

Millipore's Process Development Scientists — an extension of your development team

ARE YOU WORKING ON A RECOVERY OR PURIFICATION PROCESS for a product currently in early phase clinical trials? Do you want to make sure the production of your product occurs at a planned rate with a desired yield, purity and cost? If so, now is the time to think about technology selection, process compression and optimization, rapid and efficient scale-up, process economics and validation. Now is the time to talk to Millipore's Access® Services PDS group.

Partners...from Molecule to Market

Millipore Process Development Scientists (PDS) are a worldwide team of highly skilled and trained engineers and scientists ready to partner with you during early phase clinical trials.

As part of the Access On-Site services team, process development scientists work side-by-side with you

at the bench in your lab or pilot plant. They have the expertise, skill, and knowledge to optimize the various unit operations involving filtration and chromatography technologies. They help you streamline the development process and reduce the risk of scale-up failures.

Millipore PDS Specialists . . .

- ▶ Help you identify process objectives and success criteria.
- ▶ Plan and execute experiments and analyze results using expert methodologies.
- ▶ Optimize the process development parameters that influence success criteria.
- ▶ Understand scaling principles and follow sound, reliable scaling procedures that are validated without difficulty.
- ▶ Collaborate with your process engineers to implement robust, reliable solutions that reduce risk when changing the scale of operation.
- ▶ Help you select the appropriate technology, providing written reports and data.
- ▶ Maintain strict confidentiality.
- ▶ Deliver a comprehensive report.

All studies incorporate your process development objectives and timeline. The scope of work encompasses all aspects of process development including bench-scale testing of the most appropriate separation technology, scale-up and economic calculations. There are no additional charges for

these services. Millipore's Process Development Scientists are equipped with the proper scale-down devices and test systems required for screening and optimizing various unit operations. All work is documented in a technical report.



Process Development Scientists

Process development scientists have extensive experience in upstream recovery and clarification, downstream purification and sterile filtration processes for various products such as:

- ▶ Monoclonal antibodies
- ▶ Recombinant proteins (fermentation/cell culture/transgenic plants)
- ▶ Plasma-derived proteins
- ▶ Gene therapy products such as plasmid DNA and viral vectors

Examples of Our Applications Expertise

Upstream Recovery

- ▶ Performed competitive analysis of NFF vs. TFF options to define the ideal process for mammalian cell clarification.
- ▶ Completed studies on the integration of depth filter clarification in combination with centrifugation.
- ▶ Characterized ultrafiltration and diafiltration processes for pDNA, proteins and viral vectors from microbial lysates in a Tangential Flow Filtration system.
- ▶ Optimized and performed filter sizing of sterile filtration for bioreactor media feeds.

Downstream Recovery

- ▶ Comprehensive review of sterile filter requirements for process intermediates, chromatographic pools and process buffers.
- ▶ Optimized ultrafiltration and diafiltration processes before formulation by determining the most appropriate membrane type and format, operating flow rate and TMP, diafiltration strategy, product recovery technique and CIP procedures.
- ▶ Evaluated Dynamic Binding Capacity with Prosep A affinity chromatographic media.
- ▶ Optimized virus removal filter surface area requirements based on buffer and protein concentration as well as location within the process train.
- ▶ Developed and executed virus spiking protocol for filter validation studies, partnering with customer and CTO.

The demands of bringing a biotherapeutic product to market places enormous pressure on process designers and technology transfer engineers. Speed to market is key requiring rapid, robust, and economic process scaling and optimization. Millipore know-how and experience can help you meet those goals.

To Receive More Information on Millipore's Access Services

Call your nearest Millipore office:

In the U.S. and Canada, call toll-free **1-800-MILLIPORE (1-800-645-5476)**

In the U.S., Canada and Puerto Rico, fax orders to **1-800-MILLIFX (1-800-645-5439)**

Outside of North America contact your local office.

To find the office nearest you visit www.millipore.com/offices

Internet: www.millipore.com

Tech Service: www.millipore.com/techservice

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