

ENGINEERING

DRUG SUBSTANCE MANUFACTURING FACILITY DESIGN (EPCMV) CELL CULTURE

China - Confidential Client

PROJECT DESCRIPTION

This was a Greenfield multi-product drug substance facility. The facility was designed with hybrid equipment, developing an optimum mix between single use technology and stainless steel equipment. The equipment systems included media prep, seed and production bioreactors, harvest, buffer prep and hold, upstream purification, downstream purification, bulk drug formulation and fill, buffer preparation.

SCOPE OF SERVICES PROVIDED

- Basic, Conceptual and Detailed Design (BD, CD, DD)
- Automation Engineering - Programming & Process Modeling, Conceptual Process Design and Layout
- Basis of Design Report, Cost and Scheduling & Process and Clean Utility Equipment Specification
- 3D Process Equipment and Sanitary Piping Model
- Automation Specifications and valve matrices
- Construction Management Support
- BioReactors: Design and integration of 50L and 200L Single Use Bioreactors, and 1,000L and 5,000L Stainless Steel Bioreactors. Design included process design through PFD, P&ID, scale up and bioreactor specification, piping integrations, automation (specifications and valve matrices).

RESULTS

- PROJECT THROUGHOUT
4 x 5000L Cell Culture
- COMPLIANCE
US FDA, SFDA
- CAPEX
\$ 68 Million
- Overall
60,000 Sq. Ft.
- Clean room
18,000 Sq. Ft.

Current Equipment ID# (PFD Rev 1.0)	Type	Description	Capacity Specified	Unit	Vessel / Bag (F/M/D)	Tote / Rack	Mag Stirrer (Bag)
BRV-01	Disposable	Bioreactor	50	L	D	N/A	Y
BRV-02	Disposable	Bioreactor	200	L	D	N/A	Y
BRV-03	SS	Bioreactor	1000	L	F	N/A	N
BRV-04	SS	Bioreactor	5000	L	F	N/A	N
BRV-05	SS	Bioreactor	5000	L	F	N/A	N
R5V-01	Tank-SS	Resin Slurry Tank	700	L	F	N/A	N
Deleted	Tank-SS	Pool Mix Tank (ProA)	3000	L	F	N/A	N
MPV-02	Tank-SS	Media Prep Mix Tank	4500	L	F	N/A	N
MPV-01	Tank-SS	Media Prep Mix Tank	1500	L	F	N/A	N
MPV-03	Tank-SS	Media Prep Mix Tank	300	L	F	N/A	N

