Charles Stock, Pharmaceut Reg Affairs 2014, 3:3
http://dx.doi.org/10.4172/2167-7689.S1.014

OMICS Group Conferences
Accelerating Scientific Discovery

4th International Conference on
Pharmaceutical Regulatory Affairs
September 08-10, 2014 DoubleTree by Hilton Hotel Raleigh-Brownstone-University, USA

Applied QbD hybrid approach: A case study

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Problem Statement: For a fast track virtual bio-therapeutic company's late phase II product,

- How do we deliver a Process Validation in most expeditious manner that gets us approved (Fast Track)?
- Where, when and how do we get started?
- How much will our process validation cost?

What Attendees will Learn:

- How to apply a Hybrid QBD approach to Pre and clinical data to develop a robust Process Characterization
- How to set up for an efficient and effective Process Validation to drive best possible market introduction timelines
- How to develop a process development "roadmap" for use in subsequent product developments

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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