Technological Challenges in the Production of Biopharmaceuticals

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The process development and custom manufacturing of biopharmaceutical products faces not only many regulatory challenges. In addition customer expectations to fulfil quality targets and to improve cost efficiency are increasing. Due to customer needs and increased regulatory requirements new approaches in process development and manufacturing are required. Concepts like "Quality by Design (QbD)", "Process Analytical Technology (PAT)", "Real Time Release", and “High Throughput Screening" are reflecting the cultural change in the industrial world.

Increasing process understanding, reducing process variation and thus increasing the product quality and reducing the production costs are the common goals of all these approaches. All these strategies rely on an increasing demand for data collection, storage, and analysis. Visualization and trending should ideally be performed real-time to allow immediate reaction on process shifts, trends or deviations.

A process for a recombinant protein for pharmaceutical applications will be used as an example to illustrate the different expectations in process development and production. The focus will be on the data management and analysis applied in both areas and different solutions will be outlined and discussed.