

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 more difficult due to the various types of

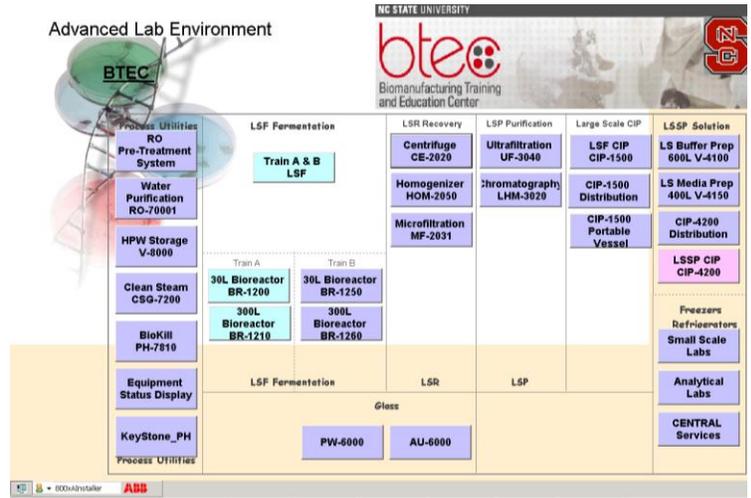
analyzers often employed such as mass spectrometers for gas analysis, NIR analyzers and cell density probes to name a few. In addition, equipment is often operated by various control systems (DCS, SCADA and simple PLCs). The common challenge is to find a single platform that enables integration of multiple 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

