Sterile Compounding: A Practical Approach to Practice in a USP 797 Environment

ACTIVITY DESCRIPTION
Despite broader acceptance and adoption of USP 797 techniques and focus on sterile compounding, incidents continue. In this session, the basic elements of aseptic technique are examined, using the shadow of previous incidents to highlight urgency for adherence. In addition, the role of 503B designated facilities are discussed, as regulatory parameters are outlined and reviewed. This session takes a practical approach to specific aseptic techniques that may be directly applied in a variety of sterile compounding practice settings.

TARGET AUDIENCE
The target audience for this activity is pharmacists, pharmacy technicians, and nurses in hospital, community, and retail pharmacy settings.

LEARNING OBJECTIVES
After completing this activity, the pharmacist will be able to:
• Describe the current regulatory oversight of compounded drugs in the United States
• Differentiate between a compounding pharmacy and a 503B registered entity
• Identify elements of an effective USP 797 sterile compounding environment and technique

After completing this activity, the pharmacy technician will be able to:
• Describe the current regulatory oversight of compounded drugs in the United States
• Differentiate between a compounding pharmacy and a 503B registered entity
• Identify elements of an effective USP 797 sterile compounding environment and technique

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Kevin has received several professional awards, including the Pfizer Leadership Award and the Innovative Pharmacy Practice Award from the South Carolina Pharmacy Association. Having served as a corporate communications trainer for Triad Isotopes, Kevin has presented to a variety of audiences, including a nuclear pharmacy symposium at the American Pharmacists Association annual meeting. Kevin has served as an independent editor for several Paradigm Publishing textbooks, and currently serves on the professional advisory board for Paradigm Publishing. Kevin’s passions lie in helping students achieve and surpass personal educational goals.

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Sterile Compounding:
A Practical Approach to Practice in a USP 797 Environment

Faculty: Kevin T. Hope, RPh

New England Compounding Center (NECC)

- 64 people dead
- 700 seriously ill
- 20 US states directly impacted
- 17,000 vials of a steroid injection were recalled

NECC

Who was responsible for oversight?

• FDA?
• Massachusetts State Board of Pharmacy?
• The Owner?

Compounded Product or Manufactured Product?

• Why does it matter?

Objectives

• Describe the current regulatory oversight of compounded drugs in the United States
• Differentiate between a compounding pharmacy and a 503B registered entity
• Identify elements of an effective USP 797 sterile compounding environment and technique
NECC: The Tip of A Larger Iceburg

CBS Look At Compounding Pharmacies: Interviews with FDA
Events Since NECC:

Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA.

Should I Register As A 503B?

• If you do not intend for all drugs compounded at your facility to be compounded in accordance with section 503B and comply with CGMP requirements, you should not register as an outsourcing facility under section 503B.

• You should not register a facility as an outsourcing facility if the only activities conducted at the facility are repackaging, compounding non-sterile drugs, compounding animal drugs, or mixing, diluting, or repackaging biological products subject to licensure under section 351 of the PHS Act, because none of the products produced at the facility would qualify for the exemptions provided in section 503B.
Should I Register As A 503B?

Outsourcing facilities:
• Must comply with CGMP requirements;
• Will be inspected by FDA according to a risk-based schedule
• Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm393571.htm

503B Observations

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

On December 12-13, 2013 we observed your clean room Technicians conducting aseptic fill processes in laminar flow hoods (ISO 5) inside the “Clean Room” (ISO 7) practicing poor aseptic techniques, such as:

1. Touching product contact surface (sterile transfer tubing) with gloved hand after sterile (b) (4)
2. Picking up items (e.g. needle and power cord) off the floor without changing sterile gloves
3. Exposed skin at wrists due to inadequate glove/gown cover
4. Mouth/nose cover sitting below the nose
5. Continuing to open and handle products with turn gowns at unclean location
6. Opening bench drawers outside of laminar flow hood without sanitizing hands
7. Leaving clean room and returning without changing gloves or gowns
8. Using non-sterile gown clothing

In addition, we inspected Testosterone Cypionate 200mg/mL, lot #031017-2KS-151385, which had completed visual inspection. We observed particles in 4 vials out of the 25 we reviewed. These particles were confirmed by Sterile Supervisor(9) and Pharmacy Technician(8). According to Sterile Supervisor(9), these vials should have been rejected per your firm’s visual inspection SOP.
"FDA Approved" ??

