

437j Optimization of Monoclonal Antibody Production Using Process Simulation and Scheduling Tools

Demetri P. Petrides and Charles Siletti

The new generation of monoclonal antibodies that are required in large quantities (hundreds of kilograms per year) present a number of manufacturing challenges to the biotech industry. Such products typically require facilities with multiple upstream and downstream suites. Furthermore, such biopharmaceuticals are often produced in multi-product manufacturing facilities. In such environments, the multiple production lines interact with each other through sharing of labor, utilities (e.g., steam, purified water), auxiliary equipment (e.g., CIP skids), buffer preparation tanks, etc. Occasionally, they also share rooms and other work areas. Sharing of resources, however, leads to scheduling bottlenecks and headaches that limit the throughput of the entire facility. Our experience in using process modeling and scheduling tools to improve the design of new biopharmaceutical facilities and the operation of existing ones will be presented using an industrial case study.