Sterile Compounding Course

ACPE Activity Number: 0651-0000-20-001-H07-P & T through to 0651-0000-20-007-H07-P & T
Release Date: September 1, 2020
Expiration Date: September 1, 2023
Activity Type: Knowledge-based
CE Credits: 9 hours

Accreditation for Pharmacists and Technicians

Lyceum, LLC is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Target Audience

This course is designed for those working in a compounding controlled environment that need to understand how to properly operate within a cleanroom.

Activity Overview

This course will provide the learner with the knowledge to properly garb for entering the cleanroom, operate inside a cleanroom, cleaning and disinfection, environmental monitoring and proper aseptic technique.

Learning Objectives and Schedule of Activities

Activity CE Information	**Title, Description and Learning Objectives**
ACPE #: **0651-0000-20-003-H07-P** **0651-0000-20-003-H07-T** CE Hours: **2.0** Activity Type: **Knowledge-based**	**Title: Engineering controls and Facility Design** This *knowledge-based activity* is of importance to all pharmacists and pharmacy technicians working inside a controlled environment (related to sterile compounding). **Learning Objectives:** At the conclusion of this activity, Pharmacists should be able to: 1. List the 4 design principles of building a cleanroom 2. Arrange the order of cleaning for both the Primary and Secondary Engineering Controls 3. List the two broad categories of disinfectants 4. Define contact time, detergent, cleaning, disinfection, sanitization, sterilization and asepsis 5. Describe the techniques used for cleaning controlled environment surfaces At the conclusion of this activity, Technicians should be able to: 1. Explain the difference between cleaning and disinfection 2. Arrange the order of cleaning for both the Primary and Secondary Engineering Controls 3. List the two broad categories of disinfectants 4. Define contact time, detergent, cleaning, disinfection, sanitization, sterilization and asepsis 5. Describe the techniques used for cleaning controlled environment surfaces

Activity CE Information	Title, Description and Learning Objectives
ACPE #: **0651-0000-20-002-H07-P** **0651-0000-20-002-H07-T** CE Hours: **1.0** Activity Type: **Knowledge-based**	**Title: Garbing for the Cleanroom** This *knowledge-based activity* is of importance to all pharmacists and pharmacy technicians working inside a controlled environment (related to sterile compounding). **Learning Objectives:** At the conclusion of this activity, pharmacists should be able to: 1. State 3 behaviors or habits that are prohibited while in the cleanroom 2. Discuss what dictates the level of garb worn for compounding 3. Discuss the maximum number of hours hazardous gowns can be worn according to USP Chapter <800> 4. List 3 often missed areas of the hand during hand sanitization 5. Explain the reason for performing gloved fingertip and thumb sampling three times initially At the conclusion of this activity, technicians should be able to: 1. Discuss cleanroom best practices to minimize contamination 2. Identify 3 components of garb that must be used in compounding sterile preparations 3. Discuss the reasons why garb is necessary 4. Explain the sequence for donning garb 5. Discuss the garbing requirements for non-hazardous drugs (HD) and HD compounded sterile preparations (CSPs) and the differences in garbing
ACPE #: **0651-0000-20-001-H07-P** **0651-0000-20-001-H07-T** CE Hours: **2.0** Activity Type: **Knowledge-based**	**Title: Cleaning and Disinfection of the Cleanroom** This *knowledge-based activity* is of importance to all pharmacists and pharmacy technicians working inside a controlled environment (related to sterile compounding). **Learning Objectives:** At the conclusion of this activity, Pharmacists should be able to: 1. List the 4 centers of excellence for cleaning and disinfection of the cleanroom 2. Explain how often surfaces of the cleanroom should be cleaned and disinfected 3. Explain the decision making process for selecting disinfectants 4. Discuss which cleaning agents are used for deactivating hazardous drugs 5. Explain how to assess cleaning efficacy At the conclusion of this activity, Technicians should be able to: 1. Discuss cleanroom best practices to minimize contamination 2. Arrange the order of cleaning for PECs and SECs 3. List two broad categories of disinfectants 4. Describe the 4 steps of clean hazardous drugs (HDs) 5. Explain what must be cleaned and disinfected within an ISO 5 area

