SPEAKER:- CHINMOY ROY

2 Days Workshop on Current issues in assuring data integrity in life sciences

04 - 05 -OCT -2017 Location 1 | Boston,MA

14 - 15 -NOV -2017 Location 2 | San Diego CA

Single Attendee

$ 1295

Contact For Group Discount

An event by:
World Compliance Seminars

COURSE SUMMARY

World Compliance Seminars WCS is known all over the world for high quality of professional training programs it offers to members of the global bio pharmaceutical community. We commit to bring you quality webinars from industry experts in a timely fashion. Ensuring your business strategy is on the right track to face the future bounties.

Topic:- 2 days Workshop on Assuring Data Integrity in the Life Science industry

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.

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.

Key Topics

Course “2017 Assuring Data Integrity in the Life Science industry“ has been Pre-approved by RAPS as eligible for up to 12 credits towards a participant's RAC recertification upon full completion.

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

Industries who can attend

- 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

SPEAKER

CHINMOY ROY

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.

Our Testimonials

David QU, senior Analytical Chemist Dalton Pharma Services.

"I learned a lot from the instructor and trainee good."

Nicola Mootoo, Senior Validation Engineer Shire Pharmaceuticals.

"Well placed, a lot of good information. Good interaction between participants.Held at a good location"

Evelyn Chang, Corporate manager Genzyme.

"Well delivered seminars, right place, good contents."

Mary Beird, Regulatory Compliance Manager
Charles River laboratories International, Inc.

"I thought the contents of the presentation and the discussion was very good"

Sajan B. Balabhadran, Watson Pharma Pvt Ltd.

"A Very Well organized event. The Speaker was just marvellous in driving to a depth of my understanding of Data Integrity and 21 CFR Part 11 aspects."

Course Outline:

Day 1 8:30 AM - 5:00 PM

Module 1

Data Integrity: concepts, requirements, guidance

- What is data, raw data, metadata, information and knowledge
- Meaning and principles of DI
- Data types and their relevance to DI
- DI dimensions with examples of 483 and Warning letters

Module 2

Primer on CSV and Part 11

- What is validation and what is the validation life cycle
- GAMP V system categories
- What are the validation deliverables and what should they contain
- 21 CFR Part 11 Scope and Application guide
- Why is Data integrity not the same as 21 CFR Part 11
- Latest Part 11 guidance for Clinical investigations

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

In the trenches – implementing DI

- PQLI and its relevance to Data Integrity
- What is the "Least Burdensome Approach" to establishing a DI program
- Why DI issues occur and how to avoid them proactively
- Top down design and bottoms up implementation
- What is the Data Integrity triad
- What DI SOPs do auditors want to see and what should their contents be

Day 2 08:30 AM - 04:30 PM

Module 5

I 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

Auditing DI for Internal auditors

- 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

Module 8

DI and CSV Case studies

- Case studies presented by trainer
- Case studies/experiences by attendees at their workplace

Register Now

PACKAGE	Single Attendee	Special Group Discount
2 days Workshop 04,05 -OCT -2017 Location 1 | Boston,MA	$ 1295	$ 3885
2 days Workshop 14,15 -NOV -2017 Location 2 | San Diego CA	$ 1295	$ 3885

Special Group Discount Register for 3 and the 4th person gets a FREE pass
For more than 1 registration from same Company Contact :844-267-7299

""Each attendee will receive 2-Day workshop materials by the speaker. Seminar Also Includes Certificate, Complimentary Breakfast, Lunch & High Tea/Coffee provided by WCS""

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