

Integrated development environment for the production of monoclonal reference material

Darryl L. Davis

Janssen Pharmaceutical, USA

Often within the biopharmaceutical industry, the focus on quality is primarily from the recombinant protein perspective. Yet quality refers to both the raw material and process and the product. With newer initiatives such as QbD and PAT slowly being adopted, and the realization that the product lifecycle is heavily weighted to post-marketing activities, there is a need to test the outcome (product quality and CQAs) alongside the impacting parameters (raw materials, formulation materials, process parameters). To this end the concept of an integrated development environment (IDE), where the growth, formulation and analysis of the protein is performed alongside the analysis of the raw materials, is presented. In this scenario, the outcome (the product profile) is not viewed as distinct from the process but instead is part and parcel of the process.

Examples will be shown of how an iterative design space which includes all pieces of protein production can be used to drive product quality, decrease development timelines, and effectively scale the process. The IDE borrows heavily from software development concepts due to similarities in the process. In addition the underpinning of the process is the informatics pipeline that drives a flexible yet quality focused analytical reporting scheme. Finally examples will shown how this process focused on a pure protein can drive similar development when working in an expanded field such as systems biology or integrative biology.

Biography

Davis holds a doctorate in Medicinal Chemistry from the Philadelphia College of Pharmacy and Science. His thesis focused on the use of MS in the characterization and quantitation of peptide phosphorylation. He started his career at J&J as a COSAT intern using MS to characterize the glycan linkages found on Remicade. Since joining J&J he has started several analytical sub-groups He has also served as the new technology and innovation lead within analytical. He has won several innovation awards within J&J for his work on automation and high-throughput analysis which continues to be his current focus.

ddavis14@its.jnj.com