



Custom Engineering

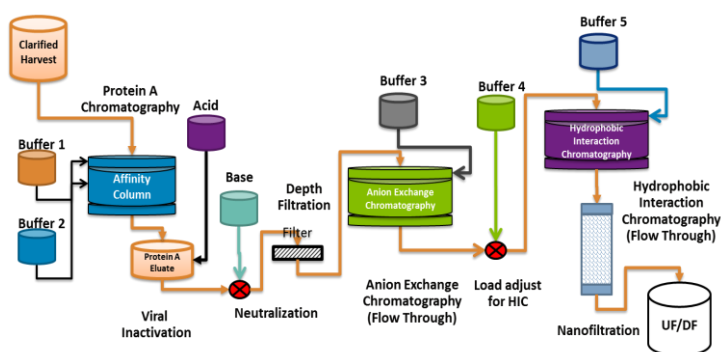
Custom Engineered Bioprocess Products and Solutions for Downstream

Bioprocess Scientists and Engineers worldwide count on Sepragen for all their custom Engineered downstream systems!!!

Since 1987, Sepragen has been developing and manufacturing downstream process systems for a wide range of industries. Today, Sepragen is a leading developer and provider of Industrial-scale separations equipment, systems, columns, Resins and other technologies used worldwide. Sepragen a world class Team of Engineers who will work with you and custom design and produce downstream Bioprocess equipment to your specifications so as to address your needs.

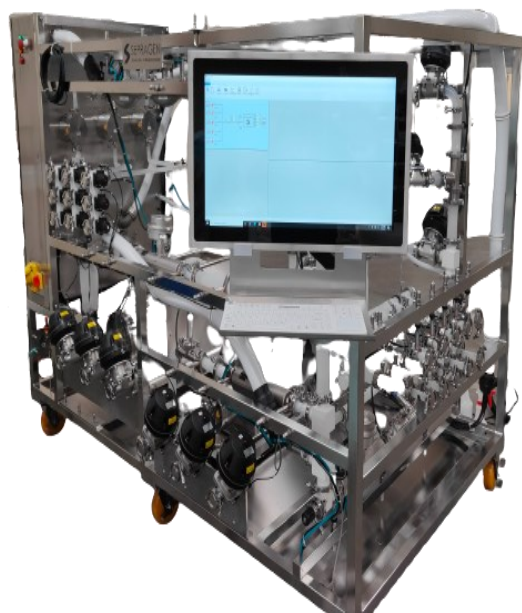
We bring our unbridled innovative spirit in service of you, the customer. We help create solutions that will help you develop and manufacture life saving drugs rapidly and cost effectively within the framework of compliance. We operate with a spirit of fairness, integrity, teamwork and mutual respect. **We always deliver what we promise!!!**

Sepragen Engineers have Combined over 100 years of Bioprocess knowhow and experience- 16 + patents in upstream and downstream process designing and building Chromatography Columns, Columns Packing Skids, Chromatography Systems, Buffer Dilutions Systems, Chromatography Resin Chemistry, Perfusion Bioreactors for mammalian Cell Culture, Gene Therapy and now for Regenerative medicine.



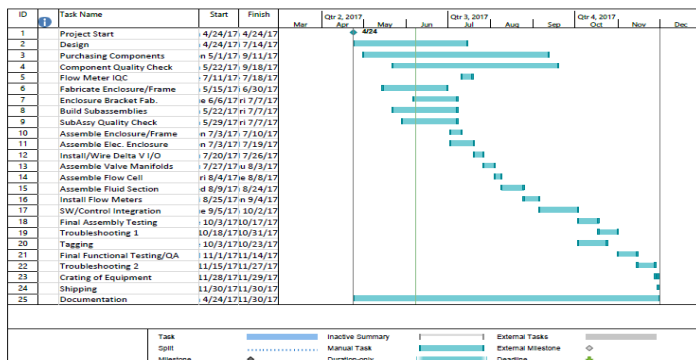
*An example of our innovation in new products is the Elite model for larger scale QuantaSeps, be it the true and tried Trusty or the single use Adept or the Continuous Chrom Fusion systems. **Here we have combined the Buffer manufacturing from stock solutions and chromatography to help reduce space and cost of the process.***

Another example is the continuous Chromatography Capture and Continuous Flow Through Chromatography platform. Developed as a continuous monoclonal Antibody isolation process for a 2000 L perfusion bioreactor, this platform consists of dual or triple column depending on the application with inline buffer blending followed by an automated continuous flow through skid for IEX, HIC and Nanofiltration steps.



