EMPOWERING MANUFACTURING DECISIONS THROUGH PROCESS SIMULATION MODELS

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The need for Clinical and Commercial manufacturing capacity continues to increase and at the same time there are “shortages” of production slots and time pressures. Whether one is a virtual, small or large company there are many considerations that go into the decision of how and where to manufacture the biopharmaceutical, cell therapy or vaccine. In this presentation, we explore approaches for using commercially available modeling tools, such as Super ProDesigner® and BioSolve™, to simulate the manufacturing of a “typical” monoclonal antibody product and a multivalent conjugate vaccine product. Through these hypothetical case studies, we will illustrate several important concepts such as forecasting site capacity, supporting the decision to manufacture in-house versus outsourcing to a CMO and estimating the impact of flexibility of the manufacturing process. Biologics developers and manufacturers need the right tools and processes to deliver the product to the patients, having robust simulation packages is one way to de-risk challenges and improve likelihood of success in the manufacturing suite.