

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

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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 definitions, 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

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