

## AQbD, ICH Q14 – Should I Bother and What Does This Mean for My CE Method Development?

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### Summary



In this presentation, a short, practical, and pragmatic overview is given on the impact of the new ICHQ14 guideline and Analytical Quality by Design (AQbD) on method development and more specifically on CE methods. The high-level guidelines are translated into a practical method development process flow, that can be applied on new methods as well as on adapting existing methods or platform methods. The discussion will focus on the need or not for AQbD outside the pharmaceutical industry and what or what not it can contribute to analytical science, as well as demonstrate that AQbD is a lot more than Design of Experiments (DoE).