Systems backed by World Class Engineering

- Our team of Mechanical and Industrial engineering professionals have mechanical design capabilities in creating columns, skids, piping, and pressure vessel design using 3D modeling.
- Our team of Electrical and Electronic design engineers have Control systems, circuit board layout and design (transmitter and stepper motor control) to panel and PLC wiring per ANSI standards.
- We offer PLC and HMI programming with Allen Bradley, Siemens, DeltaV, OPC UA, VB6, Dot Net and SQL Database.
- We can custom design, fabricate, machine, 3D print and mold our own fittings and other parts for compactness and high performance.

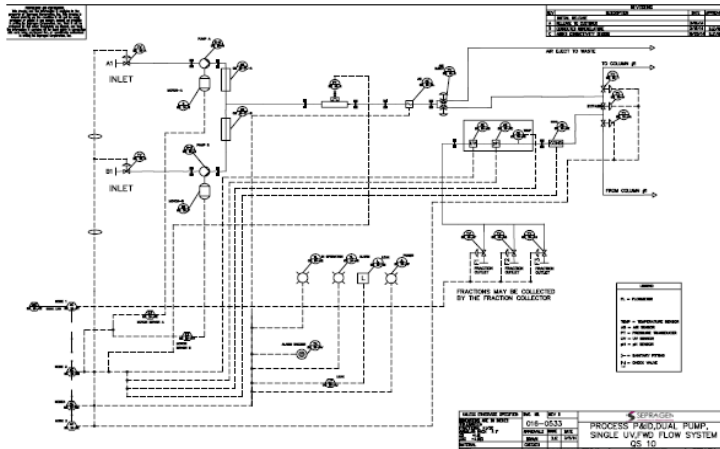


The custom Engineering process starts with meeting between Sepragen and the Client to first understand the need and the application. Our team of Engineers and Application scientists then help guide you in your design process.

The next step is to review and understand your "Functional Requirement Specifications". As we design the equipment, we share the design with the client as part of the design review and get approvals before the product goes into manufacturing.

This followed by manufacturing of various components and testing of each component followed by assembly and in-depth testing. While the Equipment is being manufactured, the required IQ/OQ plans and protocols are assembled and reviewed and signed off by the customer and Sepragen.

Subsequent to the testing, a FAT is performed along with the client and once everything is signed off, the product is crated and shipped. Once at site a SAT is performed followed by IQ/OQ.



Warranty, Installation & Support

All Sepragen products are backed by our one-year limited warranty. Installation and training, along with IQ/OQ are performed by Sepragen Service Group. Preventative maintenance and Total maintenance service is provided at added cost. Validation support packages are also available.



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Custom Engineering Process

- URS Definition with Client
- Preliminary Design
- P&ID
- Design
- General Arrangement
- Solid Modeling
- Electrical Schematics
- Software Screens
- Design Review
- Procurement
- Fabrication
- Sub-Assembly
- SA Testing
- Assembly
- Assembly Testing
- Functional Testing
- Documentation (IOM, TOP) and Tagging
- Crating and Ship
- SAT
- Install and Commissioning
- On-going PM

Manufacturing Capability

- Complete Machine shop with Superspeed 4 Axis CNCs, large and high precision Lathes, NC Mills, Grinding and polishing equipment for rapid fabrication and prototyping along with testing equipment e.g., calipers, profilometer, borescopes granite tables.
- Tube bending and tube (piping) welding and fitting; vessel and filter non ASME welding. Third party electropolishing
- Fabrication and Assembly: Pumps, Sensors, interlocks, PLC wiring, Panel and skid wiring and pneumatics assembly
- Assembly Testing: Dimensional checks, Surface finish, hydrostatic pressure, flow, leak and cavitation, electrical continuity, ground loop current, Hi Pot testing, burn in testing and 72-hour cycling.
- Functional Testing: Pump, sensor, mixing, gradient range & accuracy checks, pressure, air and leak alarms, interlock checks, valve performance, testing, alarm check points, manual and auto operation of methods
- Manufacturing Quality and Documentation generation: IQC, Assembly (in-process) testing, Functional testing, Materials certs for SS and elastomers (FDA compliance/ USP Grade VI), Welding Certs, Surface Finish Certs, Hydrostatic Pressure Rating, CE Mark

To learn more call:

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