



International Alliance for
Biological Standardization

Europe



Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

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Commercial Submission Considerations for Platform Analytical Procedures

The updates to ICH Q2 and Q14 define analytical platform procedure and offer the opportunity to conduct abbreviated method validation through use of enhanced development, establishment of an analytical platform and risk assessment. Industry has extensive experience developing monoclonal antibodies (mAbs), including method development, validation, transfer, and implementation at commercial sites around the world for in-process, release, and stability testing. This prior knowledge, experience and historical data can be used to expand the application of platform analytical procedures to mAbs and mAb-like therapeutics intended to reduce redundant work by adopting a streamline abbreviated validation approach to enable rapid commercial readiness. This presentation will focus on providing examples of content and justifications needed in a commercial submission for a strategy establishing platform analytical procedures by leveraging prior knowledge (retrospective). Successful approaches and continued challenges will be highlighted.

