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Pharmaceutical product development, manufacturing, & commercialization – Implementing quality by design

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The quality of pharmaceutical/biopharmaceutical products has been usually controlled by the end product testing (Quality Control Release). To better control the product release and increase its scientific compliance with regulatory bodies and meet the customer needs, the concept of quality by design (QbD) becomes the new paradigm to ensure these expectations are met and to minimize the risks associated with the development process, scale-up and commercial productions. In this presentation, the speaker will discuss some critical stages in pharmaceutical industy for clarifications from a scientific/technical point of view including: The concepts to be applied in the design and development of a product and associated manufacturing processes; methods to ensure critical quality attributes, which can be accurately and reliably predicted; knowledge transfer framework to enable the organizational understanding required to drive effective risk management and decision making; systems that must exist to capture and organize knowledge from the continuous processes improvement to acheive the commercial production that meets safety and effectiveness consistently.

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Understanding the US medical device premarket notification review process

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Approximately 95% of medical devices in the USA today are marketed under the Premarket Notification 510(k) requirements of the US Food, Drug, and Cosmetic Act. This session will provide the latest developments in the 510(k) review process with helpful tips on corresponding optimal regulatory strategy, when and how to contact the US Food and Drug Administration, and how to optimize opportunities for a predictable 510(k) review experience. The session will focus on a robust baseline in the fundamentals of 510(k) submissions, from underlying regulations to unique regulatory concepts, and finally the practical aspects of preparing a 510(k). There will also be discussion on postmarket requirements such as listing, registration, device modifications, marketing and promotion in the USA.

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