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Essentials in quality by design

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QbD is a systematic approach to development that begins with predefined development objectives and emphasizes product and process understanding and process control, based on sound science, data based decision making and quality risk management. Quality by Design as introduced by the FDA and EU brings modern drug development methodologies to CMC teams working on biologics, pharmaceuticals and vaccines. The presentation will discuss the application of QbD principles in the development, submission and manufacturing of drug product and drug substance. Most CMC development teams globally have little to no experience in generation of design space, selection of PAR/NOR ranges and preparing for Stage I Validation documentation and submission. This presentation will cover basic and advanced principles for the practical application of QbD in every phase of product development and control.

The presentation will cover QbD's ten guiding principles:

1. A clear line of sight from clinical indication to product release and stability
2. Quality risk management in every aspect of development
3. Enhanced product understanding
4. Assay understanding
5. Process understanding and characterization
6. Generation of transfer functions
7. Improved product specification limits and justification
8. Robust design space and edge of failure
9. Use of modern control strategies and PAT
10. Continuous improvement and validation throughout the product lifecycle

Biography

Thomas A Little a former professor from San Jose State University is President of Thomas A Little Consulting (TLC) an internationally recognized consulting firm with a proven record for achieving results in biologics, vaccine and pharmaceutical industries. Dr. Little has developed an extensive curriculum in QbD, product and process development, characterization, optimization, tolerance design and control. TLC is a partner of SAS/JMP. TLC courses are used by fortune 100+ companies to train their chemists, scientists and engineers. TLC has trained over 90,000 engineers, scientists and business professionals during his career and has written numerous articles on modern drug development.

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