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Seamless Technology Transfer Process (TTP) to CMOs

Transferring the 'Risk Based', ICH Q9 compliant, drug development and manufacture to CMOs can be subject to many pitfalls. I would like to share my experience of how we can make such Technology Transfer Process (TTP) effective, seamless and utilizing the latest regulatory, technical, practical and business tools. Considerations for preparing for the process transfer, ensuring logistics, quality based design principles, equipment and materials consistency, and post-transfer activities will be discussed; which are very crucial to the success. Key learning objectives will include: Understand the product transfer process from preparing the transfer, performing the transfer and what is required after the transfer; establish and review metrics (measurement/feedback tools) to determine product transfer success; and establish a solid Technical Quality Agreement (TQA).

Biography

Adnan Sabir is currently employed by 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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