

“The only person who is educated is the one who has learned how to learn ... and change.”
(Carl Rogers)

Continuing education has become a worldwide regulatory requirement for the pharmaceutical and biotechnology industries. The FDA enforces the Code of Regulation as follows:

‘21CFR Part 211.25 Personnel qualifications.

(a) Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions....Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.’

To assist in keeping up with the latest and ever changing standards in separation technology and Biopharm processes Sartorius created EXPAND®, a comprehensive series of technical training courses covering both theoretical and practical aspects with a strong emphasis on hands-on, practical exercises.

Each participant receives a *‘Certificate of Achievement’* that documents the seminar / workshop topic, date and instructors name. This certificate satisfies the regulatory CGMP training requirement of Part 211.25, Personnel qualifications.

[Picture of Certificate with dummy copy]

Overview:

The EXPAND® technical training program consists of seminars and workshops that are designed to ensure that each course participant understands the theoretical subject matter and/or acquires hands-on, practical skills. The ultimate aim and purpose is to enable operators, technicians, specialists, supervisors and managers perform their work safely and efficiently.

Seminars are designed to provide general information regarding filtration topics and related subject material. Each seminar takes one hour for the presentation and question and answer session. Several seminars are usually presented in either one half day or full day program.

A list of seminar topics can be found on page X. The seminars range from Basic Principles of Filtration, Integrity Testing, and Validation to System Optimization and Crossflow Filtration (TFF.) More detailed abstract summaries are located in the inside cover sleeve jacket.

Workshops are designed for more in-depth lecture presentations coupled with practical hands-on, how-to-do approaches. Common practices and troubleshooting methodologies are explored. Participants take away a fuller understanding of the specific technology and practical operational know-how. Programs are generally one to two days in length, typically held on-site.

Workshops are targeted for those staff and managers who require practical hands-on experience. We offer several focused programs;

- Sterilization and Integrity Testing of Membrane Filters
- Sterilizing Grade Filter Membranes: How to Choose and Validate
- Use of Crossflow Filtration in the BioPharm and Biotech
- Application and New Sterility Testing Methodology
- Large Scale Purification Methods Using Membrane Adsorber Technology

Who Should Attend?

These programs focus on the learning requirements for operators, technicians, specialists and managers working in process development, validation, production and quality control areas.

Table of Content	Page No.
Technical Seminars	X
Workshops Courses	X
BioPharm-Alliance Program	X
Seminar Abstracts	Rear Jacket Pocket

To enroll or further explore Training and Seminar options, simply call Sartorius Corporation (800-368-7178 X8200) to arrange for EXPAND Training and Seminar Services.

We can organize half-day or full-day seminars that present the subjects listed below. All presentations can be at your facilities or at another convenient location.

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EXPAND Your Mind Seminars

These seminars usually require one (1) hour to present, followed by time allotted for an in-depth question and answer period. This allows the participants to fully experience the training experience and to achieve the training objectives. Please see seminar abstracts in rear jacket pocket for a detailed description and learning objectives.

Integrity Testing of Filter Elements

- 862121 Test Methods for Integrity Testing
- 862122 The Water Intrusion Test for Hydrophobic Filter Elements
- 862123 Validation of Automatic Integrity Systems

Filtration Technology

- 862231 Principles of Filtration Technology
- 862233 Process Filtration in the Pharmaceutical Industry
- 862232 Adsorption Characteristics of Membrane Filters
- 862234 Practical Aspects of Air Filtration
- 862235 Steam Sterilization of Membrane Filters

Membrane Adsorption Separation Technology

- 862340 Rapid & Effective Separation Technology with Membrane Adsorbers
- 862341 Modular Design of Membrane Adsorbers for Large Scale Purification of Biomolecules

Validation & Qualification Services

- 862351 Validation Service for Filter & Current Regulatory Requirements
- 862352 Polymeric Extractables Testing and Analysis
- 862354 FACTS Services Program
- 862355 Process Simulated Bacteria Challenge Tests

Sizing and Optimizing Filtration Systems

- 862455 INCREASE® – The Process Optimization Program
- 862456 Design Optimization of Liquid Filtration Systems
- 862457 Design Optimization of Air Filtration Systems

