

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

Confidential Client

exentec

BioPharma Solutions

Pharmaceutical /
Biopharmaceutical

SECTOR OF ACTIVITY

Pharmaceutical

CLIENT

Confidential Client

YEAR OF COMPLETION

2016

SKID DIMENSIONS

12'W x 13'L x 16' H

EXENTEC PROJECT VALUE

Confidential Value



MANDATE

Exentec 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

Exentec'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.

please contact our sales department for details or for a quote

Email: sales@bpesys.com

Phone: 978-483-0943

EQUIPMENT INCLUDED

Process Equipment

- 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

- 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