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Role of Product Development in the Efficient Management of Supply Chain

Presentation: Scientific and Regulatory Challenges in Product Development and its Importance in Efficient Supply Chain Management

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Although product development has always been an integral part of product life cycle, its formal inclusion in ICH guideline Q8 (R1) reinforces its importance. This ICH guideline explains both essential and advanced (QbD) approaches of pharmaceutical development. Irrespective of the approach used, a product needs to have a well defined target profile as it relates to its quality, safety and efficacy. Among the various quality attributes of the raw material and the final product, those that are critical have to be identified, monitored and controlled. The manufacturing process has to be chosen carefully to obtain the desired target quality in the final product. Also, the critical process parameters have to be identified, monitored and controlled to obtain consistent quality in each commercial lot.

Another key aspect is to understand the factors contributing to variability in quality, and develop a robust manufacturing process that is able to tolerate the variability in inputs without a negative impact on product quality. Products that are developed to meet these expectations are better suited to changes that are expected in a product lifecycle, including changes in supply chain. With the globalization of the pharmaceutical industry, changes in suppliers are occurring at a very rapid pace, often resulting in product failure. Successful management of the supply chain depends on knowing one's product in sufficient depth, developing a robust process that can withstand unexpected variability, and creating a good working relationship with the supplier to obtain good quality products in a consistent manner.

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