IIVS WEBINAR

How GLPs Enhance the Quality of Regulated and Non-Regulated In Vitro Toxicology

October 13, 2016 | 10-11 am EST

Presenter:
Amanda Ulrey, IIVS Director of Quality & Compliance

- This will be a one-hour webinar. A Q&A session will follow the presentation.
- Slides and a webinar recording will be available following the webinar.

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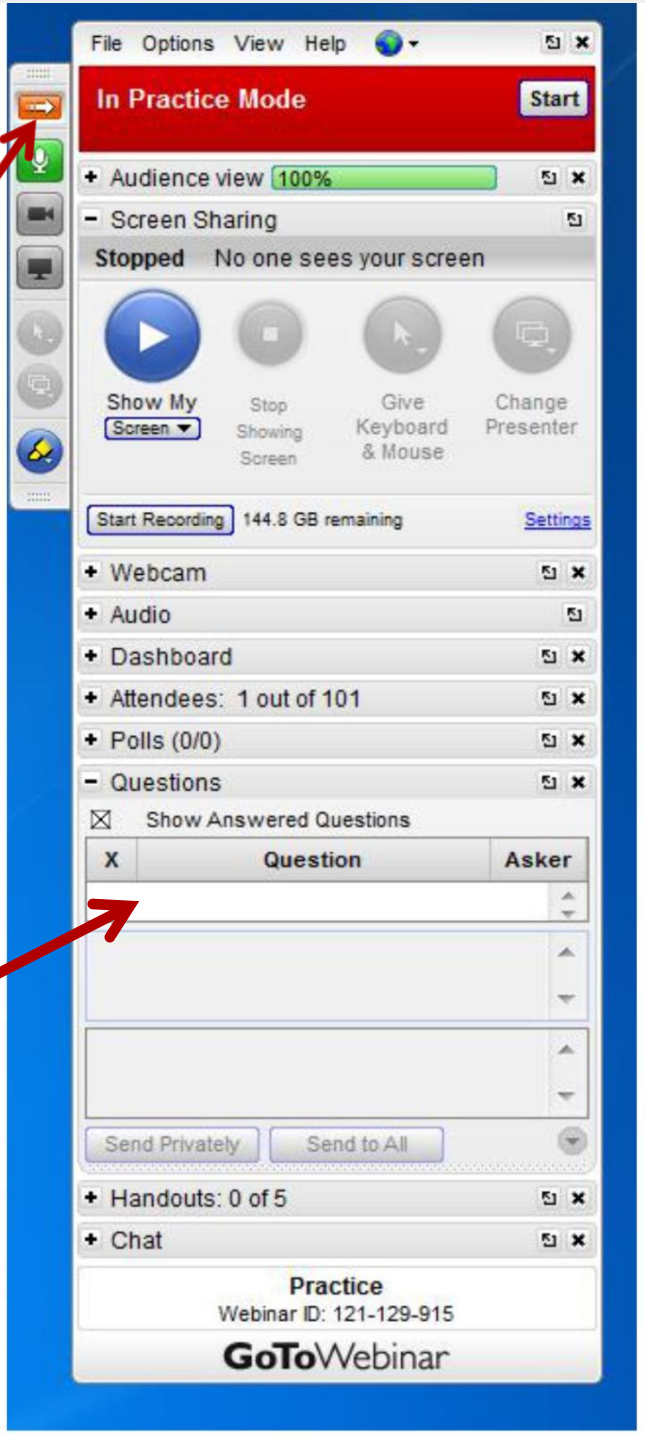

How GLPs Enhance the Quality of Regulated and Non-Regulated In Vitro Toxicology

IIVS
Institute for In Vitro Sciences
Advancing Science & Animal Welfare Together

Presented by: Amanda K. Ulrey, RQAP-GLP
Director, Quality and Compliance
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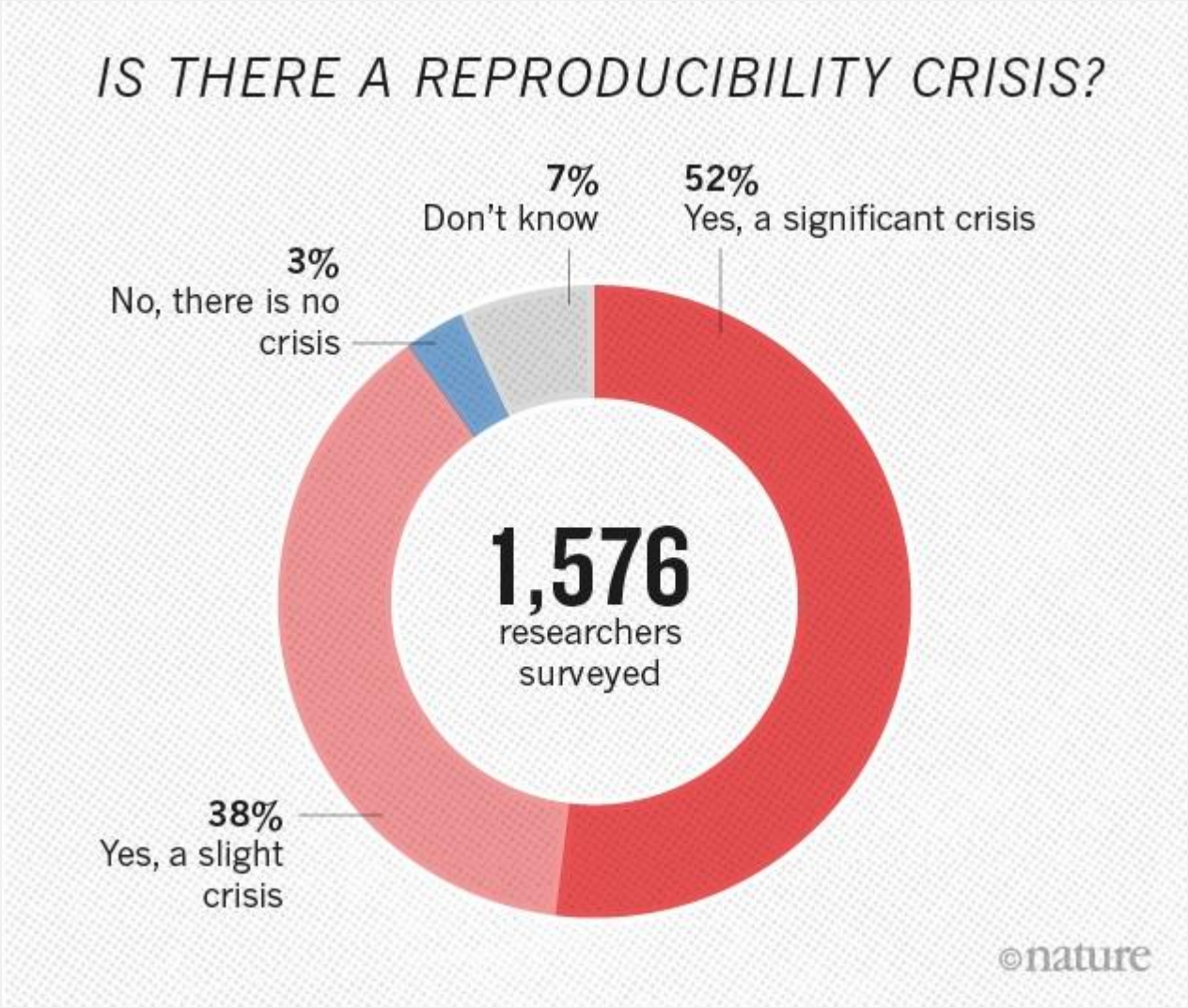
Data Reproducibility Crisis?



