

23A & 23- B Incoming Bombshell: FDA's new Process Validation guidance

Presenter

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Session Summary

In 1987, the U.S. Food and Drug Administration released *General Principles of Process Validation*, the first-ever guidance standard on process validation in the life sciences field. That document spawned many other more specific standards published by governments and industries, each reflecting the latest state of the art, until the 1987 guidance was considered by many to be hopelessly outdated. Industry standards like the ISPE *Baseline* and GAMP 5, international standards such as IPEC and SUPAC, and even competing guidances put out by individual FDA divisions such as *General Principles of Software Validation* (CDRH) and *Validation of Cleaning Practices* (CDER) all incorporate modern techniques and risk-based methodologies that simply didn't exist in 1987.

Meanwhile, CDRH, the Medical Device division, has aggressively moved ahead with its own Process Validation requirements under the separate authority granted by 21 CFR 820.75. CDRH has announced that it is going its own way and will adopt an ICH validation standard (S3/99) when inspecting Medical Device firms.

As part of its *21st Century Initiative*, last year FDA introduced a draft of *Process Validation: General Principles and Practices*, which throws the 1987 guidance out the window and moves directly to the forefront of modern validation theory. And while it is technically a *guidance* and therefore “optional,” FDA has already stated that nothing in the new standard is not already expected under Parts 211 and 820, and FDA fully anticipates issuing 483s and Warning Letters for noncompliance *immediately* upon its approval, expected later this year.

In a meeting between ISPE and FDA's authoring staff, many of the experienced industry engineers were unfamiliar with the concepts in the draft, including risk assessments, statistical methods, formally planned and documented engineering studies, and especially ongoing and never-ending process metrics. To anyone with experience in the Medical Device industry, this is likely old news; CDRH has been requiring it for more than ten years. But the new guidance is likely to shake the pharmaceutical industry with new requirements, expectations, enforcement – and benefits.

Effective and appropriate skills help create and sustain organizational values, direction, customer focus, robust processes and promote performance excellence. It is critical that we realize what is needed and how to acquire these skills. We have recognized that many quality professionals have lot of experience but not right education and training for changing role in the global market.

Every quality and validation engineer, regulatory specialist, and quality manager involved with pharmaceutical validation cannot afford to miss this presentation.

About the Presenter – Jeff Boatman

Jeff Boatman is a Quality System Senior Subject Matter Expert at QPharma, a validation and compliance-consulting firm in Morristown, New Jersey. Jeff has spent 21 years in the drug and device industries and is an expert in regulatory requirements. He has held nearly every technical position in the Medical Device field, from manufacturing technician to lab supervisor, R&D engineer to Quality Consultant, Compliance Manager to Director of Quality. Jeff is an ASQ Certified Quality Auditor and the developer of ASQ's course on the Quality System Regulation.