

FDA/OBP LABORATORY RESEARCH TO SUPPORT CONTINUOUS BIOPROCESSING

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Recently, there has been a movement in commercial biotechnology drug production to develop fully a continuous manufacturing scheme capable of consistent production of high quality therapeutics. The FDA is increasingly reviewing applications implementing elements of continuous manufacturing or enabling technologies. This includes product and process engineering, and integration of enabling technology during development. Achieving a true continuous process can be difficult and raise additional unknown regulatory concerns (i.e. how to handle process interruptions or unmatched liquid flow rates between linked unit operations, how to measure viral clearance and establish safety). This poster will provide an overview of CDER's, Office of Biotechnology Product's lab capabilities and selected regulatory research case studies on continuous biomanufacturing and enabling technologies. These lab-based capabilities are being leveraged to study continuous bioreactor cell culture production, continuous chromatography, viral safety, and Process Analytical Technology (PAT) tools to enable these operations. Preliminary results have provided encouraging data to broaden technological challenges and potential benefits of continuous biomanufacturing approaches.