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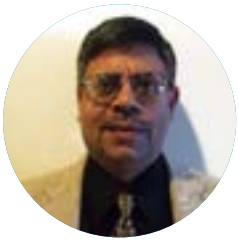

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QbD in product life cycle: Are you ready?

Today building quality into product is the most desired objective of FDA, which they would like us to achieve by implementing QbD (Quality by Design). That could be complex, confusing, perplexing, and frustrating if the spirit hidden behind the concept (QbD) is not well understood. A systemic approach can help in handling this challenge by identifying potential risks/mitigation strategies during lifecycle of a product development. Among various tools being offered for Quality Risk Management (QRM), FMEA is one of the most powerful tool which has its place not only from molecule to market but also when the product is discontinued. You should be able to learn a very generic, flexible and effective process helping you dissect the risks quantitatively, during all stages of product development, and present solutions to those risks effectively.

Biography

Adnan Sabir is currently employed at Kowa Pharmaceuticals of America, leading QA CMC activities. Previously, he was a Principal Consultant and Founder of his business Pharma Consulting Services, Inc,. He has more than 30 years of hands-on and management experience and a proven track record for formulation and process development for brand and generic products approved by FDA and other agencies globally. He served as VP of Process Development and Optimization Group at Dr. Reddy's Lab during 2009-2012. He has also worked extensively as a Consultant providing solutions for the regulatory issues, implementation of QbD/PAT, and risk based development of products to many life science customers. He has significant knowledge in CMC, cGMP, 21 CFR Part 11 and ICH guidelines, serialization and FDA regulations. He is also Invited Speaker at various forums in United States and other countries globally.

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