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Industrial Practices for Determining Biopharm Products' Critical Quality Attributes (CQAs).

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Abstract

Analytical methods have been playing a major role in creating in vitro and in vivo product characterization packages. Compiling both sets of data helps in-depth understanding of product's quality attributes (QA) and helps in the determination of product's CQAs. It is proven that some CQAs have impact on the product's safety and biological profiles. Biopharm industry is now revising their testing strategies to accelerate product development. This talk will connect analytical, CQAs, and clinical outcomes in product's development

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