

Closing the gap- Addressing similarity challenges of a biotherapeutic with the innovator product

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Biosimilar development holds the promise of increasing access of low cost medicines to patients in emerging markets and the world at large. At the core of a biosimilar program is the ability to ensure that the physico-chemical, pre-clinical and clinical data generated for the biotherapeutic is similar to the innovator product with respect to the structural properties, safety and efficacy. In this presentation, taking an in-house case study, a target-directed strategy for development of a biosimilar therapeutic will be outlined. Key aspects of process improvements and impact of both upstream and downstream process parameters on final product quantity and quality will be discussed. Process optimization efforts presented were geared towards minimizing process development time in a time sensitive biosimilar development space, whilst meeting regulatory standards for acceptable product profile of the biosimilar. Strategies discussed during this presentation will help accelerate biosimilar development in both emerging and regulated markets.