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A regulatory perspective on continuous perfusion production of rFVIII

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A REGULATORY PERSPECTIVE ON CONTINUOUS PERFUSION PRODUCTION OF RFVIII

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Continuous perfusion production has enabled flexible manufacturing of rFVIII, a large complex Biotech Product, for over two decades. Continuous improvement has driven frequent process, equipment and facility changes successfully performed utilizing comparability exercises.

Challenges in evaluating changes made to a continuous perfusion process includes assessment of impact to quality product attributes throughout the entire fermentation campaign which can be months in duration. Examples of process changes requiring more studies, those successfully supported by small scale development runs and API commercial characterization and an example resulting in non-implementation will be reviewed. Impact of changing Regulatory Environment on submission package requests will be discussed.