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1,500 scientists lift the lid on reproducibility

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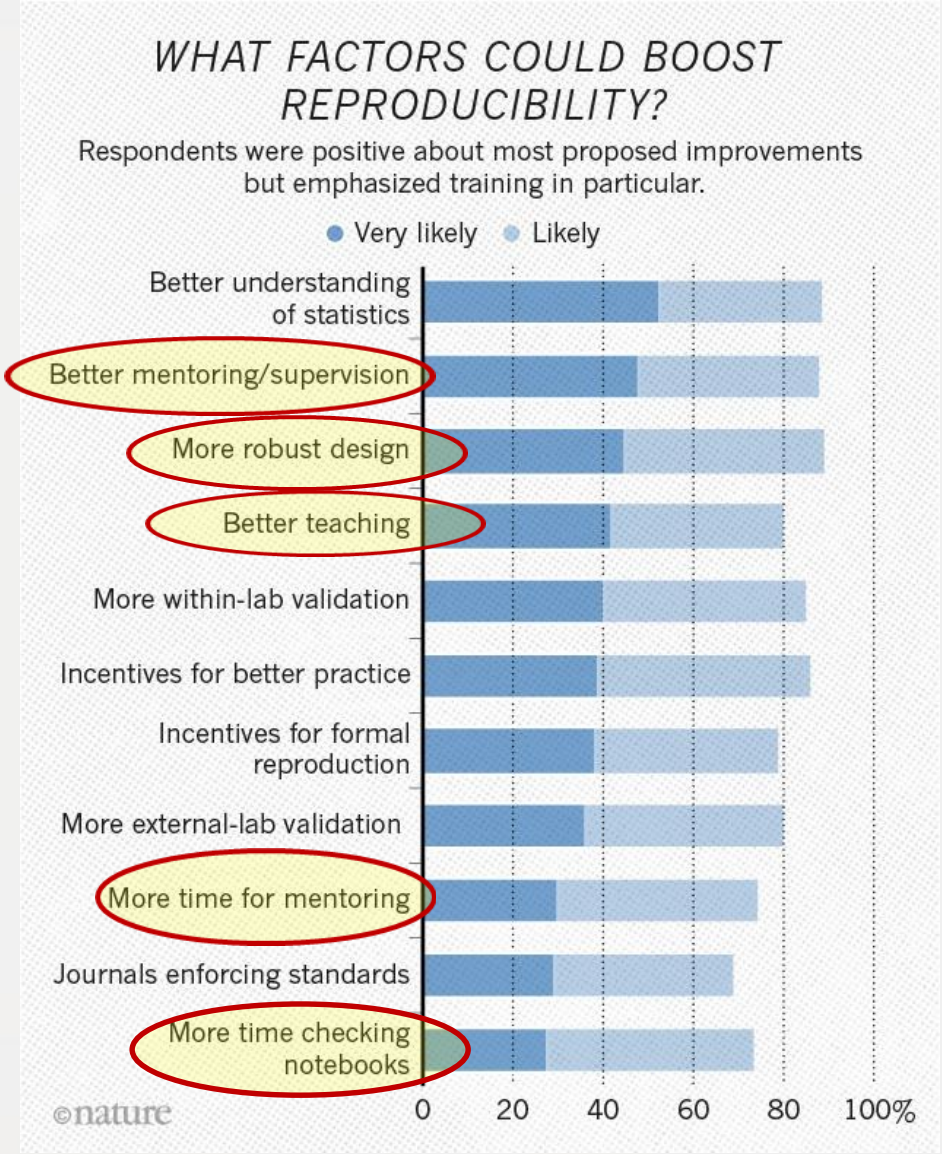

Compliance Debate?

- Does GLP enhance the quality of toxicological evidence for regulatory decisions? – Toxicological Sciences, 2016, 1-8

YES!

