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Quality risk management: Quality control perspective

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The manufacturing, distribution and use of drug (medicinal) products involve some level of risk. Quality risk management is a valuable component of an effective quality control system in the pharmaceutical industry. Built in product quality should be maintained throughout the product lifecycle such that the attributes those are important to the quality of the drug (medicinal) product remain consistent with those used in the clinical studies and production and assured by quality control mechanisms and tools. An effective quality risk management approach can further ensure the high quality of the drug (medicinal) product to the patient by providing a proactive means to identify and control potential quality issues during development, manufacturing and distribution. Additionally, the use of quality risk management tools can improve decision making in quality management systems as a whole for best quality products and not only when quality problem arises. Effective application of quality risk management principles can facilitate better and more informed decisions and provide regulators with greater assurance of a company's ability to deal with potential risks and regulatory compliance.

Biography

Jacob Adegboyega Kolawole has completed his PhD from the Ahmadu Bello University, Zaria and The Robert Gordon University, Aberdeen, UK (1996). He is the Dean, Faculty of Pharmaceutical Sciences, University of Jos and Consultant at West African Health Organization on development of guidelines and training manuals for pharmaceutical finished products, pharmaceutical raw materials, standard operating procedures for laboratories and bioavailability/bioequivalent. He has more than 40 publications in international journals.

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