<table>
<thead>
<tr>
<th>Proprietary Name</th>
<th>NDC Package Code</th>
<th>Strength</th>
<th>Dosage Form</th>
<th>Route</th>
<th>Appl. No.</th>
<th>Labeler Name</th>
<th>Product NDC</th>
<th>Nonproprietary Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>KINEVAC</td>
<td>0270-0558-15</td>
<td>5 ug/5mL</td>
<td>INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION</td>
<td>INTRAVENOUS</td>
<td>NDA017607</td>
<td>Bracco Diagnostics Inc.</td>
<td>0270-0556</td>
<td>sincalide</td>
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<tr>
<td>Sincalide</td>
<td>51808-203-01</td>
<td>3 ug/1</td>
<td>INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION</td>
<td>INTRAVENOUS</td>
<td>Anzaa-Health Corporation</td>
<td>51808-203</td>
<td>Sincalide</td>
<td></td>
</tr>
</tbody>
</table>

https://www.accessdata.fda.gov/scripts/cder/ndc/dsp_searchresult.cfm

"FDA Approved" ?

"The information provided on this webpage is intended to alert health care professionals of adverse event reports related to compounded drugs. Providing this information to health care professionals should further FDA’s goal of protecting patients from unsafe, ineffective, and poor quality compounded drugs."

www.fda.org
503B Drug

FDA Goals For 2018

• Greater efficiency and lowering costs for more compounding pharmacies to meet the higher standards for 503B outsourcing facilities

• More closely define the necessity of compounded medications
  • Should only be distributed to meet the needs of patients whose medical needs cannot be met by an FDA approved drug
FDA Goals for 2018

• Focus on examining whether there is any clinical difference between a compounded drug and a commercially available drug
  • Compounding a bulk drug in lieu of diluting a commercially available drug
• Refine regulations for communicating with individual states
• Adding and modifying the list of products that can no longer be used for compounding

Endo International vs. FDA

• Suit Filed in October 2017
• Claims that the FDA allowed compounding pharmacies to create “essentially a copy” of its blood pressure drug Vascostrict® (vasopressin)
  • “The FDA has heard concerns about compounding from bulk drug substances when the drug can be compounded from FDA approved drugs.”
“An ounce of prevention is worth a pound of cure.”

Benjamin Franklin
USP 797

Created standards for sterile compounded preparations
- Standard of practice
- Enforceable

Response to USP 797 has Varied from State to State

Joint Commission State Specific Chart:

https://www.jointcommission.org/assets/1/6/Feb_2017_State_Compounding_Regulations.pdf

(included as an appendix to the handout)
### ISMP Findings

**In a 2013 study:**

- Only 18 states directly require compliance with this standard
- Only 65.2% of hospitals adhere to USP <797> requirements for clean rooms
- Less than 17% of hospitals comply with all USP <797> requirements.

Do We Have A True Vision of Ourselves?

ASHP Sterile Product Preparation Training and Certificate Program

• Self-guided, online continuing education programs for pharmacists and pharmacy technicians
• To earn the professional certificate, participants must complete all eight modules and submit video clips and other documentation demonstrating their proficiency in aseptic technique.

https://www.ashp.org/professional-development/professional-certificate-programs
PTCB Certified Compounded Sterile Preparation Technician (CSPT™ program)

• To be eligible to apply, a technician must be a PTCB CPhT in good standing, and must have completed either: a PTCB-recognized sterile compounding education/training program and 1 year of continuous full-time compounded sterile preparation work experience; or 3 years of continuous full-time compounded sterile preparation work experience.


PTCB Certified Compounded Sterile Preparation Technician (CSPT™ program)

• To earn CSPT Certification, eligible CPhTs are required to: 1) pass the CSPT™ Exam, a 2-hour, 75-question exam; and 2) submit Competency Attestation documentation from a qualified supervisor.

• The exam covers hazardous and non-hazardous Compounded Sterile Products (CSPs) in the four domains of: Medications and Components (17%); Facilities and Equipment (22%); Sterile Compounding Procedures (53%); and Handling, Packaging, Storage, and Disposal (8%).

USP 797

Risk Levels
- Immediate Use Exception
- Low Risk (<12 hour BUD)
- Low Risk
- Medium Risk
- High Risk

What Factors Determine the Risk Level?

- Inherent potential for product contamination
- Complexity of the Preparation
  - Number of components being added
  - Types of components being added
  - Number of septum piercings
- Place of preparation
  - ISO environment ?? Countertop ??
**USP 797**

**Administration is exempt**

Unit doses may be administered as always by appropriately trained staff, using the appropriate aseptic technique.

