ABSTRACT

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Title: Risk-based approaches for process validation

Topic: This presentation gives an insight into statistically based methods to determine sample sizes for process validation. Relations between risk management and validation are explained by means of a practice-oriented example.

The need for validation using recognised statistical methods with justification of sample size is found in both FDA and ISO requirements. The process validation task should therefore be an integral part of any Quality Management System. Where appropriate, each manufacturer shall establish and maintain procedures to identify valid statistical procedures necessary to establish, control and verify the acceptability of process capability and product characteristics.

There are different methods for determining statistically valid techniques and justifications for sample size, such as Success-Run Theorem, Acceptable Quality Limit or Lot Tolerance Percent Defective sampling plans. Process risks have to be identified and an appropriate, risk-minimising implemented statistical procedure is a key to success.

Regardless of the method used to determine the statistically valid sample size and the appropriate rationale (confidence, reliability or Acceptable Quality Limit value), the method should be based on definitions of the risk associated with the process (Failure Mode and Effects Analysis), the effort associated with manufacturing the product, and the activities associated with inspection, measurement and testing, and should be applied consistently.