

REGULATORY AFFAIRS
ANIMAL HEALTH

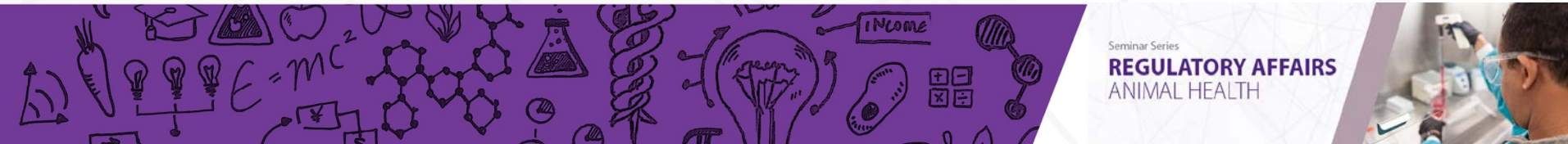


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Ensuring Data Quality in Animal Health Studies

Background/Introduction

- Data Quality
- Data Integrity
- Quality by Design

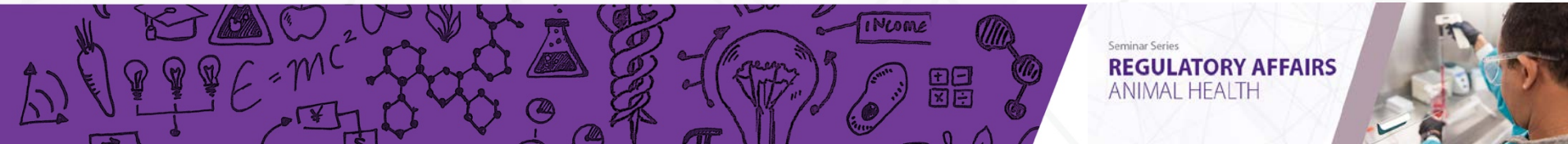


Ensuring Data Quality in Animal Health Studies

Background/Introduction

Data Quality: A perception or an assessment that the data to be collected and data generated is fit for its intended purpose in operations, planning and decision making. ALCOA

Data Integrity: refers to the validity of data; the accuracy and consistency of stored data. The reliability and effectiveness of entering data, storage of data and management of data. Consistency of data across data sources.



Ensuring Data Quality in Animal Health Studies

Background/Introduction

Quality by Design (QbD)

- Term utilized by cGMP
 - Joseph Juran 1992 (Quality/Juran Trilogy)
Juran believed that quality could be planned, and that most quality crises and problems relate to the way in which quality was planned.
 - Quality Planning
 - Quality Control
 - Quality Improvement
- Final product is scientifically designed to meet specific objectives; derived from a combination of prior knowledge and experimental assessment

Juran, J.M. (1992) Juran on Quality by Design: The New Steps for Planning Quality into Goods and Services, Free Press
Woodcock, J. "The Concept of Pharmaceutical Quality" American Pharmaceutical Review, Nov/Dec 2004



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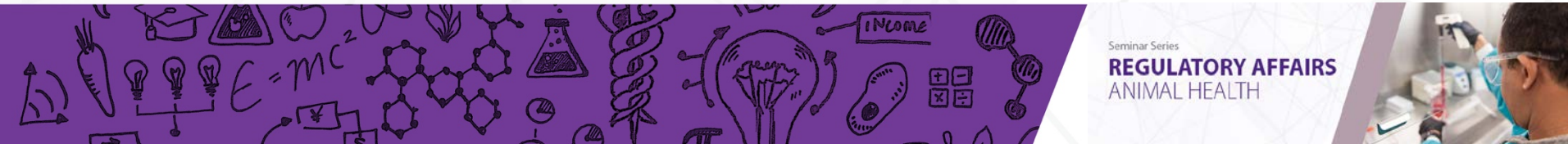


Ensuring Data Quality in Animal Health Studies

Background/Introduction

"I believe many organizations have come to realize the impact of the lack of data quality management more so in recent times. Poor decisions, in turn, can lead to inefficiencies, errors, additional costs or loss of business, which no one can afford today."

What's the Difference Between Data Integrity and Data Quality? *Rui Carvalho, Managing Director of Enterprise Solutions for S&P Capital IQ. Argyle Journal*



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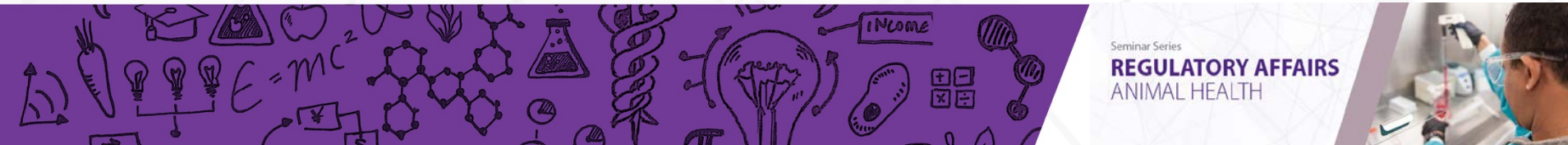
Summary of Prior Data Quality Presentations