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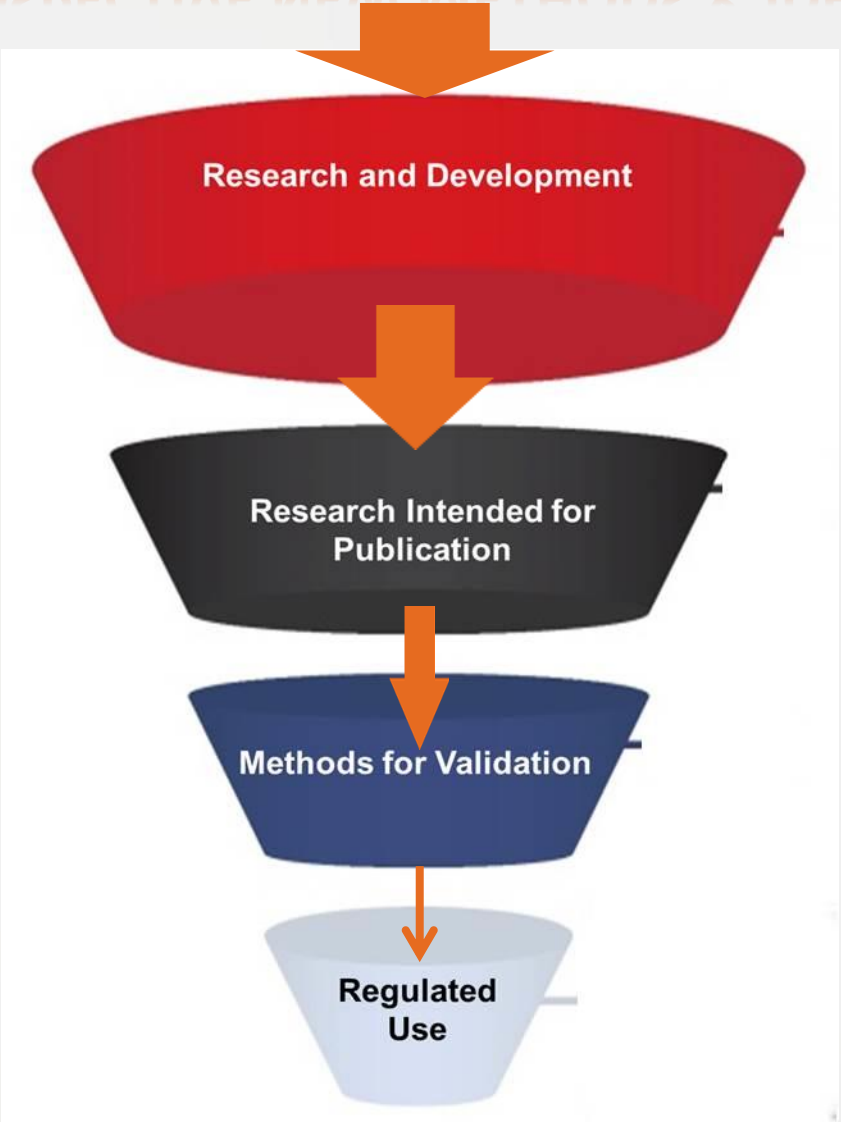
In Vitro Assay Development Pathway

PROSPECTIVE NEW METHODS & IDEAS



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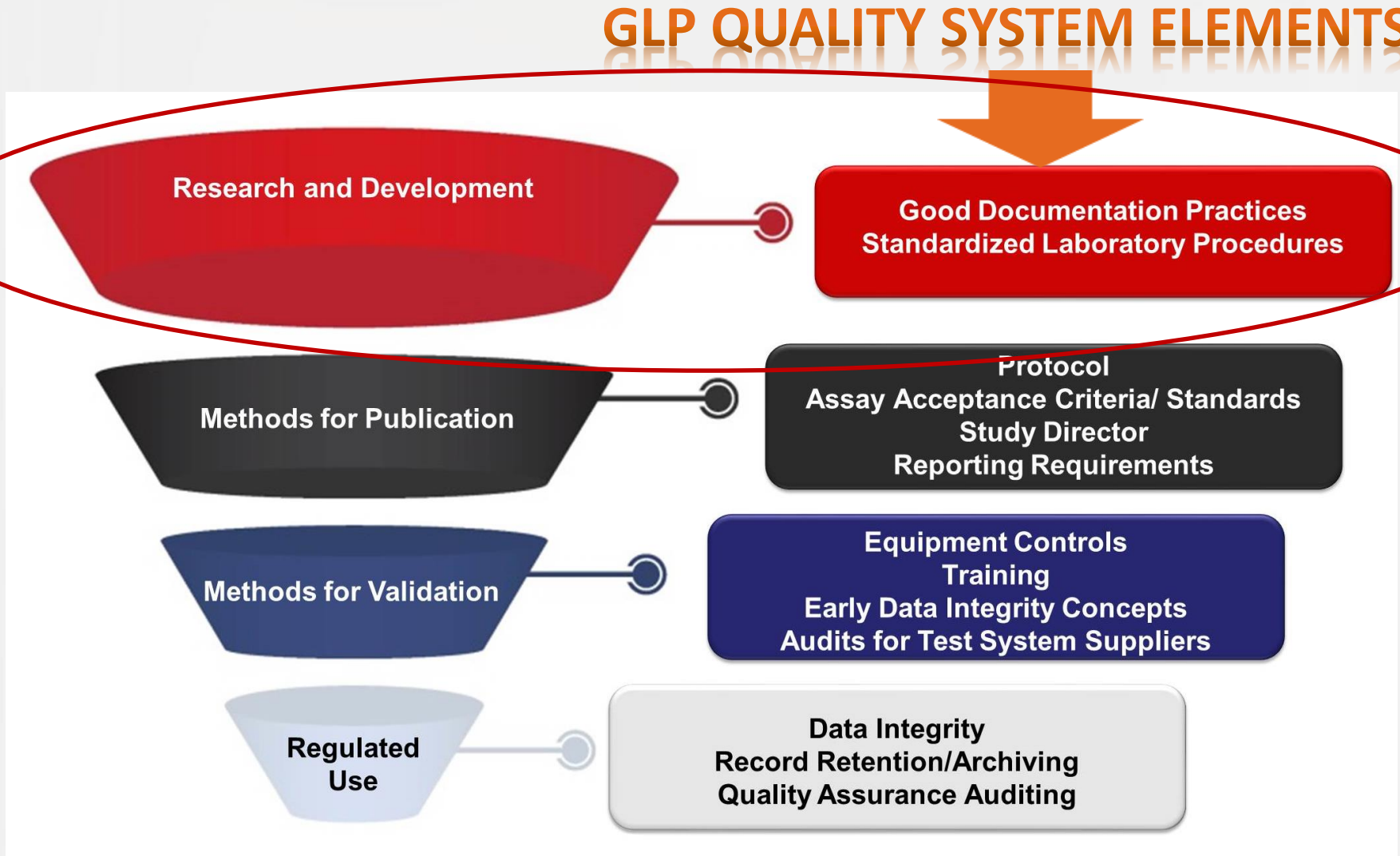
In Vitro Assay Development Pathway



