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How to improve quality and consistency of legacy products applying QbD/Six Sigma methodology

Alicia Tebar
Telstar, Spain

ICH Guidelines Q8 to Q11 are the foundations of Quality by Design (QbD). They have been agreed globally and represent an evolution of pharmaceutical quality systems from a model based primarily on inspection, to a risk-based model supported on scientific knowledge and process control. The expected benefit of QbD application has been largely described. Acquiring a thorough knowledge of the process and identify sources of variability, leads to predictable and robust processes. This in turn leads to a quality improvement that ultimately results in lower costs of remediation and inspection.

From the regulatory front, the continued process verification requires stable and capable processes, so the "state of control" has to be demonstrated. From this point of view, mature products with recurring quality problems due to poor development and a lack of process knowledge may be good candidates for a QbD redesign. This is what has come to be called reverse QbD or process reengineering. The presentation presents an application example on a tablet with quality problems, to which QbD methodology is applied in order to identify sources of variability and to propose a new control strategy to achieve consistent quality. In this case the calculation of ROI is used to justify the investment needed for the project.

Biography

Alicia Tebar is a Chemist and a Six Sigma Black Belt with 20 years of professional experience in Pharmaceuticals. She worked for diverse national and multinational companies. She was in charge of several Quality Control and Pharmaceutical Development departments. Since 2004 she has been working as a consultant on behalf of specialized life sciences consultancy firms. Presently, at Azbil Telstar, she is responsible for QbD/PAT consultancy projects. Since 2006 she has been teaching courses for technical staff in: Quality by Design/PAT, Process Validation, Quality Risk Management, applied statistics and design of experiments. She is contributing author in "Achieving Quality and Compliance Excellence in Pharmaceuticals". She is an active member of ISPE's Spanish Chapter and a Member of the Steering Committee since October 2011. Since 2012 she has been leading a task force within industry and regulatory authorities to develop recommendations about the application of the Quality by Design principles to legacy products.

ATebar@telstar.eu