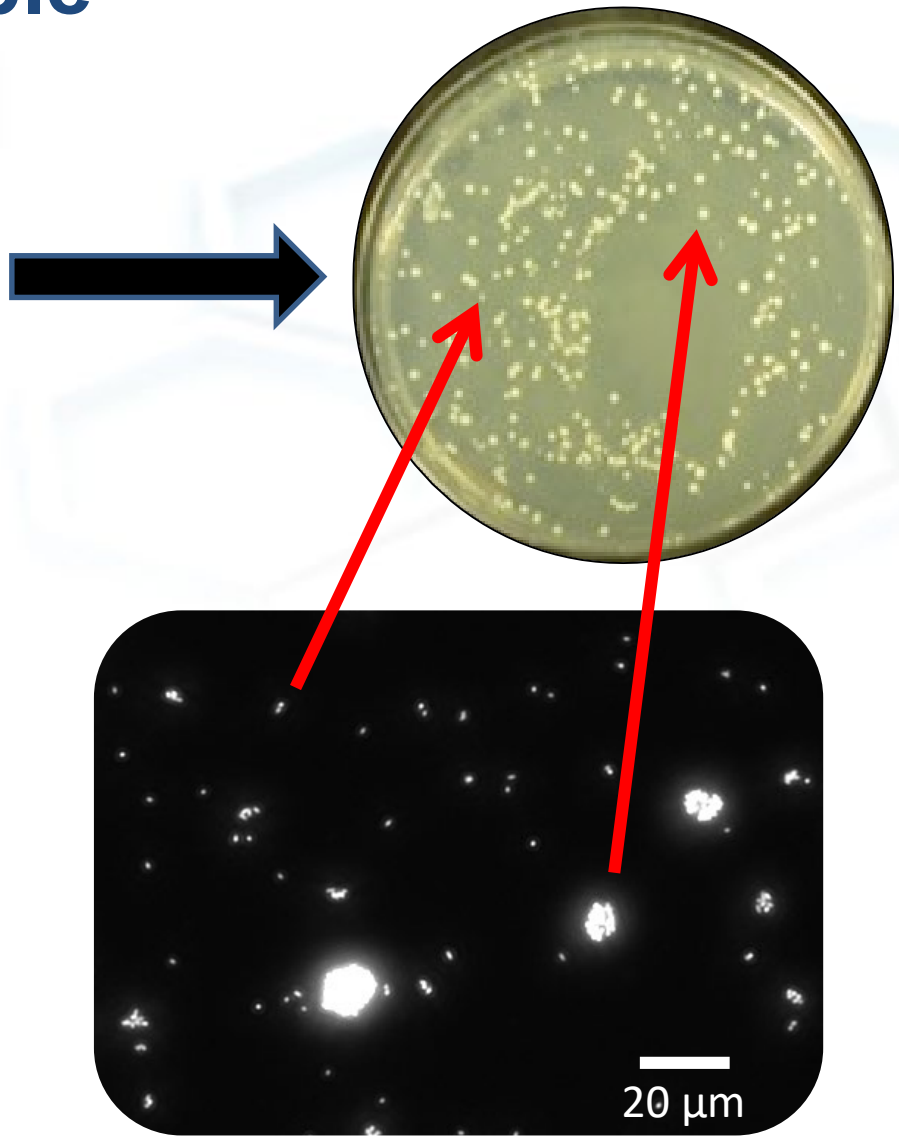
Fishbone (Ishikawa) Diagram for the Coulter Counter

to identify potential sources of uncertainty

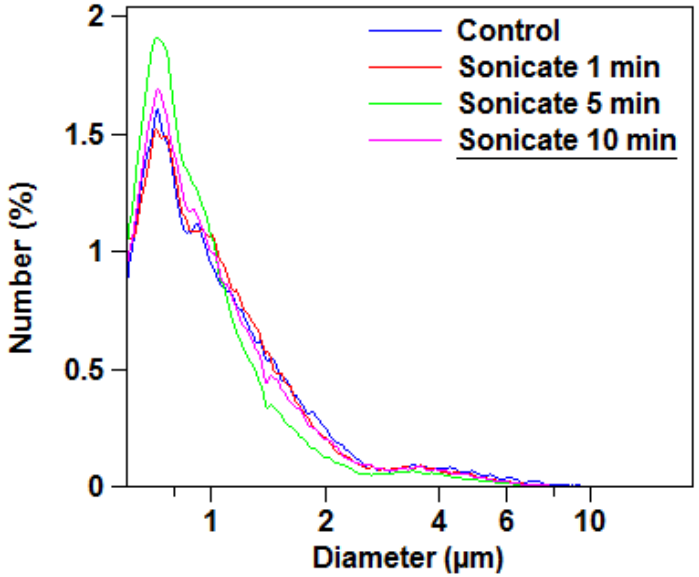
Check Assumptions When Possible

CFUs for Biofilms

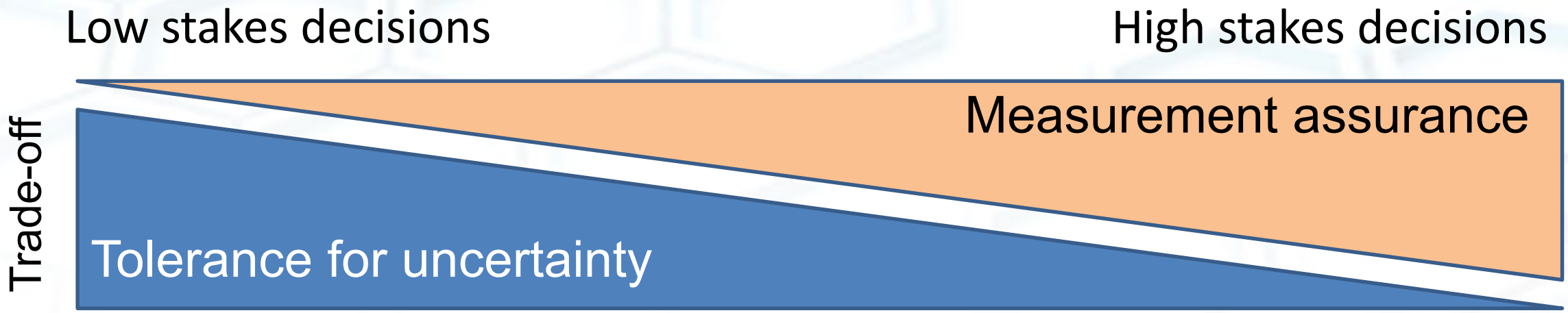




Coulter counter analysis



Concluding Thoughts



Example Efficacy Testing Workflow

Incorporating measurement assurance strategies into each step will increase confidence in results