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**Immediate Use Exception**

- Uses no more than 3 sterile products
- No more than 2 entries are made to the prepared vial
- Administration within 1 hour

1 PATIENT  
1 DOSE  
1 HOUR

USP 797: Risk Levels

LOW RISK:
• Requires an ISO-5 environment for preparation
• If preparations exceed a 12 hour BUD, ISO-5 PEC must be located inside an ISO-7 or ISO-8 cleanroom

EXAMPLES:
• Reconstitution of single-dose vials of antibiotics
• Single transfers of sterile dosage forms
• Measuring and mixing no more than three sterile manufactured products


USP 797: Risk Levels

MEDIUM RISK
• Requires an ISO-5 environment for preparation
• ISO-5 PEC must be inside an ISO-7 cleanroom

EXAMPLES
• Filling reservoirs of infusion devices with sterile drug products (i.e. chemotherapy or pain management)
• Compounding of total parenteral nutrition fluids (TPN)
• Batch preparation of syringes

USP 797: High Risk

- Use of non-sterile ingredients
- Product is exposed to an environment outside of an ISO-5 environment for more than 1 hour
- Improper garbing
- Use of multiple ampules or open containers

Beyond Use Dating (BUD)

<table>
<thead>
<tr>
<th>Assigned Risk Level:</th>
<th>Room Temperature Storage:</th>
<th>Refrigerated Storage:</th>
<th>Freezer Storage:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate Use Exception</td>
<td>1 hour</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Low Risk, &lt;12 hour BUD</td>
<td>12 hours</td>
<td>12 hours</td>
<td>X</td>
</tr>
<tr>
<td>Low Risk</td>
<td>48 hours</td>
<td>14 days</td>
<td>45 days</td>
</tr>
<tr>
<td>Medium Risk</td>
<td>30 hours</td>
<td>9 days</td>
<td>45 days</td>
</tr>
<tr>
<td>High Risk</td>
<td>24 hours</td>
<td>3 days</td>
<td>45 days</td>
</tr>
</tbody>
</table>

Storage temperatures must be monitored using a traceable thermometer

ISO Classifications

<table>
<thead>
<tr>
<th>ISO CLASS:</th>
<th>EXAMPLE:</th>
<th>MAXIMUM NUMBER OF PARTICLES (per m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 9</td>
<td>Typical Room Air</td>
<td>-</td>
</tr>
<tr>
<td>ISO 8</td>
<td>Ante Area</td>
<td>3,520,000</td>
</tr>
<tr>
<td>ISO 7</td>
<td>Ante Area</td>
<td>352,000</td>
</tr>
<tr>
<td>ISO 5</td>
<td>PEC (hoods)</td>
<td>3,520</td>
</tr>
</tbody>
</table>

Clean Room Maintenance

ENVIRONMENTAL TESTING

Temperature monitoring
Pressure monitoring (positive vs. negative pressure)
  - Hazardous materials = negative pressure
Air sampling
Clean Room Maintenance

<table>
<thead>
<tr>
<th>Site</th>
<th>Minimum Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 5 PEC</td>
<td>- At the beginning of each shift before each batch not - If ongoing compounding activities are occurring, every 30 minutes - After spills - When surface contamination is known or suspected</td>
</tr>
<tr>
<td>Counters &amp; Surfaces</td>
<td>Daily</td>
</tr>
<tr>
<td>Floors</td>
<td>Daily</td>
</tr>
<tr>
<td>Ceilings</td>
<td>Monthly</td>
</tr>
<tr>
<td>Shelving</td>
<td>Monthly</td>
</tr>
</tbody>
</table>


Competency Testing

- Media Fill Tests
- Gloved Fingertip Sampling
- Ongoing training and assessment
  - Requirements vary from state to state, but minimally annually for both low and medium risk sterile compounding
USP 797 Revisions

• The next revision to General Chapter <797> is anticipated to be published in September/October 2018 for a second round of public comment. It is expected to become official on December 1, 2019.

• While General Chapter <797> is undergoing revision, the published version of the chapter which became official on June 1, 2008 is currently official.

Gowning and Garbing

Order of Gowning & Garbing Procedure is VERY important! Occurs inside the ‘Ante-Area’!

1. Shoe Covers
2. Head Cover
3. Beard Cover
4. Handwashing Technique
5. Gown, lint free disposable
6. Hand Sanitizer
7. Sterile Gloves, powder free
8. Sterile Isopropyl Alcohol
Are You “Dressed for Success?”

- No jewelry!
- No make up!
- Well groomed & short, unpolished fingernails!
- No shorts!
- No open toed shoes!

