

Accreditation Council for Pharmacy Education

135 S. LaSalle Street, Suite 4100 Chicago, IL 60603-4810

Phone (312) 664-3575 Fax (312) 664-7008 http://www.acpe-accredit.org

UNIVERSAL ACTIVITY NUMBER (UAN): 0384-9999-22-521-L07-P

0384-9999-22-521-L07-T

Provider Name: National Pharmacy Technician Association (NPTA)

Cancel

Cosponsor(s): 9999 Joint Providership (L)

Activity Type: Application

Activity Title: Sterility Assurance Training: Day 1

Learning Objectives:

(Pharmacists)

At the completion of this activity, the participant will be able to:

 Review the minimum standards and best practices set forth in USP 797 to be followed while preparing compounded sterile preparations.

- 2. Integrate USP compliance and state specific Board of Pharmacy regulations into sterile compounding
- 3. Explain the role of the designated person and their responsibilities regarding sterile compounding.
- 4. Describe the process for proper hand washing and garbing for sterile compounding.
- 5. Discuss process validation and personnel validation for aseptic compounding.
- 6. Outline the systems and processes to prevent contamination in a sterile compounding facility.
- 7. Explain the process for performing a media fill.
- 8. Describe how sterile compounding facilities must be designed, outfitted, and maintained properly to minimize the risk of contamination of CSPs.
- 9. Discuss USP Insanitary Conditions Guidelines and the implications that has on compounding pharmacies.
- 10. Explain the importance of a monitoring program for viable airborne particles to assess microbiological air quality in all classified areas.
- 11. Review microbiological air and surface monitoring programs that must be included.

Learning Objectives:

At the completion of this activity, the participant will be able to:

(Pharmacy Technicians)

- 1. Review the minimum standards and best practices set forth in USP 797 to be followed while preparing compounded sterile preparations.
- 2. Integrate USP compliance and state specific Board of Pharmacy regulations into sterile compounding practice.
- 3. Explain the role of the designated person and their responsibilities regarding sterile compounding.
- 4. Describe the process for proper hand washing and garbing for sterile compounding.
- 5. Discuss process validation and personnel validation for aseptic compounding.
- 6. Outline the systems and processes to prevent contamination in a sterile compounding facility.
- 7. Explain the process for performing a media fill.
- 8. Describe how sterile compounding facilities must be designed, outfitted, and maintained properly to minimize the risk of contamination of CSPs.
- 9. Discuss USP Insanitary Conditions Guidelines and the implications that has on compounding pharmacies.
- 10. Explain the importance of a monitoring program for viable airborne particles to assess microbiological air quality in all classified areas.
- 11. Review microbiological air and surface monitoring programs that must be included.



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Activity Length: 7.5 Contact Hours Or 0.75 CEUs.

Target Audience: Pharmacists

Pharmacist Technicians

Home Study Format(s):

Keyword(s): Sterile Compounding

USP Chapter 797

Initial Release Date: 01/31/2023
Planned Expiration Date: 01/31/2026

Originally Submitted By: Kelly Simmons
Submission Date: 01/21/2022

Last Modified By: Kelly Simmons
Modification Date: 03/22/2023

| Date | Location | Date Entered | Format | Cosponsor | Listed in P.L.A.N ® Cancel |
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| 01/24/2022 | Houston, TX | 01/21/2022 | Seminar | Joint Providership | × |
| 04/25/2022 | Houston, TX | 01/21/2022 | Seminar | Joint Providership | × |
| 09/26/2022 | Houston, TX | 01/21/2022 | Seminar | Joint Providership | × |
| 01/31/2023 | Houston, TX | 01/31/2023 | Seminar | Joint Providership | |
| 05/08/2023 | Houston, TX | 01/31/2023 | Seminar | Joint Providership | |
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Provider Name: National Pharmacy Technician Association (NPTA)

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Cosponsor(s): 9999 Joint Providership (L)

Activity Type: Application

Activity Title: Sterility Assurance Training: Day 2

At the completion of this activity, the participant will be able to: **Learning Objectives:**

1. Discuss proper use of disinfectants to achieve adequate levels of disinfection (Pharmacists) 2. Describe cleaning techniques, daily requirements, and required documentation.

3. Evaluate standard operating procedures required for compounding sterile preparations.

4. Classify various antiseptics, disinfectants and sporicidal agents

5. Describe what needs to be documented, how to achieve proper documentation, and how to evaluate data

trending.

6. Implement a routine testing program that provides data that shows control of process, procedures, personnel,

and quality of preparations.

7. Evaluate proper techniques for working in a laminar airflow hood.

Learning Objectives: At the completion of this activity, the participant will be able to:

1. Discuss proper use of disinfectants to achieve adequate levels of disinfection (Pharmacy Technicians)

2. Describe cleaning techniques, daily requirements, and required documentation.

3. Evaluate standard operating procedures required for compounding sterile preparations.

4. Classify various antiseptics, disinfectants and sporicidal agents

5. Describe what needs to be documented, how to achieve proper documentation, and how to evaluate data

6. Implement a routine testing program that provides data that shows control of process, procedures, personnel,

and quality of preparations.

