Applied SmartFactory® Rx Analytics & Control (SFA)

Case Study: Batch Genealogy & Data Integration to contextualize data across operations

SCENARIO

Client: BTEC simulated cGMP biomanufacturing facility
Process: Raw materials to final product

CHALLENGE

The ability to ensure batch genealogy and maintain context from one unit operation to the next as well as link batch process data with performance and quality data is extremely crucial. This is made mor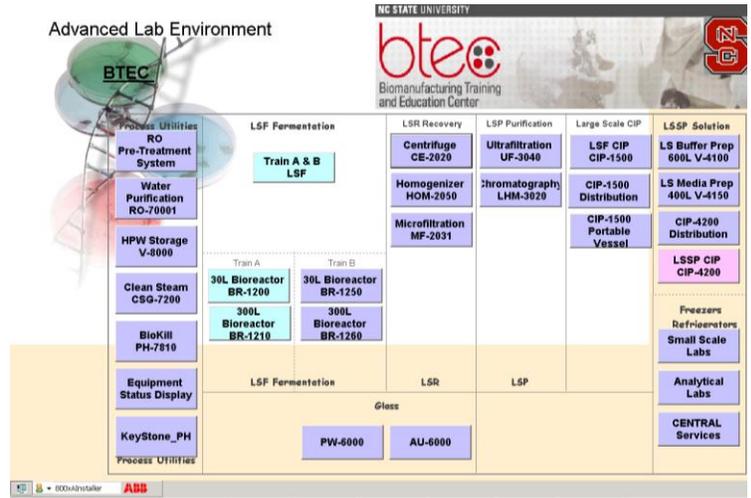e difficult due to the various types of analyzers often employed such as mass spectrometers for gas analysis, NIR analyzers and cell density probes to name a few. In addition, equipment is often operated by various control systems (DCS, SCADA and simple PLCs). The common challenge is to find a single platform that enables integration of multiple data types as well as provide the capability to build context into unit operations.

SOLUTION

Analytics & Control was implemented to build a factory layout of the facility. The integration capability also enabled the creation of contextual data and made use of advanced monitoring tools. In addition, phases within unit operations could be identified and isolated which was previously not possible. The data loader that automatically searches for new files in specified folders allows for the use of external tabular data as well as process data to build UVA and MVA models and generate limits for fault detection. This facilitates the creation of predictive models linking critical process parameters to critical quality attributes.

OUTCOMES

-Better utilization of monitoring capabilities and increased batch genealogy
-Increased control capability
-Increased ability to link CPPs to performance parameters and CQAs

Equipment layout for utilities, upstream, downstream and lab areas

An example of data integration in a 30 L bioreactor:
1- Context that can be linked between unit operations
2-Standard bioreactor parameters
3- Feedback control to equipment controller setpoints
4-External PAT probes