Joseph Lister, British Surgeon

Not well received by American physicians
- “... a finicky neurotic crank ...”
- “… real medical men wear blood coated and ‘seasoned’ lab coats ...”
- “invisible germs” were mocked

The Death of President James A. Garfield

- Shot in the chest in 1881
- 4 physicians, including the Surgeon General, probed the wound with unwashed hands & tools
- Died from pus filled wound

Hand Washing Technique

- Wash up to the elbows with soap and water for at least 30 seconds
- Work to remove debris from ‘cleanest’ to ‘dirtiest’
- Do not touch the faucet directly after the handwashing process
- Use of nail pick to clean beneath finger nails
Handwashing Technique

Donning Sterile Gloves

- Use sterile, powder free gloves!
- Don gloves in the buffer area!
- Use sterile 70% isopropyl alcohol to sanitize
- Remove outer wrapper
- Glove dominant hand first by using the non-dominant hand to pick up the inside edge of the cuff
Donning Sterile Gloves

• With the gloved hand, pick up the other glove from the package, touching only the inside of the folded cuff
• Glove the non-dominant hand

Schedule for Disinfecting Gloves

• Immediately after being donned
• Prior to and after each cleaning of the PEC
• Prior to each preparation
• Prior to re-entering an ISO-5 environment
• If contamination is known or visible
• Periodically during prolonged duration of compounding in the PEC (~ every 30 minutes)

Cleaning the Hood (PEC, Horizontal Flow)

• Any disinfectant or germicide used inside the ISO-5 PEC MUST be sterile!
  • Sterile water for irrigation
  • Sterile 70% isopropyl alcohol

• Disinfectants must be ‘Intermediate Level’ with an EPA registration number

Cleaning the Hood (PEC, Horizontal Flow)

• Remove all objects from the hood
• Place a stack of sterile gauze pads inside the hood and wet them with sterile water for irrigation
• Clean the ceiling of the hood / bar & hooks
  • Begin at the back corner and use sweeping side to side motions
  • Discard the gauze when reaching the outer edge of the hood


Cleaning the Hood (PEC, Horizontal Flow)

- Clean the sides of the hood
  - Begin in an interior upper corner and use overlapping ‘up and down’ wipes
  - Discard the wipe when the outer edge of the hood is reached
- Clean the work surface (floor) of the hood
  - Begin at a back corner and use overlapping ‘side to side’ wipes
  - Discard the wipe when the outer edge of the hood is reached
- Repeat all steps using sterile 70% isopropyl alcohol.

Basic Aseptic Tips

- Work at least 6 inches inside the PEC!
- Concept of ‘first air’ (horizontal vs. vertical flow hoods)
- Concept of “critical sites”
- Use only STERILE alcohol swabs! Swab in the same direction 3 times. Leave surface wet for at least 10 seconds!
- Wipe down supplies with a disinfectant prior to bringing them into the buffer area
- Don’t ‘punch’ the syringe through the paper wrapper! Unwrap it!
“Individual commitment to a group effort – that is what makes a team work, a company work, a society work, a civilization work.”

Vince Lombardi

NECC Fall Out

• 14 people arrested
• Top Executive charged with second degree murder
• 64 people dead
• 700 people seriously injured
Do We Have A True Vision of Ourselves?

Sources Cited

- https://www.jointcommission.org/assets/1/6/Feb_2017_State_Compounding_Regulations.pdf
- https://www.youtube.com/watch?v=llzd2Qb19A
- https://www.youtube.com/watch?v=AOvbjlnhShk
- https://www.youtube.com/watch?v=Bee_VwZDS7E
- https://www.youtube.com/watch?v=Xsph4WzU-v0
- https://www.youtube.com/watch?v=9aqv-fZGsF0
Exam Questions:

1. Of these preparation tasks for entering the Buffer Area, which task is performed LAST?
   a. Put on shoe covers
   b. Wash hands using the appropriate technique
   c. Put on a lint free disposable gown
   d. Put on a hair cover

2. The assignment of an NDC number provides assurance that:
   a. The drug has been evaluated and approved by the FDA
   b. The drug has been produced by a 503B registered facility
   c. The drug will be reimbursable by Medicare part D
   d. All of the above statements are true
   e. None of the above statements are true

3. Petunia is a nurse on the west wing of ACME Medical Center. Earlier this morning, she withdrew 5 mL of 0.9% sodium chloride from a vial to use as a flush for a patient’s IV line, using the counter top at the nurse’s station. Petunia’s supervisor tells her that she may draw another saline flush from the same vial of saline later this afternoon since it is a multi-dose container. Is this procedure supported by the exception standards for the applications of USP 797?
   a. Yes. Multi-dose containers may be used for a period not to exceed 12 hours.
   b. Yes. With supervisor approval, Petunia may bypass any applicable standards found within USP 797.
   c. No. The immediate use exception for USP 797 requires that the dose drawn from the vial be used for only one patient and then discarded.
   d. No. The immediate use exception for USP 797 requires that the dose drawn from the vial be used within 12 hours and then discarded.