Quality Concepts for Research and Development

Good Documentation Practices

21 CFR Part 58.130(e) – *All data generated during the conduct of a nonclinical laboratory study, except those that are generated by automated data collection systems, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the date of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change.*

ALCOA

21 CFR Part 58.180(a) Proposed Rule Published 24-Aug-16 – *We propose therefore that all nonclinical laboratory study data are "accurate, legible, contemporaneous, original, and attributable".*

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Quality Concepts for Research and Development

Good Documentation Practices - **ALCOA**

- Original data, recorded directly and contemporaneously
  - Determine a system for easily recording data in a lasting way so that you can do so soon after performing action in the lab

- Attributable
  - Initial and date all entries
  - Assure that what you are signing for is clear

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Quality Concepts for Research and Development

Standard Laboratory Procedures

- Control variability to more easily attribute changes in results to modifications made to the experimental design (if evaluating a test method) or the test material (if evaluating unknown materials).
- Standard equipment operation conditions and settings might not match what is needed for specialized work.
  - May identify the need to reserve equipment
  - May identify the need to provide additional work instructions to lab staff

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Media and Reagent Control

21 CFR Part 58.83– *All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date. Deteriorated or outdated reagents and solutions shall not be used.*

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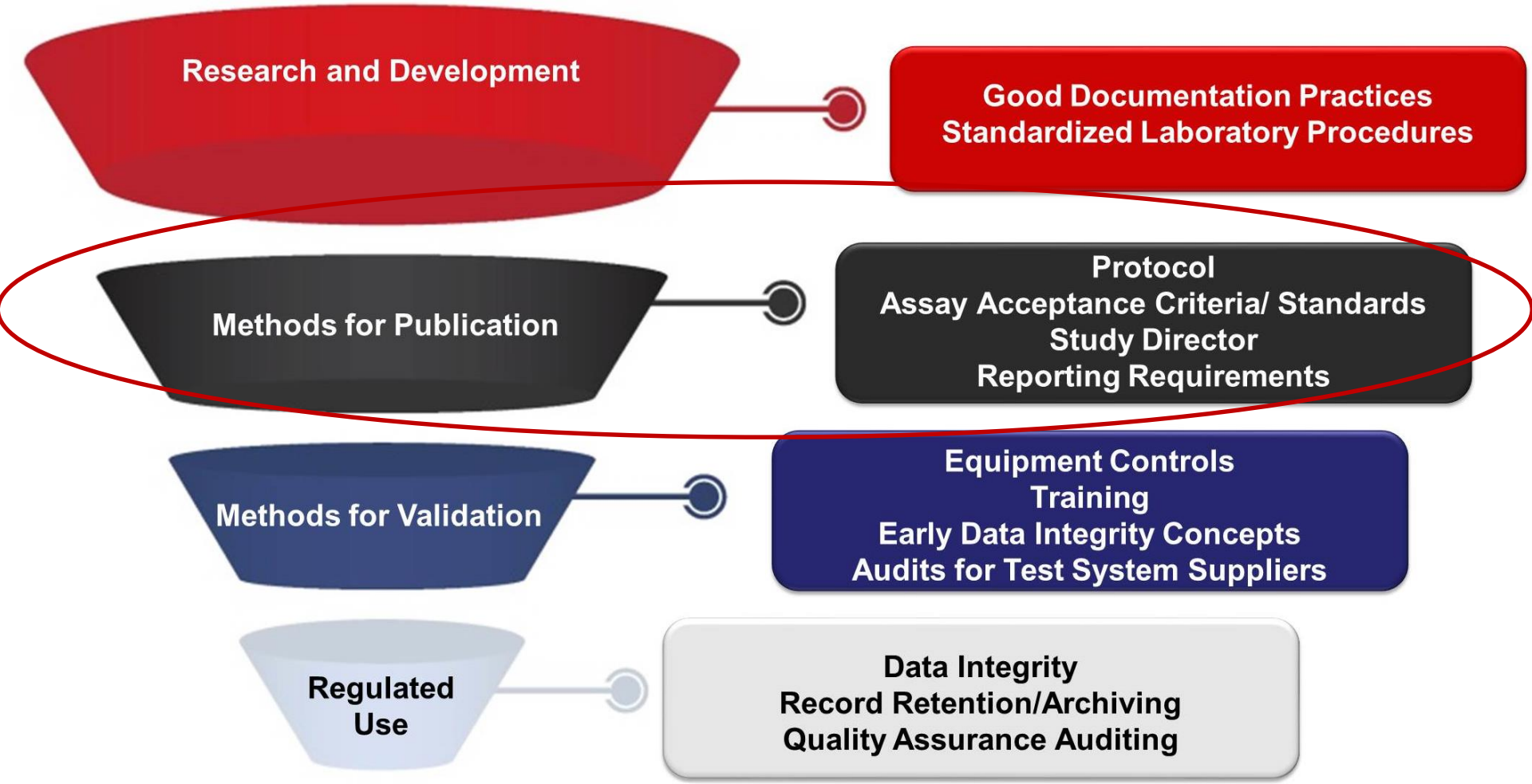
Research and Development
Good Documentation Practices
Standardized Laboratory Procedures
Methods for Publication
Protocol
Assay Acceptance Criteria/ Standards
Study Director
Reporting Requirements
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Early Data Integrity Concepts
Audits for Test System Suppliers
Regulated Use
Data Integrity
Record Retention/Archiving
Quality Assurance Auditing