7. Evaluate proper techniques for working in a laminar airflow hood.

Activity Length: 7.5 **Contact Hours Or** 0.75 CEUs.

Target Audience: Pharmacists

Pharmacist Technicians

Home Study Format(s):

Keyword(s): Sterile Compounding

USP Chapter 797

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| 09/27/2022 | Houston, TX | 01/21/2022 | Seminar | Joint Providership | | |
| 02/01/2023 | Houston, TX | 01/31/2023 | Seminar | Joint Providership | | |
| 05/09/2023 | Houston, TX | 01/31/2023 | Seminar | Joint Providership | | |
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Provider Name: National Pharmacy Technician Association (NPTA)

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Cosponsor(s): 9999 Joint Providership (L)

Activity Type: Application

(Pharmacists)

Activity Title: Sterility Assurance Training: Day 3

At the completion of this activity, the participant will be able to: **Learning Objectives:**

1. Evaluate the DQSA and understand the different regulations for a 503a vs. a 503b pharmacy.

2. Explain the FDA Biologics guidance.

3. Discuss the USP 797 regulations surrounding active pharmaceutical ingredients, inactive ingredients, and components.

4. Describe a certificate of analysis and how to utilize assays and loss on drying in your calculations.

5. Recognize the prescription requirements as specified in section 503A of the Federal Food, Drug and

Cosmetic Act.

6. Calculate isotonicity, pH, and osmolarity for compounded sterile preparations.

7. Evaluate various types of terminal sterilization (e.g., dry heat, steam, or irradiation) and when each is best

suited for the compounded sterile preparation.

8. Discuss different filters, filter types, and when to use each one.

9. Discuss beyond use dating as outlined in USP 797.

Learning Objectives: At the completion of this activity, the participant will be able to:

1. Evaluate the DQSA and understand the different regulations for a 503a vs. a 503b pharmacy. (Pharmacy Technicians)

2. Explain the FDA Biologics guidance.

3. Discuss the USP 797 regulations surrounding active pharmaceutical ingredients, inactive ingredients, and

components.

4. Describe a certificate of analysis and how to utilize assays and loss on drying in your calculations.

5. Recognize the prescription requirements as specified in section 503A of the Federal Food, Drug and

Cosmetic Act.

6. Calculate isotonicity, pH, and osmolarity for compounded sterile preparations.

7. Evaluate various types of terminal sterilization (e.g., dry heat, steam, or irradiation) and when each is best

suited for the compounded sterile preparation.

8. Discuss different filters, filter types, and when to use each one.

9. Discuss beyond use dating as outlined in USP 797.

Activity Length: 7.5 **Contact Hours Or** 0.75 CEUs.

Target Audience: Pharmacists

Pharmacist Technicians

Home Study Format(s):

Keyword(s): Sterile Compounding

USP Chapter 797

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| 02/02/2023 | Houston, TX | 01/31/2023 | Seminar | Joint Providership | | |
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0384-9999-22-524-L07-T

Provider Name: National Pharmacy Technician Association (NPTA)

Cancel

Cosponsor(s): 9999 Joint Providership (L)

Activity Type: Application

Activity Title: Sterility Assurance Training: Day 4

Learning Objectives: At the completion of this activity, the participant will be able to:

(Pharmacists)

1. Discuss the process for sterile media fills.
2. Compound sterile injections for high risk preparations.

Compound sterile injections for high risk preparations.
 Compound sterile ophthalmic preparations.

4. Describe the difference in process for aqueous vs. oil sterile preparations.

5. Evaluate a quality assurance, quality control program and discuss the required components.

6. Explain the role of the designated person according to USP 800.

7. List the components of an investigation and the CAPA system.

8. Summarize the steps in Adverse Event Reporting.

9. Describe a hazardous drug communication plan and how it will be communicated to those involved.

10. Discuss the NIOSH list of antineoplastics and other hazardous drugs.

11. Describe USP 800 terminology include C-PEC and C-SEC.

12. Evaluate required personal protective equipment (PPE), how they should be donned, doffed, and discarded.

Learning Objectives:

(Pharmacy Technicians)

At the completion of this activity, the participant will be able to:

1. Discuss the process for sterile media fills.

2. Compound sterile injections for high risk preparations.

3. Compound sterile ophthalmic preparations.

4. Describe the difference in process for aqueous vs. oil sterile preparations.

5. Evaluate a quality assurance, quality control program and discuss the required components.

6. Explain the role of the designated person according to USP 800.7. List the components of an investigation and the CAPA system.

8. Summarize the steps in Adverse Event Reporting.

9. Describe a hazardous drug communication plan and how it will be communicated to those involved.

10. Discuss the NIOSH list of antineoplastics and other hazardous drugs.

11. Describe USP 800 terminology include C-PEC and C-SEC.

12. Evaluate required personal protective equipment (PPE), how they should be donned, doffed, and discarded.

Activity Length: 7.5 Contact Hours Or 0.75 CEUs.

Target Audience: Pharmacists

Pharmacist Technicians

Home Study Format(s):

Keyword(s): Sterile Compounding

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| 05/11/2023 | Houston, TX | 01/31/2023 | Seminar | Joint Providership | | |
| 10/05/2023 | Houston, TX | 01/31/2023 | Seminar | Joint Providership | | |