Status Update: QbD

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The US Food and Drug Administration (FDA) introduced the idea of Quality by Design (QbD) in 2004 as part of the Process Analytical Technology Guidance. The purpose was to design quality into the product and process rather than try to test quality into the product at the end on the production line. It has been known for a long time that “quality by testing” is a low-yield and costly strategy. In 2005 ICH outlined the concept of design space in its Q8 guideline that focused on product development. Since that time, pharmaceutical and biotech companies – despite depending on innovation for their livelihood – have been slow to adopt QbD. This article focuses on what has happened in the interim and some of the current trends. In short, QbD is alive and well and growing.

QbD is Not New

QbD has its origins dating back to the 1950s when the first ideas of the operating window, now called the “design space” in the Pharma and Biotech world were put forth (Box and Wilson 1951). Juran popularized the term “Quality by Design” in his 1992 book. Some say that pharma and biotech are behind the times. Others see that the ‘glass is half-full’ and that pharma and biotech can come up the learning curve much more quickly than other industries did in the past by building on what has been learned in the field in over the last 30-40 years of implementation.

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