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Development and manufacturing of a biobetter therapeutic: A case study

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Abstract

Activated Protein C (APC) is a naturally occurring human protease that has both anticoagulant and cytoprotective activities, with the latter being appropriate for treatment of ischemic stroke. ZZ Biotech has created a variant, 3K3A-APC, which reduces the anticoagulant activity while retaining its cytoprotective activity, thereby avoiding the dose-limiting side effect of unwanted bleeding. We describe the development of recombinant CHO-cell production and purification of 3K3A-APC, from small cultures to 2000-liter production. By working collaboratively, scientists from both companies were able to overcome this molecule's challenges of complex post-translational modifications, enzyme isomers, and autodigestion. The result was a successful regulatory filing leading to a Phase 1 clinical trial, which recently completed.

Biography

Michiel E. Ultee, Ph.D., has more than 25 years of experience in the biopharmaceutical industry and has worked with antibodies since 1975. He serves as Laureate Biopharma's scientific head and is the leader behind Laureate's Scientific Series, which spotlights the organization's strategies and methods in working together with our clients' scientists to overcome challenges in biopharmaceutical development and manufacturing their biopharmaceutical products.

Dr. Ultee has been part of Laureate's biopharmaceutical operations team since 1987 with positions including Vice President of Process Sciences and Director of Manufacturing & Technical Operations. He is a frequent speaker at biopharmaceutical conferences, and a member of the editorial advisory boards of *Bioprocess International* and *Biopharm International*.

Kent E. Pryor, Ph.D., joined ZZ Biotech full-time in 2010 to coordinate drug development operations including manufacturing, quality systems, regulatory affairs, and clinical research. Previously, he served as Chief Operating Officer of SynthRx, Inc., Associate Director of Drug Development at Kémia, Inc., and Group Leader at Corvas International, Inc. Dr. Pryor has served on the Boards of Directors for multiple non-profit corporations and currently serves on the Advisory Board of Assay Depot. Dr. Pryor received his BA in chemistry magna cum laude from Rice University, a PhD in organic chemistry from the Massachusetts Institute of Technology, and an MBA from the Rady School of Management at the University of California, San Diego.