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FDA process validation guidance & principles vs EMA guidance

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Abstract

The discussion will clarify the differences and updates between Process validation definition & Content in the FDA Guidance document for Process Validation 1987 and the new Guidance issued 2011.

Introduction of new Terminologies to process validation instead of validating the current process to Process design as Stage 1,then Process Qualification and utilizing statistical tools for evaluation as Stage 2. Then Continues Process Verification of the Validated Process covered by Stage 1& 2 using trend analysis, OOS &Statistical/ SPC Tools for control as Stage 3.

Alignments of The validation guidance of 2011 with the ICH Q8 for pharmaceutical Development /QbD terminologies and definitions like Target product profile (TPP), Target product Quality Profile (TPQP) Critical Quality Attributes (CQAs) Critical process parameters (CPP) etc.

The New Guideline includes Modern technology scientific approach, innovation and continuous improvements through product and process understanding and uncovers new areas of Improvements.

EMA guidance update and draft issuanceto cope with FDA Guidance document for process Validation, Current differences between EMA & FDA guidance will be addressed and the content of each guidance will be discussed in brief.

Biography

Rober Remon has completed his Bachelor degree in pharmaceutical science 2007 at the age of 22 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 Egypt. 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 Products.