Quality Concepts for Research Intended for Publication

Protocol

21 CFR Part 58.120 (a) – *Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study.*

- Control against unintentional bias
- Ensure performance of the work to specifications by providing the laboratory staff with precise, written instructions

Study Director

21CFR Part 58.33 – *The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation and reporting of results, and represents the single point of study control.*

- Single point of study control shows authority
  - direct performance of the work according to the plan
  - ability to modify the plan

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Quality Concepts for Research Intended for Publication

Predetermined Assay Acceptance Criteria

- Test system justification and information
- Concurrent positive and negative controls to assess test system reliability

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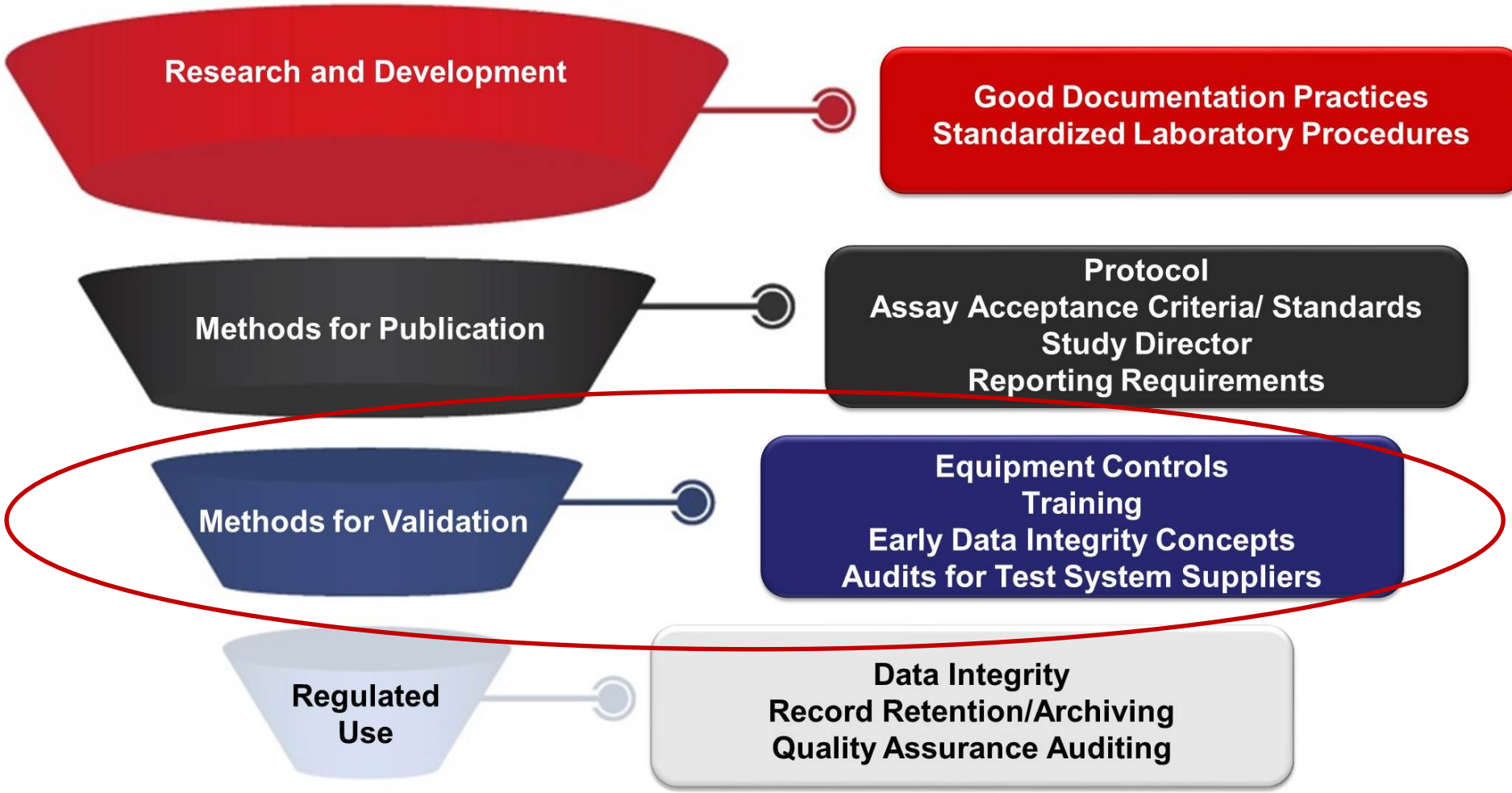
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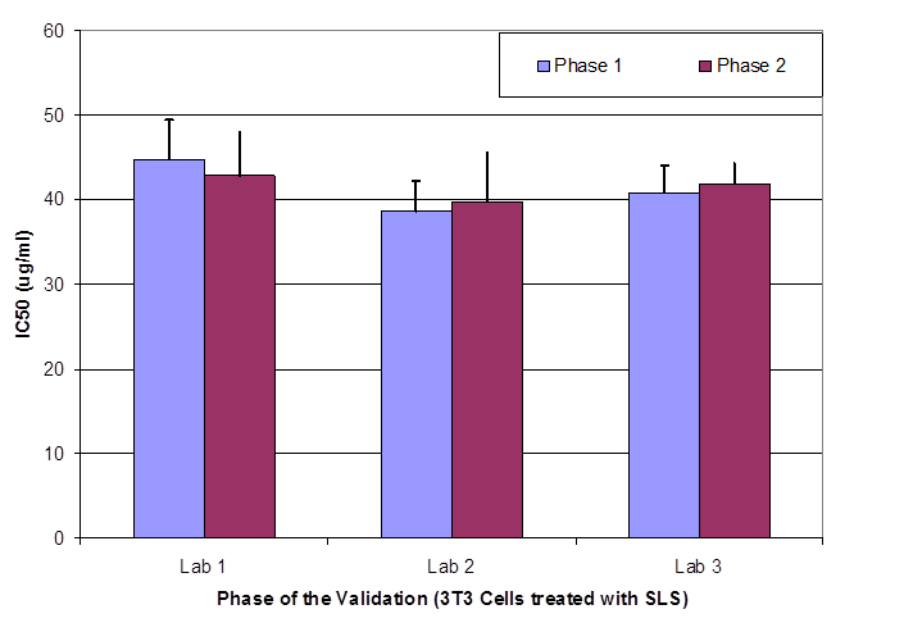
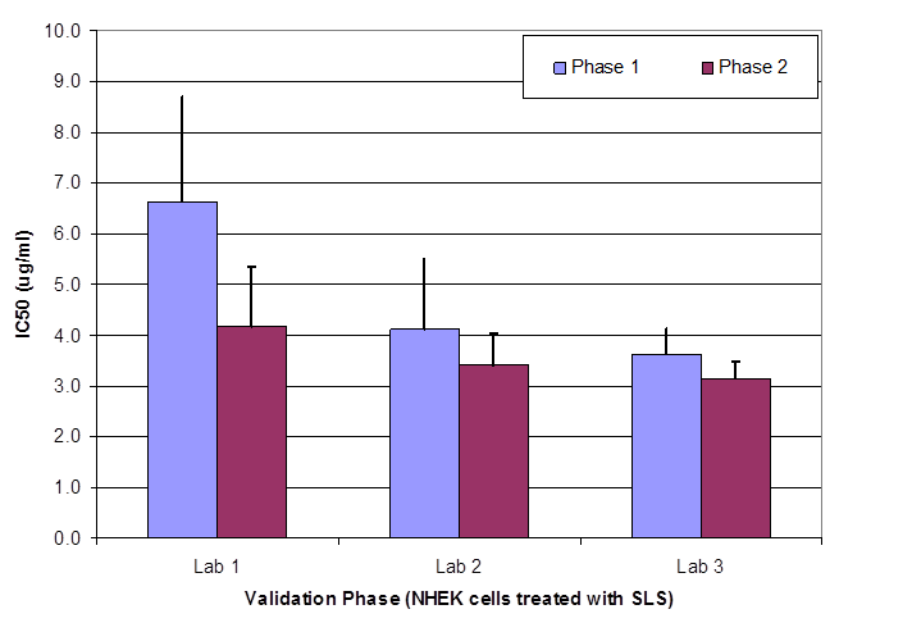
Quality Concepts for Method Validation

