EFFICIENT TECHNOLOGY TRANSFERS TO INCREASE AGILITY, FLEXIBILITY, AND PRODUCTIVITY

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The current pharmaceutical business environment requires increasing agility, flexibility, and efficiency in bioprocess manufacturing to ensure competitiveness. Excellence in technology transfer execution is one way to become more agile and to develop a competitive advantage. Roche’s large manufacturing network, using both internal and external (CMO) manufacturing capabilities, provides many examples of various bioprocess technology transfers. A consistent framework for technology transfer is used that incorporates elements of quality, speed, and risk management. The amount of complexity is dictated by the level of changes in process, scale, or analytical methods as well as by the experience level of donor and receiving parties. When external manufacturing (CMO) is included, additional complexities can arise due to differences in transfer methodologies, cultural norms, and communication styles. Despite the complexities, a unified framework for transfers has allowed for significant reductions in transfer time. A series of recent transfers for Roche commercial legacy processes will be described. Facility fit considerations for upstream unit operations, scale-up/scale-down approaches, and obstacles encountered during manufacturing campaigns illustrate challenges encountered and overcome. Specific examples to be discussed include approaches to address comparability challenges, cell culture scale-down model troubleshooting, and design modifications to media preparation equipment including high temperature short time (HTST) and bioburden control topics.