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The importance of proper change management

Change management in the regulated pharmaceutical, biologic, and medical device industries is a critical element of the Quality System. Changes occur at every phase of product lifecycle from development to product discontinuation. Changes may be critical, such as a manufacturing process change or relatively minor, such as addition of a new sampling port on a process water system. In all cases, all changes must be documented and evaluated for risk and potential impact on product quality. All changes must be evaluated by the Quality Unit and effectiveness checks are required after implementation to ensure the change achieved the intended affect. There must be assurance that no unintended consequence has occurred. Changes must be managed through a robust systematic process in order to assure compliance with regulatory requirements. Virtually all regulators require a change management procedure or program. An integral part of ICH Q10, Pharmaceutical Quality System, is a Change Management System. Regulators including the U.S. FDA and the European Medicines Agency have adopted ICH Q10 to support their GMP regulations. Additionally, the specific GMP requirements enforced by the regulators refer to the control and management of changes. This presentation will expand on the regulatory requirements, expectations by the regulators, discuss common change control program pitfalls, and discuss the elements of a robust change management system.

Biography

Peter D Smith joined PAREXEL (then KMI) in 1994 following a 22-year FDA career and works with clients in the pharmaceutical and biologics industry worldwide. At the FDA, he was an Investigator, specializing in pharmaceutical GMP/GCP and medical device inspections, later serving in FDA Headquarters where he managed the FDA's Foreign Drug Inspection Program. He has primary expertise in GMP for Active Pharmaceutical Ingredients, sterile and non-sterile dosage forms, management of Pre-Approval Inspections, GMP/Quality Systems and FDA regulatory issues. He holds a BS in Biology from Roger Williams University in Rhode Island. He is a Member of ISPE and PDA, and an Associate Adjunct Professor at the University of Rhode Island, College of Pharmacy.

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