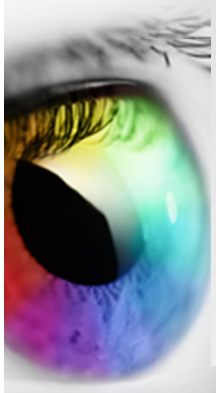


About OMICS Group

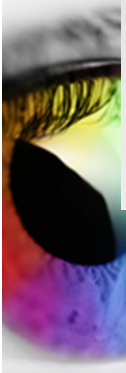
OMICS Group International is an amalgamation of [Open Access publications](#) and worldwide international science conferences and events. Established in the year 2007 with the sole aim of making the information on Sciences and technology 'Open Access', OMICS Group publishes 400 online open access [scholarly journals](#) in all aspects of Science, Engineering, Management and Technology journals. OMICS Group has been instrumental in taking the knowledge on Science & technology to the doorsteps of ordinary men and women. Research Scholars, Students, Libraries, Educational Institutions, Research centers and the industry are main stakeholders that benefitted greatly from this knowledge dissemination. OMICS Group also organizes 300 [International conferences](#) annually across the globe, where knowledge transfer takes place through debates, round table discussions, poster presentations, workshops, symposia and exhibitions.



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Preparing and Obtaining Quality Compounded Ophthalmic Preparations

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Disclosure

Linda McElhiney declares no conflicts of interest, real or apparent, and no financial interests in any company, product, or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.



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



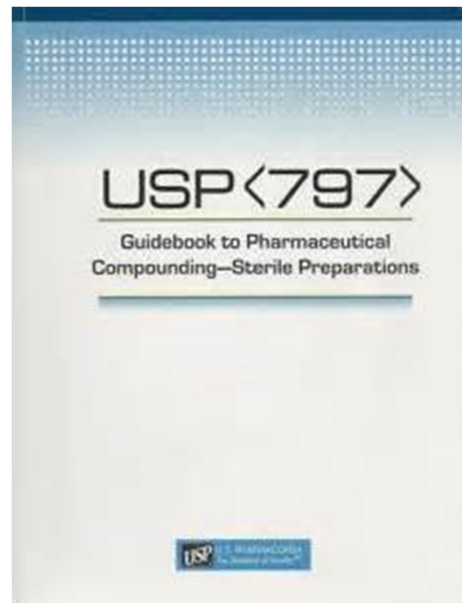
What is the USP?

- 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



DQSA

- Defines regulations for a 503(A) traditional compounding pharmacy
- Defines regulations for a 503(B) outsourcing facility



Traditional vs Outsourcing Facility

Traditional

- Regulated and licensed by State Board of Pharmacy
- Follows USP standards
- May compound for patients pursuant to a physician order or prescription
- May prepare high-risk sterile preparations from nonsterile APIs (i.e. brilliant blue g intravitreal injections)

OF

- Registered with FDA
- Follows cGMP standards
- May compound batches of sterile products and sell direct to clinics, hospitals...without a patient-specific order or prescription
- May only prepare low- and medium-risk preparations
- Limited to FDA list of approved drugs
- May not be a pharmacy



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





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