GLOBAL IMPLEMENTATION OF CELL CULTURE CHANGES: STRATEGIES, LESSONS LEARNED AND CHALLENGES

Marie-Pierre Gentile, Pharma Technical Development, Genentech, a member of the Roche group
gentile.mariepierre@gene.com

Key Words:  Post-approval, global, change control, strategy

Post-approval changes for pharmaceuticals are necessary to maintain regulatory compliance, support continuous improvement and optimization of the manufacturing process, and ensure robust product supply. However, managing post-approval changes at the global scale can be complicated and time-consuming due to differences in regional procedures, timelines and health authority expectations.

This talk will highlight challenges and strategies used to develop a global implementation plan for selected cell culture technical changes across multiples products and sites. In particular, the talk will discuss best practices and lessons learned related to quality risk management, validation and stability requirements to support process and product comparability, as well as change control, regulatory and supply chain strategies to maintain continuity of the supply during the implementation of the change.