4. Requires an ISO-5 environment for preparation:
   a. Low Risk Compounding
   b. Medium Risk Compounding
   c. High Risk Compounding
   d. All of the above are correct
   e. None of the above are correct
5. Assuming that product specific stability is not an issue, what ‘beyond use date’ (BUD) would be appropriately assigned to a compound designated as ‘low risk’ that will be stored in the facility’s freezer?
   a. 12 hours
   b. 48 hours
   c. 14 days
   d. 45 days

6. Choose the ISO classification with the FEWEST particles per unit of air.
   a. ISO 5
   b. ISO 6
   c. ISO 7
   d. ISO 8

7. A company MUST register with the FDA as a 503B outsourcing facility if the company is:
   a. engaged in non-sterile compounding
   b. compounding medications for pets
   c. engaged in sterile compounding
   d. All of the above are correct
   e. None of the above are correct

8. A 503-B registered entity:
   a. Is expected to report adverse events to the FDA
   b. Is expected to abide by all current good manufacturing practices
   c. Is subject to inspection by the FDA
   d. All of the above are correct
   e. None of the above are correct

9. Preston is a technician at a local hospital. During an inspection, the state board of pharmacy noted that Preston was observed preparing bulk product in an ISO-5 designated hood, but he was not wearing a hair cover nor a face mask. The compounding observed in this case would be deemed as:
   a. Low Risk
   b. Medium Risk
   c. High Risk
   d. Marginal Risk
10. The floors in a USP 797 clean room (buffer area) should be cleaned, at minimum:
   a. Every 30 minutes
   b. Once each day
   c. Once each week
   d. Once each month
   e. Annually

11. The ISO-5 primary engineering control should be cleaned:
   a. At the beginning of each shift
   b. After a spill has occurred in the area
   c. Every 30 minutes if ongoing compounding activities are occurring
   d. All of the above are true
   e. None of the above are true

12. The purpose of a ‘media fill test’ is to:
   a. Demonstrate that the compounder is capable of maintaining sterility while making defined maneuvers inside the ISO-5 PEC
   b. Demonstrate that the worker is capable of donning sterile gloves without contaminating the exterior of the gloves
   c. Demonstrate that the ISO-5 PEC has a positive pressure airflow
   d. All of the above are correct
   e. None of the above are correct

13. Peggy Ann has accepted a position at ACME Hospital where she will be preparing IV medications in the pharmacy. When reporting to work, Peggy Ann should NOT be permitted to enter the clean room if wearing:
   a. Makeup
   b. Shorts
   c. Artificial finger nails
   d. All of the above are correct

14. Proper handwashing technique includes washing up to the elbows for at least:
   a. 10 seconds
   b. 30 seconds
   c. 1 minute
   d. 5 minutes

15. When garbing, sterile gloves should be donned inside:
   a. The Anteroom
   b. The Buffer Area
   c. The ISO-5 primary engineering control (PEC)
   d. The general employee lounge
16. Disinfectants used inside the ISO-5 primary engineering control (PEC) must be:
   a. Sterile
   b. Have an EPA registration number
   c. Be designated as an ‘intermediate level’ disinfectant
   d. All of the above are true
   e. None of the above are true

17. Which of these areas of a horizontal laminar work flow bench should be cleaned FIRST?
   a. Ceiling of the hood
   b. Floor of the hood
   c. The left side of the hood
   d. The right side of the hood

18. After swabbing a septum with a sterile alcohol pad, the compounder should leave the septum wet for a period of at least:
   a. 10 seconds
   b. 30 seconds
   c. 45 seconds
   d. 1 minute

19. The tragedy at New England Compounding Center became a legacy case within the industry, ultimately resulting in:
   a. Multiple arrests of personnel within the corporation
   b. Multiple patient deaths
   c. Multiple patient injuries
   d. All of the above are correct
   e. None of the above are correct

20. The death of former U.S. President James A. Garfield is thought to have been most attributed to:
   a. A gun shot wound
   b. A contaminated dose of methylprednisolone
   c. A drug overdose due to a compounding error
   d. Failure of his healthcare team to wash their hands appropriately