Practical Insights into Data Integrity for the Regulated Environment

Course Programme | Delivered Online

09.00	**Introduction and Overview of Day**
09.15	**Data Integrity – Brief Refresher** • Update on current data integrity guidance documents • Understanding the scope of data integrity • ALCOA+ and ALCOA++ criteria
09.30	**Understanding the Cost of Non-Compliance** • Analysis of three FDA recent warning letters from Stason Pharma and Tender Corporation (July 2020) and BBC Group (August 2021) • What is the meaning of "current" in cGMP? **On-line Workshop** • Attendees will be presented with a regulatory citation and asked, 'what would you do?' What should you have done to avoid a regulatory love letter?
10.30	**Understanding Complete Data, Raw Data and Metadata** • US GMP requires "complete data" for laboratory control records in 21 CFR 211.194(a) • EU GMP Chapter 4 uses "raw data" but does not define the term • Data integrity guidances use the term "metadata" • What do these terms, mean and are they the same?
11.00	**Break**
11.15	**Audit Trail Review** • Update from guidance documents about audit trail review Who performs an audit trail review? • Understanding review by exception for audit trail review Does the application provide the information? Are you brave enough to use it **On-line Workshop** • Review of a CDS data audit trail. Can you identify any issues?
12.10	**Nightmare on Lab Street: Hybrid systems** • Your laboratory is full of hybrid systems: what are the problems? • Some simple approaches to resolving some problems • The PIC/S PI-041 approach to hybrid systems outlined
12.30	**Lunch**
13.30	**How to Assess a Process and Identify Data Integrity Vulnerabilities** • Assessment checklist or data process mapping? • Understanding a process and the data generated is key to success • Do I need a risk assessment? • Short term remediation versus long term solutions **On-line Workshop** • Step 1: Attendees will be presented with an analytical process to identify the data integrity vulnerabilities • Step 2: What short term remediation would you propose? • Step 3: What long term solution would you propose?
14.30	**Can Spreadsheets Meet Data Integrity Requirements?** • Spreadsheets are dynamic data and a hybrid system • What can you do to make spreadsheets secure?
15.00	**Break**
15.15	**Data Integrity Investigations** • What is a data integrity investigation and when should it be used? • Regulatory requirements and guidance for a DI investigation **On-line Workshop** • 1. Facilitated discussion of a DI Investigation caused by a software bug • 2. Review the findings from a case study data integrity investigation to find the root cause and then develop CAPA to stop the problem occurring again
16.15	**Mini On-Line Workshops** • Are there any DI issues? • 1. Review the printout of a spreadsheet file • 2. Secure electronic signatures – nothing can possibly go wrong?
16.45	**Question and Answer Session**
17.00	**End of Practical Insights into Data Integrity for the Regulated Environment**