

Large Scale Cell Culture Sequential Multicolumn Chromatography

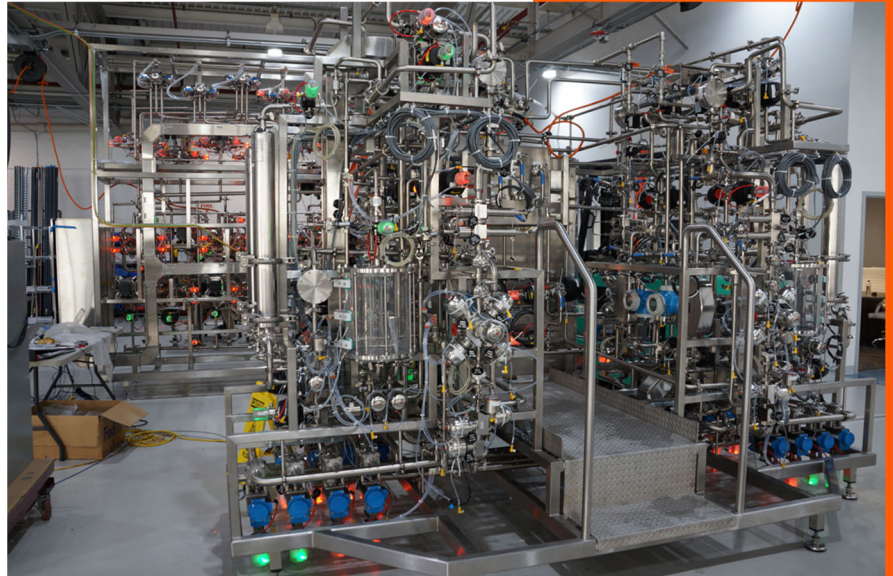
Confidential Client

Pharmaceutical and Biopharmaceutical

MANDATE

Biopharm Engineered Systems LLC (BPES) was retained to design and construct a 4-column Sequential Multi-column Chromatography (SMCC) system along with a 6-pump buffer exchange unit, capable loading the columns and delivering up to 20 different buffers to any of the system's columns.

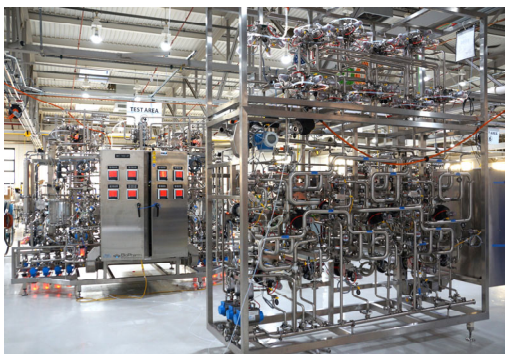
Buffer feed and product paths were designed for steam-in-place, while the internal buffer and product paths within the system were chemical sanitizable and capable of clean-in-place (CIP) with the installation of buffer feed and column CIP manifolds. To accommodate the customer's space limitations, all 4 chromatography paths were housed within a single skid frame that included a central platform for maintenance accessibility. A transfer panel accessible from the central platform also allowed configuration of the chromatography system into a 2, 3 or 4 column sequential system. To ensure that chase and elution volume requirements remained constant regardless of the number of columns utilized, care was taken to ensure that all feed and product path lengths were equivalent.



DESCRIPTION | FEATURES | BENEFITS

The Four Column Sequential Multi-column Chromatography (SMCC) system with 6-pump buffer exchange unit included the following parameters:

- 0.5-53 LPM Multi-diaphragm Feed Pumps
- Feed Static Mixers
- Bubble Traps
- Feed Filters
- Pre-Column Air Sensors
- Pre- & Post Column Conductivity & pH
- CIP Rinse Conductivity
- Post Column Dual UV Sensors
- 2-6 port block diaphragm valve
- Controls/Software
- Customer supplied DeltaV programming



SERVICES PROVIDED

BPES scope of work included the following:

- Process Engineering
 - Up to 1m Ø columns
 - Product Loading
 - Washing & Equilibration
 - Isocratic or Gradient Elution
 - Product Collection
 - Waste segregation
 - Feed & Product SIP
 - System CIP plan & manifolds
- Interconnecting wiring design
- Equipment, Valve & Instrumentation selection
- Mechanical Skid designs
 - 3D Model
 - Equipment layout
 - ASME BPE compliant piping design
 - Piping sloped for gravity draining
 - Transfer panel
 - Path length equalization
 - Maintenance accessibility
- System Fabrication
 - Skid frame fabrication
 - Pipe manifold fabrication & documentation
 - Instrumentation installation & wiring
- Quality Documentation
 - Material Test Reports
 - Video Borescope
 - Weld Mapping
 - Factory Acceptance Testing

SECTOR OF ACTIVITY
Biotechnology

CLIENT
Confidential Client

YEAR OF COMPLETION
2023

TOTAL PROJECT COST
US \$ Confidential

BPES PROJECT VALUE
US \$ Confidential