

Identifying Process Critical Parameters through the QbD Approach

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Process analytical technology (PAT) requires knowledge of critical process parameters and their effect upon critical quality attributes of the process. The quality by design (QbD) approach builds this information and makes it accessible through statistical models. Both concepts share a lot of methods for data analysis. In the interest of a lean development and application it is important to see the communalities and to make best use of it. Experimental design (DoE) is a focal aspect in this development, it provides the base for the identification of driving factors, that are linked to the critical quality parameters through a statistical model. This in turn can be used for simulation studies that help to describe the design space in a way that is easy to use and understand. A case study is used to demonstrate this process. It is the direct path to a reliable result that is obtained with the minimal amount of resources.