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Validation for the regulated industries

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Validation is a critical element in an organization's quality management system to help ensure that delivered products and services are consistent, reliable, and in compliance with applicable international regulatory requirements and standards. While the "process" of validation is typically viewed as a stand-alone activity, it is, in actuality, closely linked to risk management, quality management, design controls, and corporate strategy. To compound the issue, confusion abounds when the terms "validation" and "verification" are used - at times incorrectly.

This presentation will focus on some of the validation basics and the regulatory requirements that need to be satisfied. The validation "process" will be broken down into several buckets to help clarify the activities to be performed and the timing to do so. The concept of design space and its implications to validation will be explained.

Also to be covered are the Validation Life Cycle, validation deliverables, and the types of validation that can be performed - including the opinions of regulatory agencies with respect to each of the methods. A template for a Validation Master Plan will also be provided to participants.

Biography

Les Schnoll has more than 40 years of experience in the FDA-regulated industries. He is the Principal of Quality Docs, LLC and is also currently an Instructor in the Master of Science in Regulatory Affairs for Drugs, Biologics, and Medical Device program in the College of Professional Studies at Northeastern University and a Faculty Associate at Arizona State University, College of Nursing and Health Innovation, in the MS Regulatory Science and Health Safety Program. He has written articles for such publications as *Medical Design and Material, ISO 9000 Handbook of Quality Standards and Compliance, Pharmaceutical and Medical Packaging News, Food Quality*, and *Quality Progress*. He is also the author of *The CE Mark: Understanding the Medical Device Directives* and *The Regulatory Compliance Almanac*, published by Paton Press.

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