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Quality by Design, advances in pharmaceutical technology

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Despite continuous innovations in the pharmaceutical industry for developing futuristic new drug products, there has been a repeated set back owing their low quality and manufacturing standards. The studies and tests required to deliver a new drug to patients last up to 15 years, and cost over 800 million $. Even after a drug is invented, its development may fail due to the proven impossibility of its safe manufacture in a large scale and incompliance with the relevant specifications. The length of the approval process and the requirement to start over for a development cycle of any changes due to the stalemates, even product is licensed has led to concerns for many decades. With the consequent growing concerns and criticism, in this regard, in 2002, the current Good Manufacturing Processes (cGMP) was introduced to improve and modernize the rules that regulate the drug manufacturing and quality. Subsequently, in 2005, the guideline Q8 of the International Conference on Harmonization (ICH), which focused on the content of the Module 3.2.P.2 of the Common Technical Document (CTD), was published. The ICH instituted a series of quality guidelines all emphasizing the adoption of systematic principles of Quality by Design (QbD) and Process Analytical Techniques (PAT). QbD is a patient-centric science and risk-based approach for developing drug products with better understanding of the products and processes by planning quality at first hand in order to avoid quality crisis and using the knowledge obtained during the life-cycle of the product to work on a constant improvement. Implementation of QbD-based strategies in pharmaceutical development would provide excellence and significant time shortening in product development, and enormous flexibility in regulatory compliance. It has been emphasized before if the principles described in the ICH Q8, Q9 and Q10 guidelines are implemented together in a holistic manner, this provides an even greater assurance that the patient will receive product that meets the critical quality attributes.

Biography

Buket Aksu completed her Graduation from Istanbul University and Doctorate degree in Quality by Design (QbD) at Ege University. Currently, she continues her academic career at Istanbul Kemerburgaz University; also works as Consultant in Pharmaceutical Industry. She has given numerous speeches and training programs on QbD, Industrial Pharmacy, Management Skills, Registration and Patent, R&D and Innovative Sales.

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