



EXPAND[®] Your Mind
Seminars and Training
Courses/Workshops

CERTIFICATE OF ACHIEVEMENT EXPAND[®] YOUR MIND

Is presented to

Attendee Name

on behalf of Sartorius Corporation,

in recognition of participation in the training program:

**Seminar Program –
Training Course/Workshop Title**

Date

**"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 Federal Regulations as follows:

21CFR Part 211.25

Personnel qualifications.

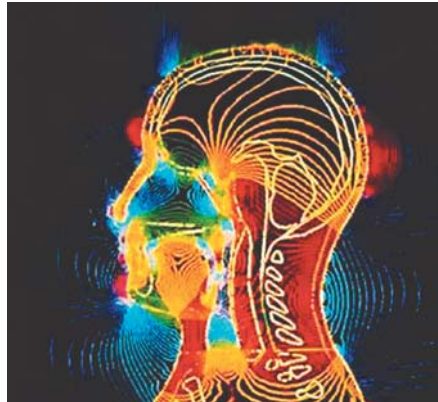
(a) Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions....Training in current good manufacturing practice shall be conducted by qualified 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 seminars, technical training courses and workshops covering both theoretical and practical aspects of these technologies, with a strong emphasis on hands-on, practical exercises.

Each participant receives a **CERTIFICATE OF ACHIEVEMENT** upon completion of the training. This certificate satisfies the regulatory cGMP training requirement of Part 211.25, Personnel qualifications.

Purpose and Objectives:

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, as applicable, acquires hands-on, practical skills. The ultimate aim and purpose is to enable operators, technicians, specialists, supervisors and managers to perform their work safely and efficiently.



EXPAND® Your Mind Seminars

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 4. Seminar topics include:

- Integrity Testing of Filter Elements
- Filtration Technology
- Membrane Adsorption Separation Technology
- Validation Et Qualification Services
- Sizing and Optimization Filtration Systems
- Crossflow Technology

Please see the abstracts in the rear jacket pocket for a detailed description of the seminars.

Who Should Attend?

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

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EXPAND® Your Mind Training Courses/Workshops

Training Courses/Workshops are designed around in-depth lecture presentations and practical, hands-on training modules where applicable. 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 including:

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

EXPAND® Your Mind Seminars

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

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 absorb the training and to achieve the objectives. Please see the abstracts in the rear jacket pocket for a detailed description of the seminars.

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 Test Systems

Validation & Qualification Services

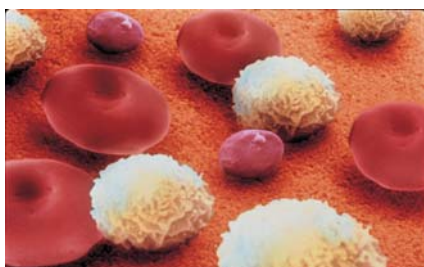
- 862351 Validation Service for Filter & Current Regulatory Requirements
- 862352 Polymeric Extractables Testing and Analysis
- 862354 FACTS Services Program
- 862355 Process Simulated Bacteria Challenge Tests

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

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



Membrane Adsorption Separation Technology

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

Crossflow Technology

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



To enroll or further explore Training and Seminar options, please contact the Sartorius EXPAND Seminar & Training Director at:

Phone: 800-368-7178, extension 8200
Fax: 631-254-4253
Email: expand@sartorius.com

EXPAND® Your Mind Training Courses/Workshops

Training Courses for the Pharmaceutical and Biotechnology Industries

Continuing education has become a worldwide regulatory requirement for the pharmaceutical and biotechnology industries. To help you in keeping 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.

Course No. 862024 Sterilization and Integrity Testing of Membrane Filters

The participants attending 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 depending on class size

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, validating filters in your process, understanding the ins-and-outs of integrity testing, and how to decide which filter type and membrane best meets your product and process requirements. PDA Technical Report No. 26 and regulatory sources are used as educational materials 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
- Validation testing services describes the when to do, what 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

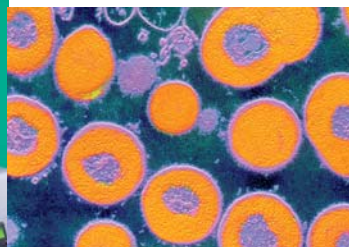
Practical exercises:

- 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 depending on class size

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.



The biopharmaceutical industry is highly regulated and confronted with ever-changing compliance parameters. In addition to complying with these regulations, companies must increase capacity and lower costs to remain competitive. Resolving the complexity of cost efficiency and regulatory compliance into a balanced solution needs the support of a comprehensive service. This total service is the BioPharm-Alliance.

The BioPharm-Alliance's multitude of services addresses the critical success factors facing the biopharmaceutical industry: time-to-market, cost of goods, production capacities, and regulatory compliance. We evaluate, analyze, and optimize each individual success factor for potential impact on regulatory compliance.

EXPAND® Seminars and Training Topics:

A detailed description and example of the learning objectives is found in the rear jacket pocket.

- FDA risk-based approach
- FDA inspection
- 21 CFR Part 11/GAMP
- Aseptic processing
- Upstream/Downstream process
- Process validation
- Cell culture
- Integrity testing
- Quality control & quality assurance

EXPAND® Training Courses and Services:

The courses listed below are typically one day. The costs and fees will vary depending on location and class sizes.

Inspection Preparation

- Preparing for Pre-Approval Inspections
- Managing FDA Inspections
- Preparing for Inspections of APIs
- Responding to an Unfavorable Inspection

Auditing

- Effective Auditing Practices and Techniques
- Systematic Techniques for Auditing Quality Systems
- Inspections of Computer Systems
- Auditing Computerized Laboratory & Manufacturing Operations

Regulatory

- Navigating Regulatory Requirements for New Facility Planning
- Managing Regulatory Risk
- Current Developments in Manufacturing APIs
- Managing Recalls

Regulatory (continued)

- Updates on FDA Regulatory Trends and Emerging Issues
- Fundamentals of CGMP Regulations for Senior Management
- Fundamentals of Pharmaceutical CGMP Regulations for Technical Personnel
- Pharmaceutical GMP Regulations for Biotechnology Companies
- cGMP Regulations for Sterile Products
- cGMP Regulations for Production of Investigational Medicinal Products
- cGMP for Active Pharmaceutical Ingredients (APIs)
- CGMP Regulations for Blood Collection Facilities
- Update on FDA's CBER Initiatives
- cGMP Regulations in the QC Laboratory

Quality Systems

- Quality Systems Theory and Design
- Out-of-Specification (OOS) and Failure Investigations
- Effective Change Control Systems
- Standard Operating Procedures and Documentation Control Systems

Validation

- Planning Qualification Studies for New Facilities
- Analytical Methods Validation
- Fundamentals and Essentials of Validation
- Validation Master Planning
- Preparing Validation Policies and Project Plans
- Preparing Validation Protocols
- Preparing System Specifications
- Validation Optimization - Current Trends
- Fundamentals of Cleaning Validation

Manufacturing Technology

- Aseptic Technique in Sterile Pharmaceutical Production
- Pharmaceutical Water Systems
- Technology Transfer Planning
- New Drug Development Planning
- Validation of Computer-Controlled Processes
- 21 CFR Part 11: Electronic Signatures and Electronic Records

Process Improvement and Control

- Risk Assessment Techniques for Bio-Pharmaceutical Manufacturing
- Integration of Risk Assessment with Quality Systems
- Root Cause Analysis

We can provide a consultative service atmosphere to explore specific process and quality problems. Whether the topic is addressing regulatory issues such as filing 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.

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