North America

Data Integrity Seminars

September 2018 Agenda

Presenters

- Dr. Bob McDowall (BM)
- Thomas Rohrer (TR), Software and Professional Services Business Development Manager

About Bob McDowall

Dr. Bob McDowall is a renowned industry expert in Data Integrity and 21 CFR Part 11, with 35 years of experience in laboratory information management system (LIMS), and the author of over 900 literatures on LIMS, computerized system validation, and analytical workflows. One of his many accolades is being a recognized scientist in bioanalytical sample preparation, and method validation, laboratory automation and informatics especially laboratory information management systems (LIMS) and validation of computer systems including 21 CFR 11. Bob was a co-author of the redraft of USP <1058> on Analytical Instrument Qualification.

Bob McDowall has collaborated with METTLER TOLEDO on numerous occasions – he completed the compliance assessment of LabX 2017 with the requirements of FDA 21 CFR Part 11. He has also given similar seminars on behalf of MT in other MOs, including China and United Kingdom.

Data Integrity Training Course Focus on Laboratory Systems	
Time	**Content**
08:30	**Arrival, Registration & Drinks Reception**
09:00	**0. Introduction to Course and Instructor** ▪ Outline of the day ▪ Set expectations and introduction to the trainer
09:10 (BM)	**1. Why is Data Integrity Important?** ▪ Background to the current data integrity issues ▪ Data Integrity Training for FDA and EU Inspectors: summary of the training ▪ Inspection of computerised systems is changing: paper to on-line ▪ Summary of recent company warning letters dealing with data integrity ▪ Overview of MHRA, WHO and FDA data integrity guidance documents
10:15 (BM)	**2. Principles of Data Integrity** ▪ The ALCOA+ criteria for data integrity ▪ Paper versus hybrid versus electronic systems ▪ Scope: production information versus laboratory data: why are laboratory data higher risk?
10:45	**Break**

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11:00 (BM)	**4. Control of Blank Forms and Master Templates** ▪ All Data Integrity guidance documents require the control of blank forms or templates ▪ Understanding the regulatory reasoning for control of blank forms ▪ Controls for creating and approving the master template and blank forms ▪ Do you really want to work this way?
11:30 (BM)	**Lunch**
13:00 (TR)	**5. Presentation: LabX & Data Integrity** ▪ An Enhanced strategy for Data Integrity – summary of BM content ▪ Summary / Introduction into hands on demos
13:30 (TR)	**6. Hands on Demos** ▪ Station 1: XPE Analytical – Standard Preparation ▪ Station 2: Tx & XPE Analytical – SmartSample ▪ Station 3: UV-Vis & XPE Analytical – Sample Prep and Integration (LIMS) ▪ Station 4: pH – Automated Workflow
14:45	**Break**
15:00 (BM)	**7. US 21 CFR 211 and EU GMP Chapter 4: Complete Data vs Raw Data** ▪ Why complete data and raw data are important for understanding data integrity ▪ EU GMP Chapter 4 requirements for raw data ▪ 21 CFR 211 requirements for laboratory records: complete data ▪ FDA Level 2 guidance: paper versus e-records Complete data / raw data example for an analytical workflow.
15:30 (BM)	**8. Second Person Review Including Audit Trail Review** ▪ Regulatory and guidance document requirements for the second person review ▪ Role and scope of a second person review ▪ Which audit trail to review and frequency of audit trail workshop ▪ Documenting the review
16:30	**Closing**

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For more information

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