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A risk based scientific approach to analytical method development and validation activities for regulated laboratories

Shib Mookhaerjea

ValQual International, USA

Abstract

Key Topics

• An overview of global compliance issues, global harmonization initiatives, role of ICH, relevance of Validation activities & the Paradigm Shift

• Quality Control and Quality Assurance in analytical, R&D, QC, PD laboratories: General considerations, quality systems, QC procedures, QA oversight, process control measure.

• Perspectives of ICH ISO integration: ICH Q1 (stability studies), Q2 (Analytical Methods), Q3 (Impurities), Q7 (Pharma Process), Q9 (Risk Assessment), Q10 (Quality Systems), etc.

• Measurement, measurement uncertainty, measurement resolution, total error, and bias

• Analytical measurement: Process Model & Risk Assessment (REMS)

• A generic, science based outline of Methods Development & Validation [*ab initio*]

• Perspectives of QbD, PAT Directives: On-Line Measurements vs. Off -Line

• Validation parameters, their generic defi nitions, and their practical applications to various methods

• Highlights of the guidelines derived from International standards - ISO 17025, AOAC, WHO, GLP, GMP, EMEA, USP/EP/ JP, etc.

• Standardization/qualification/verification/validation: The implicit continuum

• A generic approach to analytical method optimization during development

• Some case histories and applications for improvement of validation characteristics

• Data integrity and statistical evaluation of analytical data: SQC, control charts

• Methods development and optimization in HPLC, UV-VIS including assessment of peak purity, as examples of the most recent techniques widely used in analytical laboratories

• Methods validation & regulatory submissions: IND/ ANDA/ NDA/ CMC

• Method development and validation by examples (group exercise): How to systematically develop and validate an assay for a trace component in a very complex sample matrix, develop the schematic template of a validation protocol

• Perspectives of qualification of various analytical systems (IQ, OQ, PQ) GAMP, USP