Di	Tool	Equipment Tag Id	E	Equipment Tag Description	L	ProcessType	E3 Data Item
M	BR1250	ContextArea		ContextArea	LS	Bioreactor_Type	ContextArea
M	BR1250	ContextName	1	ContextItem1	LS	ABB_Bioreactor_Type	ContextItem1
M	BR1250	PT07013:IO.Value		Pressure	LS	ABB_Bioreactor_Type	Pressure
M	BR1250	XV05002:IO.Cmd.Value		Exhaust Valve	LS	ABB_Bioreactor_Type	ExhaustValve
M	BR1250	FT02014:IO.Value		Spurge Oxygen Flow Rate	LS	ABB_Bioreactor_Type	SpurgeOxygenFlowRate
M	BR1250	Batch.OpStatus		ContextUnitOptID	LS	ABB_Bioreactor_Type	ContextUnitOptID
M	BR1250	FT02025:IO.Value		Overlay Air Flow Rate	LS	ABB_Bioreactor_Type	OverlayAirFlowRate
M	BR1250	PCV05004:IO.SP.Value		Back Pressure Control Output	LS	ABB_Bioreactor_Type	BackPressureOutput
M	BR1250	XV06016:IO.Cmd.IO.Value		Exhaust Condensate Valve	LS	ABB_Bioreactor_Type	ExhaustCondensateValve
M	BR1250	FC02009:IO.SP.IO.Value		Spurge Air Flow Rate Setpoint	LS	ABB_Bioreactor_Type	SpurgeAirFlowRateSetpoint
M	BR1250	FT02009:IO.Value	2	Spurge Air Flow Rate	LS	ABB_Bioreactor_Type	SpurgeAirFlowRate
M	BR1250	LT07015:IO.Value		Foam Probe	LS	ABB_Bioreactor_Type	FoamProbe
M	BR1250	TIC01003:Out.Forward.Value		Temperature Control Output	LS	ABB_Bioreactor_Type	TemperatureControlOutput
M	BR1250	FT02214:IO.Value		Spurge CO2 Flow Rate	LS	ABB_Bioreactor_Type	SpurgeCO2FlowRate
M	BR1250	_bBatchConnection.Appl.Acquired		Appl.Acquired	LS	ABB_Bioreactor_Type	Appl.Acquired
M	BR1250	XV06016:IO.Cmd.Forced		ExhaustCondensateForced	LS	ABB_Bioreactor_Type	ExhaustCondensateForced
M	BR1250	EM2-Agit:InteractionPar.SP		Agitation Speed Setpoint	LS	ABB_Bioreactor_Type	AgitationSpeedSetpoint
M	BR1250	EM18-PRS:DevPar.HSICmdPIC.SP.ManVa...		PressureSetpoint	LS	ABB_Bioreactor_Type	PressureSetpoint
M	BR1250	FT02114:IO.Value		Spurge Nitrogen Flow Rate	LS	ABB_Bioreactor_Type	SpurgeNitrogenFlowRate
M	BR1250	Context.PhaseID		Context.PhaseID	LS	ABB_Bioreactor_Type	Context.PhaseID
M	BR1250	LT07016:IO.Value		Level Probe	LS	ABB_Bioreactor_Type	LevelProbe
M	BR1250	Context.Site		Context.Site	LS	ABB_Bioreactor_Type	Context.Site
M	BR1250	WT07024:IO.Value		Bioreactor Weight	LS	ABB_Bioreactor_Type	Bioreactor.Weight
M	BR1250	LT07014:IO.Value		Condenser High Foam Probe	LS	ABB_Bioreactor_Type	CondenserHighFoamProbe
M	BR1250	Batch.RecipeName		Context.RecipeID	LS	ABB_Bioreactor_Type	Context.RecipeID
M	BR1250	Context.Location		Context.Location	LS	ABB_Bioreactor_Type	Context.Location
M	BR1250	FT07009:IO.Value		Bioreactor Temperature	LS	ABB_Bioreactor_Type	Bioreactor.Temperature
M	BR1250	FC02009:IO.SP.Forced	3	AirFlowForced	LS	ABB_Bioreactor_Type	DOProbe
M	BR1250	FC02025:IO.SP.IO.Value		Overlay Setpoint	LS	ABB_Bioreactor_Type	AirFlowForced
M	BR1250	EMS-Overlay:InteractionPar.MOPStat		OverlayAirFlowRateSetpoint	LS	ABB_Bioreactor_Type	OverlayAirFlowRateSetpoint
M	BR1250	EM4-Air:InteractionPar.MOPStat		SpurgeAirMOP	LS	ABB_Bioreactor_Type	OverlayMOP
M	BR1250	Batch.LotID		Context.LotID	LS	ABB_Bioreactor_Type	SpurgeAirMOP
M	BR1250	EM1-Temp:InteractionPar.MOPStat		Temperature Mode of Operation	LS	ABB_Bioreactor_Type	Context.LotID
M	BR1250	EM18-PRS:InteractionPar.MOPStat		Pressure Mode of Operation	LS	ABB_Bioreactor_Type	TemperatureMop
M	BR1250	EM4-Air:InteractionPar.COFIC		Spurge Interaction Setpoint	LS	ABB_Bioreactor_Type	PressureMOP
M	BR1250	EM5-Overlay:InteractionPar.FICCO		Overlay Interaction Setpoint	LS	ABB_Bioreactor_Type	SpurgeIntSP
M	BR1250	_bBatchConnection.OldBatchID		Previous Batch ID	LS	ABB_Bioreactor_Type	OverlayIntSP
M	BR1250	_bBatchConnection.BM.Acquired		BM.Acquired	LS	ABB_Bioreactor_Type	SpurgeOldBatchID
M	BR1250	EM18-PRS:InteractionPar.MOPStat		PressureSetpointPIC	LS	ABB_Bioreactor_Type	BM.Acquired
M	BR1250	Ch2Prop1:IO.Value		NIR Glucose Concentration	LS	ABB_Bioreactor_Type	PressureSetpointPIC
M	BR1250	OD07017:IO.Value	4	Cell Density	LS	ABB_Bioreactor_Type	NIRGlucose
M	BR1250	EMS-Overlay:InteractionPar.MOPStat		Agitation Mode of Operation	LS	ABB_Bioreactor_Type	CellDensity

- 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