

Large Scale Cell Culture Ultrafiltration/Diafiltration (UF/DF) TFF

Confidential Client

Pharmaceutical and
Biopharmaceutical

MANDATE

Biopharm Engineered Systems LLC (BPES, a CPS Group Company) was retained to design, fabricate, test and document an Ultrafiltration/Diafiltration (UF/DF) TFF process skid for Confidential Client as part of a plant expansion. Confidential Client is an American subsidiary of a multinational pharmaceutical and biopharmaceutical company & produces a drug for the prevention of respiratory infections in infants.



PROJECT SCOPE

BPES's main project scope included a self-contained, fully integrated UF/DF skid for concentration and diafiltration of protein solutions in accordance with FDA current GMP guidelines and regulations. Project challenges included getting creative with component selection due to the footprint and height restrictions of the manufacturing space. For example, the mechanism of removing the level probe out of a 5,000L vessel with a low ceiling had to be considered. Other logistical challenges included shipping it in pieces due to its large size (multiple crates, including tanks). Assembly at the site included erecting the skid components outside and rigging it into the suite.

Process Equipment (Including but not Limited to)

5,000 L Retentate Tank
3x30" Liquid Filter
4-High Universal TFF Holder
Alfa Laval SRU5 Pump
Automated Hydraulic Closure System
Allen Bradley VFDs

Software / Communications

HMI Process Control System (PCS) via Ethernet

Equipment / Services Provided (Including but not Limited to):

- Structural Frame & Platform Design
- Process Piping Engineering
- Instrumentation Datasheets
- General Arrangement / 3D Model Review
- Pump Performance Verification
- Control System Architecture
- Junction Box Layout & Wiring Diagrams
- Electrical Panels
- Slope Check Walkdown
- Dimension Check
- Pressure / Leak Test
- Valve Position Test
- Hydro-Testing
- Passivation
- As-Built Drawings (Detailed Package)
- Validation of the Control System
- Unloading & Install On-Site
- Field Support & Training
- Telephone & On-line Support
- Warranty

SECTOR OF ACTIVITY

Pharmaceutical

CLIENT

Confidential Client

YEAR OF COMPLETION

2016

SKID DIMENSIONS

12'W x 13'L x 16' H

BPES PROJECT VALUE

Confidential Value



BioPharm Engineered Systems
A Critical Process Systems Group Company