Large Scale Cell Culture
Inline Caustic Dilution System

Confidential Client

Pharmaceutical and Biopharmaceutical

MANDATE

Biopharm Engineered Systems LLC (BPES, a CPS Group Company) was retained to design and construct an Inline Buffer Dilution System (IDS) to support the manufacture of Monoclonal Antiboties (MAb's) at a Confidential Client Site. This scope was in support of the sites Phase 2 Expansion. During Phase 1 BPES had provided multiple large Pre-viral and Post-viral Ultrafiltration and Diafiltration process skids to the site.

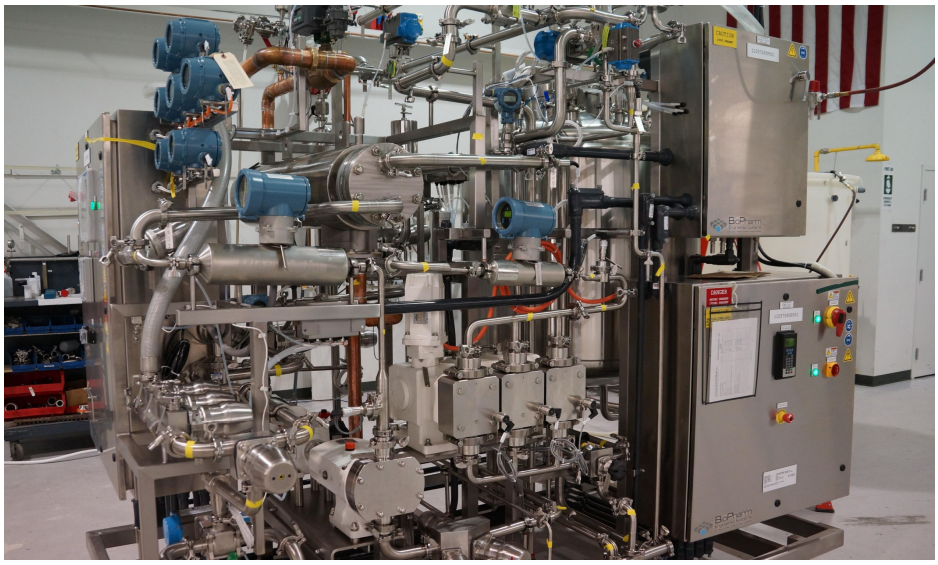
Confidential Client is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. Over the past decade Confidential Client has invested >$1B on major expansions at its biologics facility designed to accelerate development of the company's growing portfolio of biologics medicines. Included among these expansions was the addition of a Lab Office Cafeteria (LOC) building for administrative support, Large Scale Cell Culture (LSCC) building for the production of high volume product, Biologics Development Building (BDB) for designing processes for the early production of investigational medicines, and a Clinical Manufacturing Building (CMB) where investigational medicines will be produced to support clinical trials. All told these projects represent the single largest capital investment in Confidential Clients history and signal the company's transformation from a traditional pharmaceutical company into a global biopharmaceutical powerhouse.

DESCRIPTION | FEATURES | BENEFITS

The Inline Buffer Dilution Skid (ILD) allowed the Confidential Client to prepare buffer solutions over a wide range of concentrations by diluting 8N sodium hydroxide solution to 5N, 0.5N and 0.1N solutions for Process and Clean-In-Place operations. The system design included the option to dilute caustic solution concentrations directly by volume using mass flow-meters and/or conductivity measurements. This skid supplied diluted product to a buffer hold tank held at 350mbar. Process/Equipment parameters included:

- Dilute 8N NaOH to 5N, 0.5N and 0.1N,
- Final dilution accuracy <1.5% based on flowrate while operating in closed loop flow control, and
- Final dilution flow rate ~45 LPM @ 30 psig at skid outlet.

Controls: AB based control system with SCADA communicating with plant DELTA V supervisor.



DELIVERABLES

ITEM	DESCRIPTION
1	Process / Mechanical Deliverables
▪	Piping and Instrumentation Diagrams
▪	Equipment List with Utility Requirements
▪	Module Layout / Model
▪	Line List
▪	Equipment Data Sheets
▪	Component List
▪	Instrument Data Sheets
▪	Engineering Calculations
2	Electrical Deliverables
▪	Control System Architecture (CSA) Drawing
▪	Electrical / Control System / Solenoid Panel
▪	Motor and Power List
▪	Power Distribution One Line Diagram(s)
▪	Interconnect Wiring Drawing(s)
▪	DeviceNet Segment Drawings(s)
▪	Pneumatic Distribution Drawing(s)
3	FAT Deliverables
▪	System Commissioning Plan
▪	Commissioning and Performance Test
▪	Review existing system documentation
4	Equipment Fabrication and FAT execution

SERVICES PROVIDED

BPES scope of work included the following:

- Mechanical/Electrical/Process Engineering
- Automation, Instrumentation, and Controls
- Equipment Fabrication
- Factory Acceptance Testing
- Field Installation Design

SECTOR OF ACTIVITY
Biotechnology

CLIENT
Confidential Client

YEAR OF COMPLETION
2016

TOTAL PROJECT COST
Confidential

BPES PROJECT VALUE
Confidential