Quality Management

Release Date: April 24, 2019  
Expiration Date: April 24, 2022  
Activity Type: Application-based

Accreditation for Pharmacists

The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Target Audience

This program is intended for pharmacists managing and developing cleanroom personnel and/or compliant compounding facilities.

Activity Overview

The program provides 38 hours of ACPE continuing education for pharmacists, incorporating recorded presentations, readings, video demonstrations, and exercises in curricular modules. The program covers sterile product preparation practice standards and regulations, pharmacy calculations, facilities and engineering controls, environmental monitoring, cleanroom personnel behaviors, sterile compounding components and procedures, stability and sterility, beyond-use date assignment, nonsterile to sterile compounding, hazardous drugs, managing products until final check or disposal, patient care, and overall quality management. After completing all of the modules, participants should be proficient in the both basic compounding techniques and advanced skills required to lead and manage safe and compliant sterile product preparation in a cleanroom environment.

Learning Objectives and Schedule of Activities

<table>
<thead>
<tr>
<th>Activity CE Information</th>
<th>Title, Description, Faculty, and Learning Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACPE # 0204-0000-19-754-H07-P</td>
<td>Title: Quality Management</td>
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<tr>
<td>CE Hours: 3</td>
<td>This activity describes managing all the components associated with ensuring high quality sterile product preparation operations including personnel training, environmental monitoring, and standard operating procedures.</td>
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<tr>
<td>Activity Type: Application</td>
<td>Learning Objectives:</td>
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- Summarize components of a sterile product preparation training program. 
- Contrast personnel education and testing methods to ensure safe and compliant sterile product preparation. 
- Propose a plan for remediating sterile product preparation competency. 
- Identify mechanisms for ensuring employee safety during the compounding process. 
- Differentiate methods for analyzing and reporting cleanroom safety events. 
- Design an employee Medical Surveillance Program. 
- Develop an environmental and personnel sampling program. 
- Restate equipment and cleanroom certification and maintenance requirements. |
CE Activity Announcement

- Distinguish key components for developing and revising master formulation records, compounding records, and standard operating procedures.
- Evaluate outsourced compounded sterile preparations and services using key variables, decision points, and regulatory standards.
- Recommend a plan for conducting routine inspections of internal compounding operations and outsourced compounding services.
- Identify challenges and opportunities for working with internal facilities and environmental departments.

Faculty Information

Elaine Strauss, Pharm.D., M.S.
Pharmacy Clinical Consultant
The WorkingBuildings Group
Atlanta, Georgia

Disclosures

In accordance with the ACPE’s and ACCME’s Standards for Commercial Support, anyone in a position to control the content of an educational activity is required to disclose to the accredited provider their relevant financial relationships. In accordance with these Standards, all potential conflicts of interests have been resolved. An individual has a relevant financial relationship if he or she (or spouse/domestic partner) has a financial relationship in any amount occurring in the last 12 months with a commercial interest whose products or services are discussed in the activity content over which the individual has control.

As defined by ACCME, a commercial interest is any entity producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on, patients. The Standards for Commercial Support do not consider providers of clinical service directly to patients to be commercial interests.

- Elaine Strauss, Pharm.D., M.S., WorkingBuildings Group: consultant
- All other planners, presenters, reviewers, and ASHP staff report no financial relationships relevant to this activity.

Methods and CE Requirements

This online activity consists of a combined total of 16 learning modules. Pharmacists are eligible to receive a total of 38.00 hours of continuing education credit by completing all 16 modules within this certificate program.

Participants must participate in the entire activity, complete the evaluation and all required components to claim continuing pharmacy education credit online at ASHP eLearning Portal. Follow the prompts to claim credit and view your statement of credit within 60 days after completing the activity.

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
CE Activity Announcement

System Requirements Courses and learning activities are delivered via your Web browser and Acrobat PDF. Users should have a basic comfort level using a computer and navigating web sites.

View the [minimum technical and system requirements](#) for learning activities.