



# Integrity Testing Training and Certification

A course teaching current theories and methods of integrity testing

Thousands of people from more than 30 multinational companies have attended Millipore's two-day certification course on integrity testing. The course objective is to teach participants membrane filter integrity testing theory and methods. Experienced instructors combine hands-on laboratory exercises with interactive classroom instruction to present the most up-to-date methods of integrity testing.

Attendees perform bubble point and diffusion integrity tests on several hydrophobic and hydrophilic cartridge filters. These manual integrity tests are conducted at individual laboratory stations. Each laboratory is fully-equipped with all the typical instrumentation of an integrity testing lab, including automatic testing equipment.

Millipore offers integrity testing courses several times throughout the year at customer sites and Millipore facilities. Attendees receive a complete training manual that includes all the information covered in the course. Small class sizes guarantee individual attention.

To achieve certification, participants are required to conduct integrity tests on filters with documented integrity test results. A comparison of the documented results and the students' results determine if the attendee has mastered the methods of integrity testing presented in the course. Millipore presents an integrity testing certificate to participants who successfully complete this requirement.

## Who Should Attend?

This interactive course is designed for pharmaceutical, biotechnology and medical device manufacturing personnel who use integrity test filters. Participants should include quality and validation personnel, operators, technicians and supervisors.

## Why Is the Course Offered?

Current Good Manufacturing Practices (cGMP) require operators to be experienced and trained on day-to-day operations, including integrity testing. According to the Code of Federal Regulations 21 CFR §211.25, "Each

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## What You Will Learn

- ▶ The fundamentals of integrity testing theory
  - ▶ Types of filters, how they function, and their applications
  - ▶ Sound troubleshooting techniques
  - ▶ Proper methods for performing manual bubble point and diffusion tests
  - ▶ How principles apply to automatic integrity test systems
  - ▶ Become certified to conduct integrity tests per cGMP requirements
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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." Millipore's Integrity Testing Certification course will prepare participants to meet cGMP criteria.

### Accreditation

Millipore is an authorized provider of Continuing Education Credits through IACET. IACET (International Association of Continuing Education and Training) is an internationally recognized organization dedicated to improving the quality of continuing education. 1.1 CEUs are available to trainees upon successful completion of this course.

### About the Instructors

A group of experts developed and teach this course. Laboratory instructors have extensive experience conducting filtration integrity tests for the medical device, biotechnology

and pharmaceutical industries. Class instructors are current on integrity testing theory, practice and validation requirements. They are also knowledgeable about new industry standards and will share their knowledge and experience during the training.

### How to Register

To request a registration form or receive additional information, call your Millipore Applications Specialist or the Millipore office nearest you. You can also find information about Millipore training programs on-line at [www.millipore.com/training](http://www.millipore.com/training).

This Integrity Testing course is only one of many technology, operation, and validation support programs in place that ensure that Millipore products meet the high standards of the biopharmaceutical industry.

### To Receive More Information

For additional information 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)**

Internet: [www.millipore.com/training](http://www.millipore.com/training)

Tech Service: [www.millipore.com/techservice](http://www.millipore.com/techservice)

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