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Implementing a periodic validation review program: A case study

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Problem Statement: For a multi facility and site sterile products manufacturer,

- Regulatory Agencies require us to have a Periodic Validation Review Program
- What does "periodic" mean?
- How to develop a defendable rationale behind the actual program
- How do we get started and maintain it without draining our resources

What Attendees will Learn: Develop an understanding of how to,

- Define this program to align with Regulatory expectations
- Align this program with the new FDA Process Validation requirements and current owner validation programs
- Leverage existing review programs like environmental monitoring, annual product reviews, product trending reports, maintenance and calibration reports to reduce redundancy

Biography

Charles Stock offers more than 34 years of technical, compliance and process/operations experience in the technical manufacturing industries. He has relevant experience with facility and equipment start-up, commissioning and qualification, operations management, project management, product development, process development and transfer, training and compliance. His operations and compliance expertise encompasses facility start-up, manufacturing process analysis and streamlining, facility turnover and commissioning, operations training/staff management and logistics planning. He has also developed and presented training programs for C&Q project planning, Quality Systems, topics on leaning out capital projects, development of operating strategies and performing risk assessments. His operations and start up experience encompasses medical device, biotechnology, aseptic/sterile, OSD, and specialty dosage form facilities.

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