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Case study: Lessons learned during tech transfer at a multi-product legacy launch facility

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Case Study: Lessons Learned During Tech Transfer at a Multi-product Legacy Launch Facility

Genentech's original GMP production facility in South San Francisco, California, was approved by the FDA in 1985 and today is licensed to manufacture 10 marketed products. This legacy manufacturing plant has evolved over the years to become a complex multi-product facility that supplies both clinical and commercial products utilizing a 96,000 liter-capacity on the CHO line. The site's flexibility along with proximal location of key functional areas including Operations, Process Development, Quality and Regulatory well position it as a launch site for new molecules. Balancing flexibility with older qualified equipment presents unique opportunities when launching new molecules in an aging multi-product facility. Some constraints include equipment resource overlap between clinical and commercial, reliance on single probes on bioreactors, ensuring adequate raw material inventory across multiple products and providing heightened process monitoring support with legacy automation systems. This poster will discuss the above challenges encountered and mitigation measures adopted during a recent new molecule licensure campaign at the Genentech South San Francisco Manufacturing facility.