Activity CE Information	Title, Description and Learning Objectives
ACPE #: **0651-0000-20-004-H07-P** **0651-0000-20-004-H07-T** CE Hours: **1.0** Activity Type: **Knowledge-based**	**Title: Proper Compounding Aseptic Technique** This *knowledge-based activity* is designed for those working in a compounding controlled environment that need to understand how to properly operate inside secondary and primary engineering controls. **Learning Objectives:** At the conclusion of this activity, Pharmacists should be able to: 1. Discuss the purpose of using "just-in-time" or "on-demand" use of materials 2. Discuss why moving slowly and deliberately in the cleanroom is so important 3. Explain the requirements for routine sanitization of operators while performing sterile compounding 4. Explain the importance of disinfecting gloves upon re-entering the PEC 5. Explain how analyzing a process can prevent a potential contamination At the conclusion of this activity, Technicians should be able to: 1. Identify the proper way to bring materials into the room 2. Explain 3 behaviors that are not appropriate for the cleanroom and why 3. Discuss the principle of "first air" as it relates to critical sites 4. Discuss one technique for improving the glove sanitization process 5. Discuss the importance of proper staging of materials and the 3 issues it can prevent
ACPE #: **0651-0000-20-006-H07-P** **0651-0000-20-006-H07-T** CE Hours: **2.0** Activity Type: **Knowledge-based**	**Title: Cleanroom Environmental Monitoring** This *knowledge-based activity* is of importance to all pharmacists and pharmacy technicians working inside a controlled environment (related to sterile compounding). **Learning Objectives:** At the conclusion of this activity, Pharmacists should be able to: 1. Discuss two types of sampling that must be included in an environmental monitoring program according to USP 797 2. Explain the relevance of 0.5 and 5 micron sized particles in air sampling 3. Discuss how frequently surface sampling must be performed according to USP <797> 4. Discuss the minimum frequency total particle counts need to be performed according to USP <797> 5. Discuss the point at which an investigation into a contamination should be conducted At the conclusion of this activity, Technicians should be able to: 1. List 3 factors that increase the risk of a compounding procedure 2. List the 3 types of environmental monitoring samples that can be taken 3. Describe the motion used to perform surface sampling 4. Discuss 3 activities that can be assessed using particle counts 5. Discuss the main limitation to viable air sampling

Activity CE Information	Title, Description and Learning Objectives
ACPE #: **0651-0000-20-007-H07-P** **0651-0000-20-007-H07-T** CE Hours: **1.0** Activity Type: **Knowledge-based**	**Title: Interpreting Cleanroom Certification Reports** This *knowledge-based activity* is of importance to all pharmacists and pharmacy technicians working inside a controlled environment (related to sterile compounding). **Learning Objectives:** At the conclusion of this activity, pharmacists should be able to: 1. Discuss the relevant parts of a cleanroom certification report 2. Identify what constitutes an action level for both particle counts and viable sampling 3. Discuss the importance and significance of 0.5 micron sized particles in a cleanroom environment 4. Discuss the concept of "just in time" as related to materials brought into the cleanroom and why it's important At the conclusion of this activity, technicians should be able to: 1. Discuss the difference between viable sampling and non-viable sampling or total particle counts 2. Explain why non-viable sampling isn't the most accurate term 3. Discuss the importance of keeping particle counts in your cleanroom as low as possible 4. Discuss the importance and significance of 0.5 micron sized particles in a cleanroom environment

Faculty Information

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Disclosures

All planners, speakers, authors, and reviewers involved with content development for continuing education activities provided by Lyceum are expected to disclose any real or perceived conflict of interest related to the content of the activity. Detailed disclosures will be included in participant materials or given prior to the start of the activity.

Methods and CE Requirements

This online activity consists of a combined total of 6 learning modules. Pharmacists and pharmacy technicians are eligible to receive a total of 9.00 hours of continuing pharmacy education by completing all 6 modules.

To receive credit, registrants must attend the activity; complete a course learning assessment or quiz, Activity Evaluation; and, and submit their NABP e-profile ID and date of birth (MM/DD). LyceumCE.com will distribute CE credit through submission of the completed activity to CPE Monitor.

Important Note – ACPE 60 Day Deadline:
Per ACPE requirements, CPE credit must be claimed within 60 days of being earned – no exceptions!
To verify that you have completed the required steps and to ensure your credits have been reported to CPE Monitor, we encourage you to check your NABP eProfile account to validate your credits were transferred

successfully before the ACPE 60-day deadline. After the 60 day deadline, ASHP will no longer be able to award credit for this activity.

System Technical Requirements

Computer with Internet and web browser (Chrome, Firefox, Safari or Internet Explorer) and speakers