Leveraging Analytical and Bioprocess Platforms for Biological Product Development and Commercialization

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Title: Analytical Platform Case Study: Is The Charge Assay Suitable As Platform Procedure

Charge separation analytical procedures are commonly used for biological product characterization and quality control. To enable a fast an easy applicability of this technology for monoclonal antibodies and similar products entering our development pipeline, we used AQbD tools such as risk assessment and DoE to define critical method parameter and ranges for robust charge variant quantification of several molecules. For the establishment of the platform procedure, 12 different IgGs were analyzed using 3 different columns under variations of several method parameters. The method parameter design space was later fully validated at the min/max acceptable ranges using 3 IgGs. The predefined parameter ranges and understood interactions of method inputs to method outputs relevant to achieve the desired method performance enable easy parameter set-point adaptions to achieve a reliable charge variant resolution for the new molecules. Challenges however remain for the registration of the platform procedure adaptation, transfer and submission strategy of a potentially abbreviated validation, when the platform procedure is applied for new IgGs that enter the market application phase.