
Session Chairs: Juliana Kretsinger, Eli Lilly and Company and Aston Liu, GlaxoSmithKline

This plenary session will discuss analytical life cycle related topics, including its impacts to process development and process control. There is significant awareness of the need for process changes during the life cycle of therapeutics, resulting in ongoing discussions about expectations for comparability studies to support these process changes. The changes that are needed for the analytical methods and process controls during the life cycle of a therapeutic sometimes receive less attention. Resisting any changes does not allow sufficient flexibility over the long term, but the ability to implement changes can be very challenging for therapeutics with approvals across the globe. The speakers in this session will discuss the analytical life cycle and the considerations needed to implement post-approval changes to analytical methods and process controls. Additionally, there will be discussion of the use of older technologies in new ways to find convergence of old and new technologies, as well as implementation of new technologies that can significantly advance analytical methods for process development and control.