

PROCESS ANALYTICAL TECHNOLOGY (PAT) IN CONTINUOUS BIOPROCESSING

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In recent years biotech companies have been emphasizing on the implementation and utilization of process analytical technology (PAT) in continuous bioprocessing. An overview of PAT concepts for biotech processes with emphasis on integrated continuous bioprocessing and production of monoclonal antibodies will be presented.

Biotech processes consist of several unit operations, with each unit operation serving a defined purpose. For some of the product quality attributes, a certain level of redundancy in the process is expected. The need for appropriate control of each step and continuous evaluation of its performance is of great importance.

The objective of commonly used unit operations in downstream processing of biotech products are to isolate the product of interest from the process stream that comes from the harvest unit operations and contains a variety of impurities. These impurities include product-related variants that might closely resemble the desired product and have an equivalent potency and safety profile. Spectroscopy is being proposed as an on-line PAT tool for continuous measurement of numerous critical quality attributes. In addition, real-time data collection will assist in the development of chemometric models used for predictive estimation of properties of a process and hence help in process analysis, optimization, monitoring and control.