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Cell Culture Engineering XV | Proceedings

Spring 5-13-2016

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RETROSPECTIVE IMPLEMENTATION OF QUALITY BY DESIGN FOR LEGACY COMMERCIALIZED ENZYME REPLACEMENT THERAPIES

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Key Words: QbD, enzyme replacement

Quality by Design (QbD) has been widely adopted by the pharmaceutical industry as a tool for transforming development, manufacture, and commercialization of drug products. QbD ensures that quality is built into a manufacturing process to consistently produce desired product. As per a FDA guidance[1], QbD should be employed at the product development stage to ensure manufacture of a product with predefined quality. Here we present a retrospective QbD approach employed at Shire to define an improved control strategy for a commercial process using risk-based process understanding and characterization. Key challenges and considerations of implementing a QbD strategy on a commercial process are presented with examples of critical quality attribute review, parameter impact assessment, parameter classification review and updated control strategy.

[1]US Food and Drug Administration. Guidance for industry: Q10 quality systems approach to pharmaceutical cGMP regulations (FDA, Rockville, MD, September 2006).