



International Alliance for
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Europe



Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

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Industry Perspectives: Sponsors Platform Analytical Procedures and Opportunities From ICH Q2 Q14

The new version of ICH Q2 (R2) “Validation of Analytical Procedure” and the new ICH Q14 “Analytical Procedure Development” are addressing topics in the mood of time (Real-Time-Release, multivariate models, ...), these two guidelines bring the concepts of Analytical Quality by Design through the description of an “enhanced approach”. The two texts also address the topic of platform analytical procedures but not in great details, and probably to an extent that does not allow the immediate realization of the game changing potential of the application of AQbD concepts to platform analytical procedures development, validation and lifecycle.

The objective of the presentation is to share a vision where the concepts from the enhanced approach (ATP, risk management, knowledge management, validation, assay control strategy, change management) can accelerate the availability of more robust validated platform analytical procedures, can facilitate the extension of usage to new products, and contribute to the reduction of product development lead time. The positioning will be knowingly progressive in order to stretch towards the most ambitious vision and to envisage together the long-range benefits that are possible but not promised and, in any case, depend on how we will implement ICH Q2 and Q14.

