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Use of modern chromatography media for process modernization and simplification of downstream processing operations for biologic product purification

With implementation of the biosimilars approval pathway, providing more affordable biologic drug products have become closer to a reality for the United States. Although several biosimilar versions of innovator biologics have already been approved, regulatory barriers still continue to be shaped. Past regulatory barriers, a primary challenge to produce a biosimilar version of an innovator is for the cost to be a fraction of the original process which allows this biosimilar to be introduced to the global market for an ultra-competitive price, driving market competition within and between different biologic treatment options. In the development of a manufacturing process, up to 80% of the cost comes from downstream operations, so use of modern chromatography media to meet safety, purity, and potency requirements are a direct way to impact cost of goods when developing a manufacturing process for a biosimilar. During this workshop, process modernization of a bacterially expressed protein from a four step purification process, to a two-step purification using modern chromatography media process will be discussed. Additionally, a second case study will be presented within this downstream workshop will feature optimization of an alternative purification method for a biosimilar version of Adalimumab, with evaluation of process productivity to a legacy process.

Biography

William Rushton is a Process Chromatography Support Scientist for Bio-Rad in North America. He obtained a M.S in Biomedical Sciences from Philadelphia College of Osteopathic Medicine in 2005 and his B.S in Biology from St. Joseph's University in 1994. Prior to Bio-Rad he worked at Centocor (wholly owned subsidiary of Johnson and Johnson) from 1997-2007 in the Process Development Group. While there he worked on ReoPro, Remicade and developed the downstream purification processes for Simponi and Stelara. In 2007 he joined Charles River Laboratories as the manager of the Process Evaluation/Validation group performing viral clearance studies for Pharmaceutical and Bio-Tech companies. Upon leaving Charles River in 2009, he supported the BLA filing and post marketing activities for Xiaflex at Auxilium Pharmaceuticals as a Senior Scientist in the Process Development group. His work resulted in development of highly purified versions of the collagenases to improve analytical assay sensitivity as well as column validation work.

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