Crossflow Technology

- 862571 Crossflow System Capabilities
- 862572 Scale-up of Crossflow Systems
- 862573 Principles of Crossflow Filtration

How to register or for more information please contact:

Sartorius EXPAND Seminar & Training Director at

Phone: (800)-368-7178 X 8200

Fax: (631)-254-4253

Expand® Your Mind Training Courses / Workshops

Continuing education has become a worldwide regulatory requirement for the pharmaceutical and biotechnology industries. To help you in keep up with the latest and ever changing standards in separation and biopharmaceutical technology, Sartorius offers a series of technical training courses / workshops. The programs cover theoretical, practical aspects and troubleshooting, while emphasizing a strong hands-on learning experience.

Training Courses for the Pharmaceutical & Biotechnology Industries

Course No. 862024 Sterilization and Integrity Testing of Membrane Filters

The participants in this training course on steaming-in-place and in-place integrity testing will acquire theoretical knowledge and practical experience in the handling of filters used in sterile filtration.

Theoretical aspects include:

- Basic principles of filtration (depth filters, membrane filters)
- Integrity testing of membrane filters (methods, testing equipment)
- Physical and theoretical principles of the steam-in-place sterilization of filter assemblies

Practical aspects include:

- Performing integrity tests
- Practical tests with in-line steam sterilization of filter cartridge assemblies

Total course time: 1-2 days

Who Should Attend?

Staff working in the areas of process development, pilot plant, production, quality assurance and quality control.

Course No. 862025 Sterilizing Grade Membrane Filters: How to Choose and Validate

This course will educate and be a practical guide to sterile liquid filtration, to validating filters in your process, to understanding the ins-and-outs of integrity testing, and how to decide which filter type and membrane best meets your product and process requirements. It uses PDA Technical Report No. 26 and regulatory sources as educational materials that will be used during the course.

- Explanation of sterilizing membrane filters, materials of construction used in production.
- How to choose a filter based on physical and chemical characteristics.
- How to choose a filter based on operating and processing parameters and constraints.
- Integrity tests: Bubble Point, Diffusive Flow: when and why to test, troubleshooting failures.
- Bacterial Challenge Testing and correlation to integrity testing.
- Examples validation testing services describes the when to do, which to conduct and how to design in order to meet NDA and CGMP requirements.
- Discussion sessions give participants opportunities to ask questions concerning their work problems and to identify solutions.

Total Course Time: 1 day

Who Should Attend?

Staff working in the field of validation, quality assurance / quality control, regulatory affairs, and production

Course No. 862008

The Use of Crossflow Filtration in Pharmaceutical and Biotechnology Industries

The participants will acquire practical knowledge about CGMP-compliant processing using crossflow filtration (TFF.)

Theoretical aspects include:

- Crossflow filtration theory
- Membrane characterization / membrane selection
- Factors critical to performance
- Scaling up
- Operating conditions
- Clean-in-place (CIP)
- Steam-in-place (SIP)
- Integrity testing
- Separation & Clarification applications in biotechnology

Practical exercises:

- Operational set-up of the systems
- Determining the flux rate for water
- Demonstration of steam-in-place (optional)
- Cell and particulate retention by microfiltration
- Concentration of protein solutions by ultrafiltration
- Removal of low-molecular weight constituents by diafiltration
- Cleaning
- Analysis and discussion of the results

Total course time: 1-2 days

Who Should Attend?

Staff working in areas ranging from research to production. The modular structure of the course is suited for participants with various levels of knowledge and allows them to request their own topics.

BioPharm-Alliance Program:

Customized more advanced seminar /work groups programs can be designed to meet the specific needs for those personnel involved in:

- Process Development and Scale-up Production
- Regulatory Compliance and cGMP issues
- Quality Assurance, Quality Control and Analytical services
- Operations – Plant and Utilities Management
- cGMP-compliant process control
- Process Validation and System Qualification
- Sterile production – Aseptic Processing
- Downstream processing – Crossflow Systems
- Integrity Testing: Operations and Qualification
- System Sizing and Optimization

We can provide a consultive service atmosphere to allow exploring specific process and quality problems. Whether the issue is addressing regulatory issues such as; filling IND, expediting NDA, Compliance problems, 483's or focusing on process scale-up and time-to-market, we can bring industry experience and experts to assist you in problem solving programs.