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Quality risk management methodology in pharmaceutical industry (ICH Q9/FDA/WHO)

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Since a couple of years, quality risk management (QRM) has become a mandatory regulatory requirement towards healthcare organizations either they are active in the sectors of Medical Devices or in Pharmaceuticals industry.

The objective of quality risk management should aim at raising the level of protection for the patient, by the reduction of the risk to which that patient is exposed at the time he receives a drug product.

This general objective can only be achieved if the implemented policy of quality risk management exceeds the unique intend of GMP compliance by increasing the control of the organization on developed processes to improve.

Discussion of the methodology including risk assessment phase through identification, analysis and evaluation then risk control phase either by reduction or acceptance and finally risk review, the risk tools (HAZOP/HACCP/FMEA/FTA) will be illustrated briefly with some examples from Pharma industry.

Biography

Rober Remon Saad Habashy has completed his bachelor's degree in pharmaceutical science in 2007 from Misr International University School of Pharmacy. He completed his Total Quality Management (TQM) Diploma from the American University in Cairo 2009. He became certified Six Sigma Black Belt (CSSBB) from the American Society for Quality (ASQ) October 2011 as well as Diploma in Quality Assurance in the same year from the American supplier institute (ASI). He is the Training Chair at the American Society for Quality Local Member Community (LMC) in Egypt. He is a core member senior Research & Development pharmacist at Amoun Pharmaceutical Company, Cairo, He works at the R&D Department and responsible for Analytical test method development and Validation as well as formulation and pre-formulation studies, Product /process design for human/vet Pharmaceutical product.

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