Training

21 CFR Part 58.29(a) – *Each individual engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.*





Quality Concepts for Method Validation

Equipment Controls

21 CFR Part 58.63(a) – *Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated and/or standardized.*

- Equipment use, settings, and calibration procedures should be known for all participating laboratories so that differences in equipment use and functionality can be ruled out as a cause of variability in test results.

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Quality Concepts for Method Validation

Data Integrity Concepts

MHRA GxP Data Integrity Definitions and Guidance for Industry: Draft for Consideration July 2016– *There should be adequate traceability of any user defined parameters used within data processing activities. Audit trails and retained records should allow reconstruction of all data processing activities regardless of whether the output of that processing is subsequently reported or otherwise used.*

- Controlled conditions for data processing (e.g. locked cells on custom Excel spreadsheets, specific instructions including settings and parameters for use in common statistical processing programs, etc.).

- The data processing should be governed by the protocol and ultimately controlled by the management team to protect against accidental and unauthorized modifications.

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Quality Concepts for Method Validation

Critical Vendor Audits

- Vendor management is an important part of any quality system
- Manufactured or purchased biological *in vitro* test systems used in an assay should be shown to meet minimum standards for performance and quality prior to international acceptance of the assay.

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Quality Concepts for Method Validation

Critical Vendor Audits

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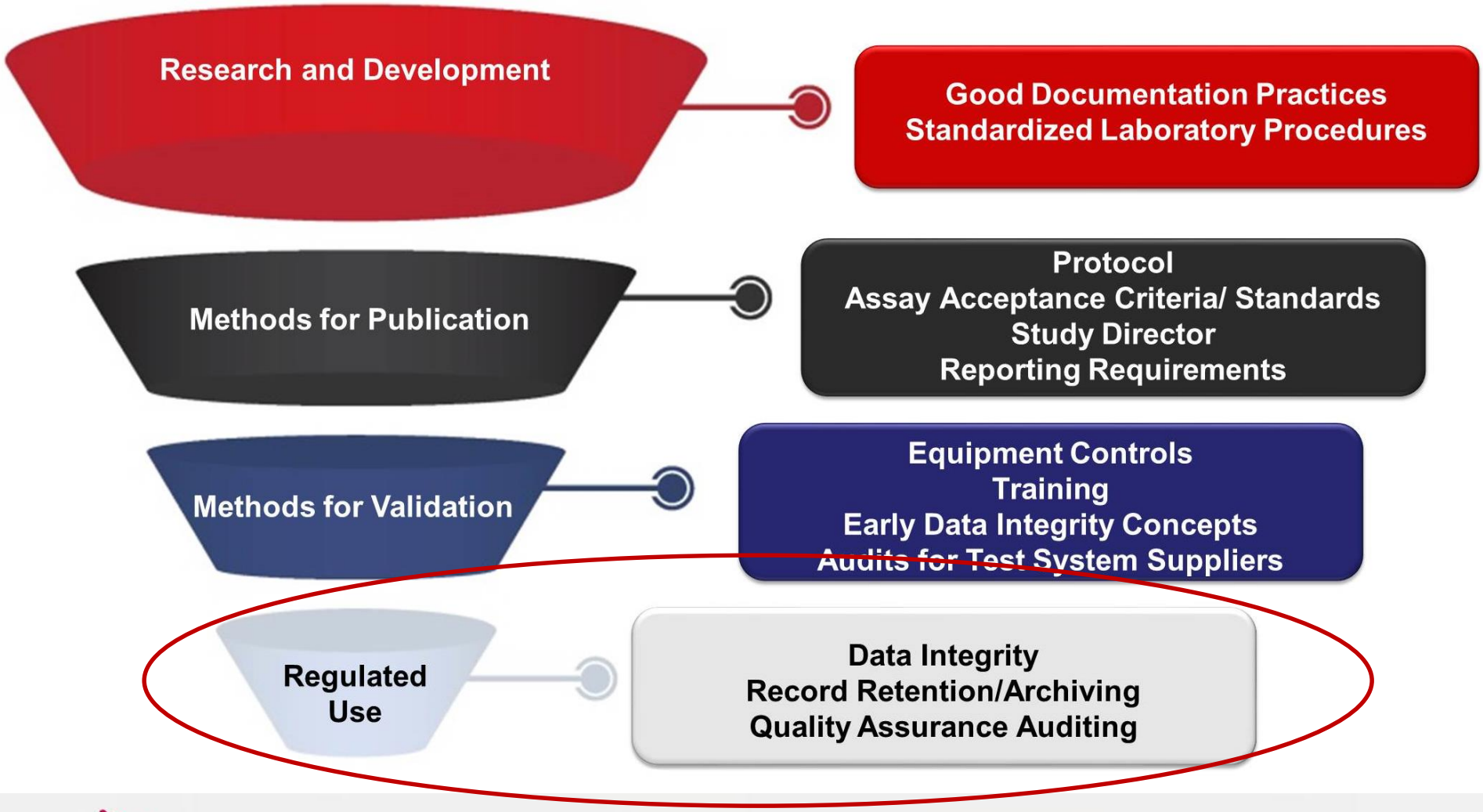
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Quality Concepts for Regulated Assays

- Complete data integrity pathway - protocol generation to reporting and data archival.
- Independent Quality Assurance Units to satisfy auditing requirements.
- Facility reporting structure strengthened to establish facility management's control over the facility procedures, Study Director control over specific studies, and QA independence.

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Conclusion

- A GLP Quality System addresses many of the areas that can be bolstered for improving reproducibility in scientific work.
- A Modular approach to quality allows for an assay's quality framework to progress alongside the assay's general acceptance
- Validation studies in particular benefit from following GLPs.
- Following a modular quality roll-out scheme can shorten the time between regulatory acceptance of an assay and widespread availability of the assay to be performed within a GLP-compliant laboratory.

