Maximizing the Value of your Biologic Development Program: The Importance of Maintaining Control of Your Manufacturing Analytical Data during the Product Lifecycle

Webinar Date/Time

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Presenter(s)

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FULL ABSTRACT

While the biologic manufacturing adage 'The Process is the Product' was coined in the 1980s, it still remains true today. Even though analytical capabilities have markedly improved during this time, especially in mass spectrometry, we still cannot sufficiently characterize the structure of a biologic product to ensure that the final product testing adequately establishes control of its safety, identity, strength, purity or quality (SISPQ). Therefore for biologics, the industry must continue to test (under cGMPs) cell banks, key intermediates, Active Pharmaceutical Ingredients (APIs) s and Drug Products (DP), as well as, demonstrate control of the manufacturing process during clinical development.

Manufacturing processes continue to be modified during the clinical lifecycle of a biologic and frequently change due to process scaling needed to produce large quantities of commercial material. Since a manufacturer's primary criteria for defining its processes and products come from the requisite analytical assays, it's critically important to ensure control of one's cGMP analytical methods beginning with production of the toxicology lot all of the way through process validation and post-commercial launch. The timeframe to demonstrate control of the product and process can easily extend beyond a decade.

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To ensure control of one's analytical assays during this product lifecycle requires significant effort and oversight. By far, the best mechanism to ensure control of a biologic's analytical data throughout its lifecycle is to utilize a 'Centralized cGMP Testing Laboratory' to demonstrate control of a key intermediate, API, DP, associated stability testing and key process steps. Shortsightedness, thinking only about an individual manufacturing lot and not establishing data links between cell banks, key intermediates, API or DP and their long term stability will almost certainly result in lower value to the ultimate stakeholder trying to market the biologic to patients.