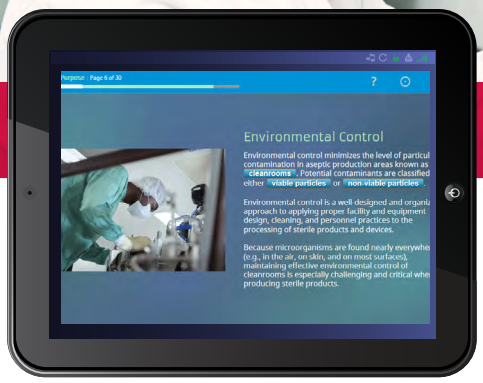
Basics of Aseptic Processing



Quality & Compliance Essentials

"As a GMP trainer, I need to provide awareness training to our sterile manufacturing team on aseptic processing principles and regulatory expectations.

"The challenge is keeping up with US, EU and ISO standards to keep the material up-to-date."

Aseptic processing includes sterilization of products as well as any component, container, and closures. Companies that manufacture sterile products must ensure that the production workforce is aware that a high-quality and controlled environment must be in place to prevent potential microbiological and particulate contamination.

GMP Trainers and Operation Development Teams often pull from a number of regulations, including guidelines and standards such as ICH Q9 and ISO 14644.

UL's Basics of Aseptic Processing courses deliver this education in an engaging and interactive online format. The courses have been authored by industry-leading subject matter experts and focus on critical areas of aseptic processing.

QA teams can deliver these courses to the entire aseptic processing team in a cost-effective manner, eliminating the need to collect the research and develop this regulatory content on their own.

The Basics of Aseptic Processing program includes these five courses:

- Principles of Aseptic Processing
- Principles of Sterilization
- Principles of Cleaning Validation
- Gowning for Sterile Manufacturing
- Environmental Control and Monitoring

Principles of Aseptic Processing — PHDV71

Because microbiological and particulate contamination can potentially cause serious health problems in animals and humans, it is vital that sterile products be manufactured, filled, and packaged in an aseptic environment.

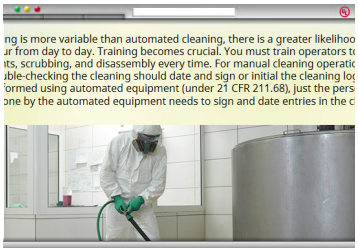
This course will address the general principles and practices necessary to assure product sterility and safety related to aseptic processing.

Principles of Sterilization — PHDV81

This course discusses the purpose of sterilization and basic principles of several commonly used sterilization techniques. The course covers such topics as sterilization, moist heat, dry heat, gas, radiation, chemical, filtration, and sterility assurance. After completing this course, the learner will be able to identify six types of sterilization, recognize methods for validating sterilization, and identify the key aspects of sterility assurance.

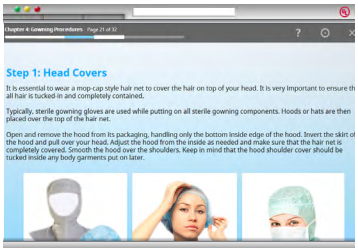
Principles of Cleaning Validation — PHA37

The cleaning of equipment used in a pharmaceutical operation can be a complex process. Even the smallest amount of chemical residual material in equipment can be extremely dangerous. This course will identify the basics of cleaning validation in pharmaceutical manufacturing operations. After completing this course, learners will be able to recognize why a cleaning Standard Operating Procedure is necessary.



Gowning for Sterile Manufacturing — PHA63

Employees involved in the production of sterile products must have a basic knowledge of sanitization and sterilization, the microbiological principles involved, and the importance of proper gowning and working in cleanrooms. This course covers the regulatory requirements of both the European Union (EU) and FDA.



Environmental Control and Monitoring — PHDV87

This course examines the regulatory requirements for environmental control and monitoring and how to prevent particulate and microbiological contamination of sterile products and devices. This course covers the control, monitoring, documentation and prevention. After completing this course, learners will be able to recognize the methods of environmental control and monitoring, and identify how to prevent contamination.

An Engaging Learning Experience

To ensure the learners retain the material, each course contains "interactive quizzes" that must be completed before learners can move to the next chapter. Learners can take these quizzes as often as possible to achieve the 80% passing score. These attempts are not reflected in their qualification record.

In addition, courses contain a number of interactive buttons that learners must click before continuing to the next page. This idea of "chunking" information has been proven to improve retention in adult learners.

Affordable Pricing

Pricing for the set is based on an organization's employee size. For a firm with 500 employees, for example, the subscription cost works out to approximately $20 per learner. These courses can be delivered in one of three methods:

- SCORM: Course files are provided in SCORM, so they can be delivered via your organization's SCORM-compliant learning management system. Optional maintenance fees are available, in the event that the courses are updated to reflect new regulations.
- AICC: Course files are delivered as AICC, so they can be delivered via your organization's AICC-compliant learning management system.
- ComplianceWire®: Courses can be delivered through UL's ComplianceWire learning management system for an additional fee.

Get Started

To learn more about the Basics of Aseptic Processing courses, or arrange a demo, please contact Pat Thunell at pat.thunell@ul.com.