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Preparing and Obtaining Quality Compounded Ophthalmic Preparations

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Disclosure

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Objectives

- Review and understand the USP<797> standards for compounding ophthalmic preparations

- Discuss how the Drug Quality and Security Act (DQSA) of 2013 will impact obtaining compounded ophthalmic preparations from pharmacies or outsourcing facilities

- Learn how to use tools to choose a pharmacy or outsourcing facility that meets USP standards or legal requirements of the DQSA.
Poll

- How many practitioners prepare their intraocular injections, eye drops, irrigations... at the practice site?
- How many practitioners prepare their sterile ophthalmic preparations in an ISO 7 clean room in an ISO 5 hood or compounding aseptic isolator?
- How many practitioners prepare their sterile ophthalmic preparations in a medication room on the countertop?
Sad But True Story
What is the USP?

• Independent, private organization that has a core staff and hundreds of volunteers that serve on committees that write and revise chapters and monographs for the *USP*

• In the 20th century, the *United States Pharmacopeia* sets standards for the pharmaceutical industry

• The *USP* also sets standards for compounding medications within a practice setting, such as a pharmacy, hospital, clinic, practitioner’s office...

• *USP* is recognized by the U.S. federal government and most state governments
What is the USP<797>?

• The USP<797> chapter is the standards for compounding sterile preparations in a practice setting
• All ophthalmics are sterile preparations and must be prepared according to the USP<797> standards
Getting Started to Prepare Ophthalmics In-House

- Read and understand the USP<797>
- Train and verify staff to do sterile compounding
- Write SOPs and formula sheets
- Set up the proper compounding environment
- Quality assurance
Train and Verify Staff

- Receive training by expert personnel through live instruction, audio-video sources, and professional publications on theoretical principles and practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 conditions
- Must learn personal hygiene and garbing
- Must perform didactic review
- Must pass written test
- Must pass media-fill testing annually
SOPs and Formula Sheets

- Standard operating procedure is a written step-by-step set of instructions on how to perform a task
- Formula sheet is a written step-by-step set of instructions on how to prepare a medication
- Provides consistency on how a procedure is done or how a medication is prepared

*If it is important to do, there should be a written standard operating procedure!*
Ideal Sterile Compounding Environment

- PECs provide an ISO Class 5 environment
- PECs should be located in an ISO Class 7 environment
- Ante area should be ISO Class 8 or better environment
- May assign longer BUDs
Sterile Compounding Environment For Office Setting

- PECs provide an ISO Class 5 environment
- PECs should be located in a segregated compounding area
- Must follow Low-Risk CSP with <12-hour BUD criteria
Quality Assurance

- Visual inspection
- Double-check system for compounding accuracy
- Identity and strength verification of ingredients
- Review compounding worksheet
- Check labeling
• Defines regulations for a 503(A) traditional compounding pharmacy
• Defines regulations for a 503(B) outsourcing facility
## Traditional vs Outsourcing Facility

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<thead>
<tr>
<th>Traditional</th>
<th>OF</th>
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<tbody>
<tr>
<td>• Regulated and licensed by State Board of Pharmacy</td>
<td>• Registered with FDA</td>
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<tr>
<td>• Follows USP standards</td>
<td>• Follows cGMP standards</td>
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<tr>
<td>• May compound for patients pursuant to a physician order or prescription</td>
<td>• May compound batches of sterile products and sell direct to clinics, hospitals...without a patient-specific order or prescription</td>
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<tr>
<td>• May prepare high-risk sterile preparations from nonsterile APIs (i.e. brilliant blue g intravitreal injections)</td>
<td>• May only prepare low- and medium-risk preparations</td>
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<tr>
<td></td>
<td>• Limited to FDA list of approved drugs</td>
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<td>• May not be a pharmacy</td>
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How to Find a Reputable Source for Compounded Ophthalmics

Traditional

- Use IACP’s CPAQ™ tool
  www/iacprx.org
  download as printed survey
- Check PCAB website for board-certified compounding pharmacies
  www/pcab.org
- Visit and inspect local compounding pharmacies

OF

- Check FDA website for registered outsourcing facilities
  www.fda.gov
- Use ASHP’s Outsourcing Sterile Products Preparation Contractor Assessment Tool
  www.ashpfoundation.org/SterileProductsTool
  use online only
- Visit and inspect OFs
ANY QUESTIONS?
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