What to expect in the next 25 years?

"Right now, manufacturing experts from the 1950s would easily recognize the pharmaceutical manufacturing processes of today. It is predicted that manufacturing will change in the next 25 years as current manufacturing practices are abandoned in favor of cleaner, flexible, more efficient continuous manufacturing." - Janet Woodcock, Director CDER, FDA (AAPS meeting, 2011)

Pall Life Sciences is assessing the needs process analytical technology (PAT) as an overall mandatory, but also the entire process flow must be coordinated and equipped with second-level control systems that supervise and align the work of individual unit operations.

In contrast to batch processing, in which local control of each piece of equipment is in direct measure CQAs, ability to monitor multiple process parameters, easy-to-use instrumentation, the selection of appropriate PAT tools is a crucial step toward setting efficient monitoring and control strategies in continuous processes.

The ideal continuous controls platform combines automation, analytics and process control strategy; empowering users to execute advanced processes with excellence in quality, yield, and ROI.

The perfect continuous tools (sensors, PAT, new data processing approaches)

In order to ensure product quality, mAb concentration monitoring is one of the CQA’s

OUTLOOK

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True continuous tools (sensors, PAT, new data processing approaches)

Data Management, Data Analysis, Data Insight and Automation

Fill in the gaps using established platforms to meet new continuous requirements

Value of PAT implementation

Ensure consistent product quality and increase robust overall manufacturing performance reducing heterogeneity

Enable end-to-end continuous process by implementing lean, flexible and portable biomanufacturing

Advanced computational tools enhance continuous monoclonal antibody production

Integration of process analytical tools for monoclonal antibody toxicity measurement can be achieved

Process time and cost savings can be achieved through automation and continuous integration in existing facilities