Current issues in assuring data integrity in life sciences : 2 Days Seminar

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Organizer : WCS Consulting Inc. - NewYorkEventsList http://www.NyEvent

Venue :

Location : 11025, Vista Sorrento Pkwy
San Diego, CA, USA, ZIP: 92130

Current issues in assuring data integrity in life sciences : 2 Days Seminar

Data Integrity is a major concern of regulatory agencies worldwide as evidenced by the increasing number of Warning Letters issued in that area. Some managements have proceeded to implement data integrity programs on the lines of those implemented in “big data”. This has resulted in the escalation of costs and it is disproportionate to the benefits gained. Some even wonder why they continue to receive Warning Letters in spite of spending the dollars to implement programs such as Data Governance etc. etc.

This training focuses on implementing Data Integrity programs using “the least burdensome” approach, a technique that regulators themselves employ to conduct their audits. The training also addresses the evolving concepts and guidance from regulatory agencies such as the recently issued industry guidance on Part 11 for Clinical Investigations among many others.

Addressed will be case studies, inspection approaches, and trends in the issuance of data integrity 483s and warning letters in the recent past. Take back to your work, samples of Data Integrity related directives and SOPs such as Data Integrity Policy, Maintenance of Electronic Records directive and many more that are required to establish a data integrity infrastructure in your company.

This workshop is for novices as well as experienced personnel from QA, IT, manufacturing, regulatory and validation groups. It addresses data integrity issues in all life science industry sectors where data is required to fulfill regulatory requirements. These sectors include medical

devices, biologics manufacturing, quality control laboratories, clinical trials, blood establishments, compounding pharmacies etc.

Areas Covered

What is Data integrity

Data Life Cycle design and controls

Elements of a Data Integrity Assurance program

Roles and responsibilities of different groups in ensuring data integrity

What data integrity SOPs do auditors expect to see during audits

Validating Data Integrity

Who will Benefit

- Pharmaceutical industry / Medical device industry / Healthcare industry personnel
- Developers of software for use in Life Sciences industry
- Validation service providers, IT service providers
- Manufacturing personnel, Manufacturing Automation system vendors and system integrators
- Regulatory Affairs group, Quality Unit
- Laboratory personnel
- Users of Cloud
- Clinical Trial Sponsors

Learning Objectives

Some advanced Data Integrity topics include:

Data Integrity triad

Data Integrity Maturity Model

Developing critical thinking skills

Data Integrity Audit trends

Course Outline:

DAY ONE (08:30 AM to 05:00 PM)

Module 1

Data and Data Integrity: concepts, meaning of integrity, data dimensions

• Practically speaking, what is data, raw data, metadata

• Meaning and principles of DI

• Data types and their relevance to DI

• DI dimensions with examples of 483 and Warning letters

• Why is DI not considered to be a new requirement

Module 2

Primer on 21 CFR Part 11

• 21 CFR Part 11 (P11) and Annex 11 (A11) fundamental concepts

• P11 Scope and Application guide

• Why is Data integrity not the same as x11 (P11 and A11)

Breakout group exercise: Mapping DI to Part 11

Module 3

Data Integrity Guidance from USFDA/MHRA/EMA/WHO/PCS

• What are similarities and differences between the guidance

Module 4:

"Implementing a DI assurance plan using the “Least burdensome approac”

• PQLI and its relevance to Data Integrity

• What is the “Least Burdensome Approach”

• Why DI issues occur and how to avoid them proactively

• DI implementation plan: the 5p model and the Controls Triad

• What DI SOPs do auditors want to see and what should their contents be

DAY TWO (08:30 AM to 04:30 PM)

Module 5:

Data Integrity in IT and Manufacturing IT systems

• Data Integrity impact due to the architecture of IT system

• Implementing Active Directory service, Group policy etc. to attain DI

• DI susceptibilities of hybrid systems commonly found in manufacturing IT systems

• DI risks when generating electronic records which are true copies of paper records

• What data integrity items to review for during a Electronic Batch review

Module 6

Data Integrity in the Laboratory

• Why is laboratory Data Integrity the key focus of all regulatory audits

• Laboratory Data Integrity audit trend and what is needed to avoid citations

• Conducting DI risk assessment, trainee participation required

• Core documentation that you must have to demonstrate laboratory Data Integrity

• What should be the contents of the documents

• What is the role of the laboratory manager in fulfilling DI

Breakout group exercise: Develop an Audit Trail review SOP

Module 7

Data Integrity considerations in Clinical Trial Systems (CTS)

• Mobile computing issues

• Latest US FDA's Part 11 guidance for CTS

• US FDA's latest Cybersecurity guidance for CTS

Module 8

How is Data Integrity audited

• Developing a Data Integrity audit checklist

• Critical thinking skills for Internal Auditors

• How can you effectively use your Data Integrity Maturity Model during audits

• FDA's new approaches to data integrity audits

Speaker

Chinmoy Roy*BSEE, MSCS US FDA Expert Data integrity & CSV*

Subject Matter Expert: Data Integrity, GAMP, CSV, CFR 21 Part 11, Annex 11, Quality Risk Management, Manufacturing Process Automation and IT systems

Chinmoy Roy has 37+ years of experience. He is an internationally recognized subject matter expert in CSV, CFR 21 Part 11, Annex 11, Data Integrity and manufacturing process automation systems. He has been invited to speak and conduct training workshops at several international

conferences such as ISPE, WBF, Shimadzu's annual conference for Asia Pacific, etc.

His expertise stems from his experience in implementing and obtaining "fit for use" certification for over 200 IT systems. He has worked at and consulted with leading US based companies such as Roche, Genentech, Bayer, Novartis, Johnson and Johnson etc. His pioneering efforts in implementing CFR 21 Part 11 compliant manufacturing IT systems in 1999 while employed by Genentech, was a precursor to FDA's issuance of Part 11's Scope and Application guidance in 2003. His workshops are unique in that he blends his field experience to provide case studies to explain the intricacies of implementing regulations. Chinmoy is an Electrical Engineer and a Computer Science post graduate.

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