ACCELERATED PROCESS DEVELOPMENT AND COMMERCIALIZATION – BRINGING LIFE-SAVING DRUGS TO MARKET

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With an increasing number of large molecule drugs getting breakthrough designation and other accelerated approval pathways by the health agencies worldwide, the timelines for late-stage process development and commercialization have reduced significantly. However, the product and process understanding in the pre-licensure as well as the post-licensure phase continue to remain crucial to support manufacturing investigations and ensure uninterrupted supply of these life-saving breakthrough therapies to the patients. It is imperative for late-stage process development teams to utilize innovative approaches and tools to meet these aggressive filing timelines while still delivering a robust control strategy and a commercial process.

In this talk, we present a few case studies to showcase the innovative strategies we have used in the late-stage process development, commercialization, and post-licensure stages of large molecule which enable faster filing timelines and ensure uninterrupted supply to patients. The case studies will outline an approach which encompasses use of mathematical modeling techniques, advanced digitization and automation platforms to expedite technology transfer timelines and reduce the need for at-scale engineering batches whilst ensuring successful validation campaigns. In addition, we will present utilization of high-throughput systems to build a robust control strategy as well as raw material control strategy in the post-licensure phase. Lastly, we will present use of predictive modeling approaches such as Bayesian statistics to build stability models for drug substance and drug product as part of an exhaustive accelerated comparability package which enables faster time to clinic and licensure.