



Integrity Test Training and Certification



Accurate testing of filter integrity is critical to ensuring efficient, safe pharmaceutical production and regulatory compliance. Effective training of personnel to assure an understanding of the knowledge, skills and competencies related to integrity testing is also critical. International GMP regulations require that personnel should receive training appropriate to the duties assigned to them, and continuing training should be given. Pall can help you meet these requirements by providing high quality training through experienced instructors to assure immediate application of integrity test principles and techniques in your operation.

Course Description

The Integrity Test Training is an interactive course designed for manufacturing operators and other relevant staff to assure an understanding of the integrity test from basics of filtration and integrity testing, regulatory requirements, various types of integrity tests, instruments used, troubleshooting, and hands-on application.

Features and Benefits

- ▶ Courses designed and led by experts in pharmaceutical and biotech applications.
- ▶ Each course is customized to ensure maximum relevance to your operation following 1:1 discussion with our training experts.
- ▶ Ensures optimal use of training budgets.
- ▶ Can be held locally or at Pall's specialized training facilities.
- ▶ Pall staff can work with your local training department to ensure course meets any specific requirements.

Who Should Attend

- ▶ Manufacturing operators, supervisors and managers requiring a working knowledge of integrity testing
- ▶ QA/QC staff

Course Content

- ▶ Filter Overview/Basics
 - Filter Purpose
 - Filter Construction
 - Lot Number
- ▶ Integrity Test Basics
 - Why Integrity Test?
 - Test Requirements
 - Regulatory Requirements
- ▶ Types of Integrity Test
 - Destructive Tests
 - Bacterial Retention
 - Non-destructive Tests
 - Bubble Point
 - Forward Flow
 - Water Intrusion Testing (WIT)
- ▶ Troubleshooting (Forward Flow/Bubble Point Tests)
 - What To Do
 - Industry Reference (PDA) Decision Tree
 - Pre/Post Use Recommendations
- ▶ Water Intrusion Test (WIT)
 - Why WIT?
 - Concept and Correlation
 - Troubleshooting
- ▶ Summary/Wrap Up of Basic Training Session (“pre-practical summary”)
- ▶ Integrity Test Instrument Training
- ▶ Discussion/Q&A

Course Objectives

The course delivery and content is customized to ensure that attendees:

- ▶ Understand the importance of testing filters for integrity as a critical step in the manufacturing process to make sure that the filter functions as intended.
- ▶ Understand how the theory and practice of the range of integrity tests available differ.
- ▶ Can apply practical experience of operating manual and automatic integrity test instruments and systems.

Additional Notes

- ▶ Course includes practical section using integrity test instrumentation, as well as a quiz to measure competency and understanding.
- ▶ Certificate of Training is included for all attendees who have successfully completed the course.
- ▶ Course evaluations help Pall improve content and delivery of training.

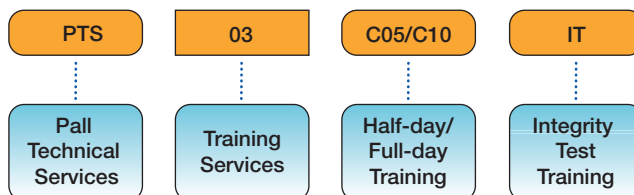
Course Duration

Training can be provided in half day or full day depending upon your specific needs and depth of training required.

Location

On-site or at Pall's local training facility.

Ordering Information



Charges

Where possible, Pall provides a fixed price in advance. When this is not possible, Pall will give an estimate to assist you in budgeting and cost control. The final invoice provides detail on items such as labor, materials, etc.

Contact Us

Contact your local Pall representative or email us to discuss your specific training requirements.

Global Expertise...Delivered

Visit us on the Web at www.pall.com/biopharm
e-mail us at biopharm@pall.com

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The information provided in this literature was reviewed for accuracy at the time of publication. Product data may be subject to change without notice. For current information consult your local Pall distributor or contact Pall directly.



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