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2.1.3.2 Clarification of AIQ Terminology2.1.3.3 A Continuum of Analytical Apparatus, Instruments, and Systems; 2.1.3.4 Mapping USP Instrument Groups to GAMP Software Categories; 2.1.3.5 Enhanced Data Quality Triangle; 2.1.4 Risk-Based Approaches to Analytical Instrument and System Qualification; 2.1.4.1 Expanded Instrument and System Categories; 2.2 Efficient and Economic HPLC Performance Qualification; 2.2.1 Introduction; 2.2.1.1 The Importance of Analytical Instrument Qualification; 2.2.1.2 Terms and Definitions; 2.2.1.3 Continuous Performance Qualification: More by Less
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3.4 Overview of Process to Develop Requirements for Procedure Performance3.5 Decision Rules and Compliance; 3.6 Calculating Target Measurement Uncertainty; 3.6.1 Coverage Factor, k, and Data Distributions; 3.7 Types of Decision Rules; 3.7.1 Decision Rules That Use Guard Bands; 3.8 Target Measurement Uncertainty in the Analytical Target Profile; 3.8.1 Cost of Analysis; 3.9 Bias and Uncertainty in a Procedure; 3.10 ATP and Key Performance Indicators; 3.11 Measurement Uncertainty; 3.11.1 What Uncertainty Is; 3.11.2 Reporting Measurement Uncertainty; 3.11.3 How Uncertainty is Estimated
3.11.4 Uncertainty Contains All Sources of Random Variability

Sommario/riassunto

This second edition of a global best-seller has been completely redesigned and extensively rewritten to take into account the new Quality by Design (QbD) concept in pharmaceutical manufacturing. As in the first edition, the analytical requirements during the entire product lifecycle are covered, but now a new section is included on continued performance monitoring and the transfer of analytical procedures. Two case studies from the pharmaceutical industry illustrate the concepts and guidelines presented, and the standards and regulations from the US (FDA), European (EMA) and global (ICH) regul