Verification and Validation - Product, Equipment / Process, Software, QMS+

1.OVERVIEW

Develop / review a company's Master Validation Plan for major cGMP deficiencies. Address the U.S. FDA's newer and tougher regulatory stance. One major failing is lack of sufficient or targeted risk-based V&V planning:

- Start with a Master Validation Plan;
- Evaluate its elements against ISO 14971 and ICH Q9 for hazard analysis and product risk management;
- The Individual V&V Plan;
- V&V Project Management;
- “Risk-based” per ISO 14971, ICH Q9, and/or GAMP/JETT;
- Two key input analysis tools;
- Change control and “drawing a line in the sand”;
- Develop meaningful V&V Files and Protocols

2. LEARNING OBJECTIVES

- Understand Verification and Validation, differences and how they work together
- Develop a “Working Definition” of V&V, Qualification, and related terms
- Discuss recent regulatory expectations
- How to document a “risk-based” rationale, and use it in a resource-constrained environment
- Determine key “milestones” and “tasks” in a project; device sample provided
- Locate and document key subject “inputs”
- Compile “generic” Master and Individual Validation Plans
- Lean the key element of a Product V&V File / Protocol
- How to develop Process and/or Production / Test Equipment V&V Files / Protocols
- Basic Test Case / Script construction
- Sample sizes and their justification

FACULTY JOHN E. LINCOLN

32 YEARS EXPERIENCE IN U.S. FDA-REGULATED INDUSTRIES

Our trainer has over 32 years experience in U.S. FDA-regulated industries, 18 of which as a full time independent FDA-regulated industry consultant. Mr. Lincoln has worked with companies from start-up to Fortune 100, in the U.S., Mexico, Canada, France, Germany, Sweden, China and Taiwan. He specializes in quality assurance, regulatory affairs, QMS / CGMP audits and problem remediation and FDA responses, new / changed product 510(k)s, process / product / equipment including QMS and software validations, ISO 14971 product risk management files / reports, Design Control / Design History Files, Technical Files.

Verification and Validation - Product, Equipment / Process, Software, QMS+

3. AGENDA

Day 1

- Introductions; Housekeeping Announcements; Workbook Walk-Through
- V&V Planning; The Master Validation Plan; The Individual Validation Plan
- Break and Q & A
- “Risk-based” -- Evaluate its elements against ISO 14971 and ICH Q9 for hazard analysis and product risk management – File Narrative, Hazard Analysis, FTA, 3 FMECAs (Design, Process, Use[r], and a possible 4 th , Software); also GAMP / JETT approaches
- V&V Project Management – “Milestones” and “Tasks”
- Two key input analysis tools – The Process Map / Flow Chart, and the Cause and Effect Diagram (templates supplied)
- Change control and “drawing a line in the sand”
- Break and Q & A
- Elements of a V&V File / Protocol:
- Intro / Purpose / Scope
- Protocol Material / Equipment
- DQ or Requirements Specs
- ASTM2500
- IQ (or equivalent)
- OQ (or equivalent)
- PQs (or equivalent)

End, Day 1

Day 2

- Develop and Employ Meaningful V&V Files and Protocols for:
- Products;
- Process;
- Production Equipment;
- Monitoring and Test Equipment;
- Software;
- Quality Management System – 21 CFR 11, Electronic Records / Signature
- The FDA’s 11-element software matrix simplifies "as-product", in-product", process and equipment software V&V – what they mean, how to research and how to document
- The QMS, ERP and 21 CFR Part 11 V&V – “Cloud” Issues; “White box” and “Black box” Testing; Basic Test Case Development
- V&V, Senior Management / IP and Limited Company Resources
- U.S. FDA Audit Issues and “Responsible” Documentation
- Course Highlights and Q & A

4. WHO WILL BENEFIT

- Senior and middle management and staff
- Regulatory Affairs
- QA/QC
- IT/IS
- R&D
- Production Management
- Manufacturing Engineers
- Process Engineers
- Software Engineers
- Project Managers
- Hardware and software vendors, sales and marketing

Verification and Validation - Product, Equipment/Process, Software and QMS

REGISTRATION FORM

Name **Email**

Organization **Department** **Position**

Phone **Mobile**

Register Online At www.worldcomplianceseminars.com

or by calling our offi ce : 844-267-7299

Terms And Condition

- Registration shall be reconfirmed only once payment has been made prior to the course.
- Cancellation of participant/s shall be submitted in writing to WCS ten days (10 days) before the course. There is a 50% liability on all bookings once made.
- WCS reserves the right to make alterations to the conference/executive briefing content, timing, speakers without notice. The event may be postponed or cancelled due to unforeseen events beyond the control of WCS. If such a situation arises, we will refund your registration fee or we will try to reschedule the event.