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Accelerating biosimilars mabs to market: A predefined process coupled with consultative services

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Abstract

Biosimilars manufacturers face unique challenges, in a fast growing segment of the biotech industry. Process parameters for biosimilars are defined early in molecule development, with limited scope for later revisions. Process development and characterization occur simultaneously. Speed in development must include rapid optimization of all parameters. Therefore, it is vital to design manufacturability into the process at this early stage. We propose a template designed for biosimilars mAbs manufacturers to accelerate speed to clinic and minimize risk of failure. A process is defined for rapid production of mAbs at 100 g scale, with the majority of the process control parameters predetermined and fixed. Parameters such as chromatography column flow rates, buffer selection, column height, membrane and column loading, auxiliary filtration and buffer management are all preconfigured both in terms of process inputs and single use engineered systems. This enables clarified cell culture through purification and formulated bulk drug substance with minimal process development. The benefits include little to no process development time, minimal risk in scale up and tech transfer, and reduced capital investment. Data for two mAbs illustrates this plug and play approach. This process design, with large scale proven products coupled with consultative services, enables an accelerated approach to the biosimilars mAbs market.

Biography

Jennifer Campbell is the Director WorldWide Biosimilars Market for Process Solutions at Merck Millipore. Jennifer has 20 years of industry experience, including research and development, assay development, process development, cGMP manufacturing, and technical consulting. She is published in the fields of animal research, biopharmaceutical validation, and viral clearance.