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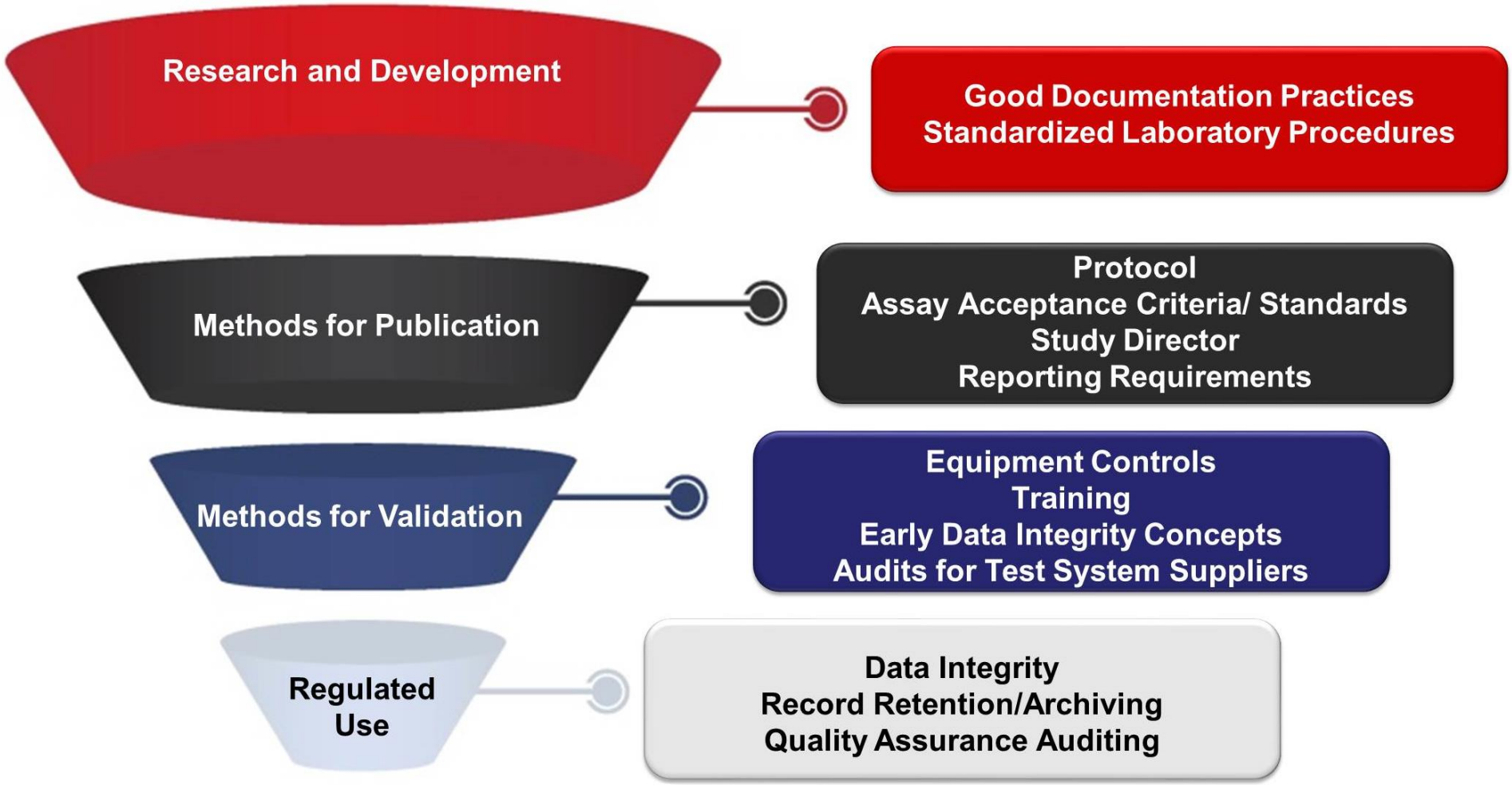
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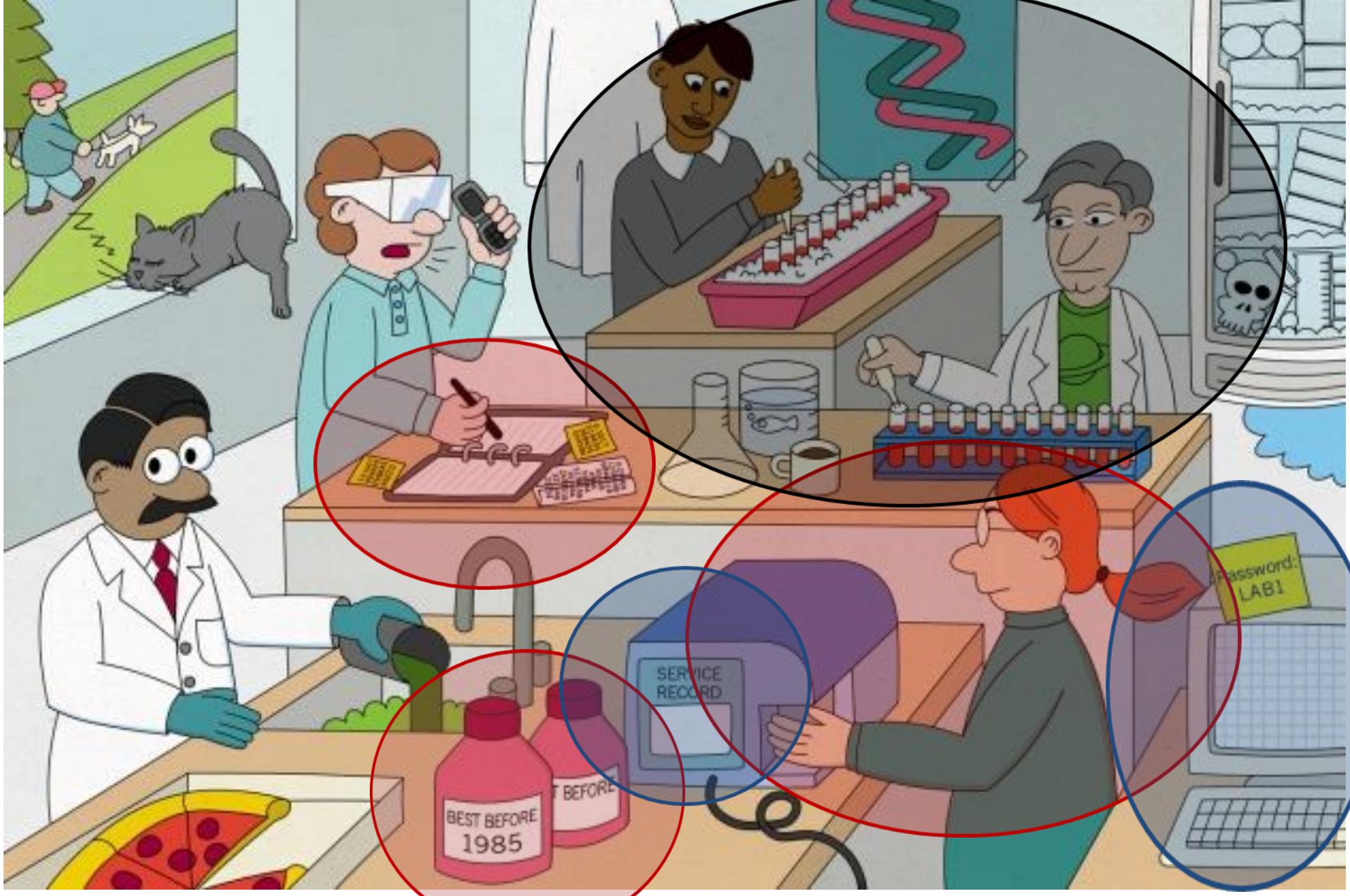

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Questions?

January 26-27, 2017 | Arlington, Virginia

2nd

Good Laboratory Practice Compliance SUMMIT

January 26 & 27, 2017
Arlington, VA

http://exlevents.com/good-laboratory-practice-compliance-summit/

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Thank you for your participation!

- Thank you for attending our webinar. Additional questions not addressed during this webinar can be sent to our presenter:

Amanda Ulrey: aulrey@iivs.org

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Contact Us!

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