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.

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3. AGENDA

Day 1

Introduction (personal / course information)

Session 1 – Master V& V Planning (ends with a short break)

- V&V; “Working” Definitions
- Key Areas in Product Validation
- Key Equipment, Process, Software and QMS V&V Activities
- The Master Validation Plan
- Requirements
- Protocols / Test Cases; Proving (V&V) the Requirements
- DQ, IQ, OQ, PQs, and PPQs
- The Test Report
- Life Cycles; Regulatory “Hot Buttons”

Session 2 – Human Factors Engineering

- IEC 62366-1 and -2
- The “Interface”
- The 9 Stages of Usability / Human Factors Engineering
- The UE/HF File

Session 3 - Data Integrity and Cyber security

- Data Integrity / GDP
- Cybersecurity

End, Day 1

Day 2

Session 4 – Software / Firmware V&V

- Documentation – The 11 Elements
- V&V “Models” – For the 4 Types of SW Validations
- 21 CFR Part 11, “Electronic Records / Signatures”
- Legacy, Hybrid, New and ER / ES Systems
- Life Cycle and “Cloud” Considerations
- Types of Testing
- Test Case Examples
- A “Typical” Test Report
- GAMP® 4 & 5
- IEC 62304

Session 5 – Product Risk Management

- Patient Hazard / Risk Management per ISO 14971:2019
- Risk – What?
- QMS / System Level
- Device / Product Level
- File / Review (Benefit / Risk)
- Narrative / Descriptive Information
- Hazards
- FTA
- D-, P-, U-FME[C]A + Normal
- The Product Risk Management File / Report / Review

Session 6 – Project Management

- Work Breakdown Structure
- Gantt
- CPM
- PERT
- Usage in FDA-regulated industries; Examples

Conclusion

- Documentation Hierarchy
- Course summary
- Final Q & A

End, Day 2

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