2013 Data Quality Webinar presented by CVM

2013 Data Quality Webinar Q&A document

2017 SQA Presentations presented by CVM

2017 SQA AHSS Q&A document

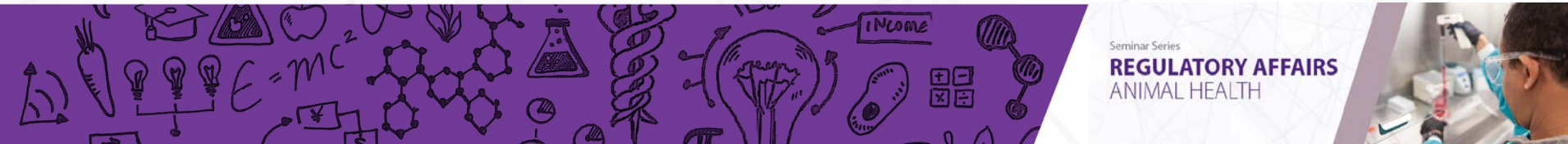


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Summary of Prior Data Quality Presentations

5 Critical Areas where improvements to Data Quality are most valuable:

- Protocol Development
- Selection of Study Sites/Training (Prior to In-Phase)
- Study Conduct and Data Management (In-Phase)
- Reporting Study Results
- Submission

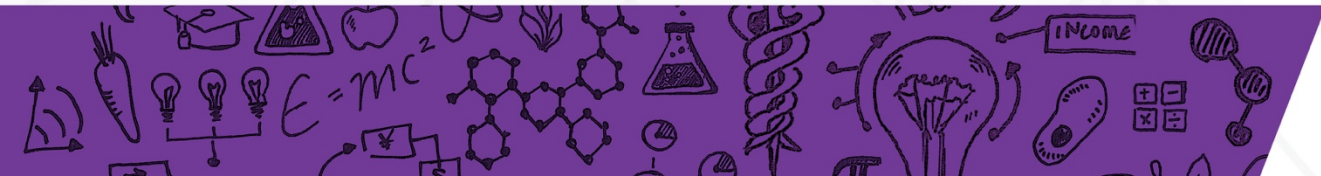


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Summary of Prior Data Quality Presentations

Protocol Development

- Presubmission conference
- Overall study design
- Protocol Concurrence
 - Not required; but encouraged
 - Reviewed for scientific validity
 - Does not represent compliance with a quality standard (GLP/GCP)



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Summary of Prior Data Quality Presentations

Selection of Test Sites

- Qualified Personnel

- Secure storage for data and test material

- Inspection History

Training

- Protocol

- SOPs as applicable

Study Conduct and Data Management

- Stability

- Documentation



Ensuring Data Quality in Animal Health Studies

Summary of Prior Data Quality Presentations

Reporting of Study Results and Submission

High quality submissions have ALWAYS been the expectation

- Poor submission and data quality continues to be an issue
 - Final Study Reports are not an accurate reflection of raw data
 - Data missing from submissions
 - Training missing from submission
 - Lack of adequate monitoring/QA
 - Discrepancies in test article and test system accountability
 - Unreported deviations/Deviations generated late



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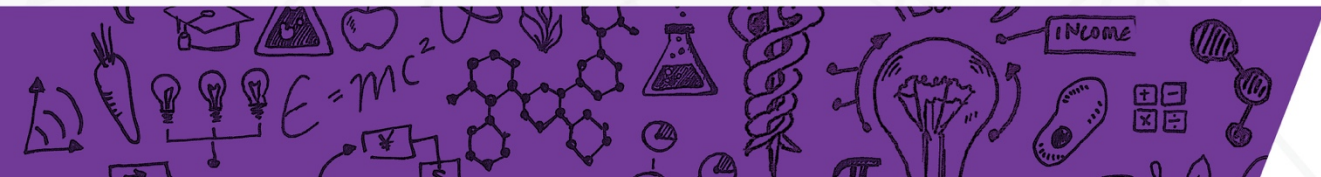
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Summary of Prior Data Quality Presentations

Question: Why does it seem CVM data quality expectations are more higher?

Animal studies and human studies are very different by design.

- CVM strives to reduce the number of animals needed for a study
- Population of the target species in animal studies is much smaller than the human population for human trials.
- Therefore, the data for each case/subject/animal is “more important” due to the smaller population. CVM is making an assessment to approve on a significantly smaller population.



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Ensuring Data Quality in Animal Health Studies

Summary

Ensuring Data Quality and Integrity throughout the process from study design to submission is critical for accurate, reliable data and product approval.



High Quality Datasets:

- Allow for a quicker and effective review
- Easier to reconstruct the study
- Confirmation of adherence to the study protocol and requirements
- Efficiently analyze study results
- Confidence that the results accurately reflect the safety or effectiveness as tested in the study



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