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Prior knowledge assessments: A knowledge compilation process that can be used to bring about more focused process characterization and development studies for platform products

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Abstract

Recent guidance documents highlight a regulatory expectation that prior knowledge should be leveraged to increase overall process understanding. ICH Q11, in particular, calls for the use of prior knowledge from platform processes and products. Information commercial development studies, process characterization and other sources related to products and processes with similar motifs (such as monoclonal antibodies) can be used to improve the efficiency and targeting of process characterization studies. This paper describes how process knowledge from a number of sources across multiple platform products can be compiled and analyzed. The knowledge gained from these assessments can be used to better focus process characterization studies and commercial process development activities for new platform products.

Biography

Dr. Jim Seely has nearly 30 years of experience in the biotech industry, over twenty of which were spent at Amgen. Most recently he was the Director of Knowledge Management for Amgen Process Development. Prior to that, he led the purification process development group at Amgen Colorado. During his time at Amgen, Dr. Seely developed and led several groundbreaking efforts in process characterization and process validation for protein products and is an author of several seminal papers on the subject. Prior to Amgen, Jim was with Pitman-Moore and helped develop processes for porcine and bovine somatotrophin products. Jim received his PhD in Biochemistry from the University of South Dakota. Dr. Seely retired from Amgen in 2012 and is currently an independent bioprocessing consultant.