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Alliance for Pharmacy Compounding

Compounding the Joy of Living®

Below is a brief, practical outline pharmacy owners can use when hosting a legislator, attorney general, board member, or staffer for a sterile compounding pharmacy tour.

Sterile compounding pharmacy tour outline

1. **Welcome and framing**

Begin with a brief orientation before entering any operational areas.

Suggested framing: "Today, we're going to follow the journey of a single patient's prescription. We'll start with a physician determining that a compounded medication is medically necessary, then walk through every step required to safely prepare that medication, from the people that perform the work, to ingredient sourcing, sterile preparation, quality assurance, and ultimately delivery to the patient."

Emphasize that the purpose of the tour is to show **care and compliance in action** – not as abstractions, but as daily operating discipline. Explain that sterile compounding is not simply "mixing drugs." It is a highly controlled, documented, pharmacist-supervised process designed to prepare medication for an identified patient pursuant to a prescriber's order.

Before discussing the prescription itself, explain that none of the work visitors will see can occur without properly trained and qualified personnel. The investment in staff includes (but is not limited to):

- Initial training before an employee is permitted to compound sterile medications.
- Competency assessments to demonstrate proficiency in sterile technique.
- Ongoing education and periodic requalification.
- Media-fill testing, gloved fingertip testing, and other competency evaluations required under USP standards.
- Documentation demonstrating that personnel remain qualified to perform sterile compounding.

2. **Start with the prescription and clinical need**

Now that we've met the people who are qualified to prepare the medications, let's look at where every compounded prescription actually begins: with a patient's clinical need and a prescriber's order.

Cover:

- The patient-specific prescription
- The prescriber's role in determining clinical need (The pharmacy can advise, but pharmacies don't decide when a patient gets a compounded drug, prescribers do.)
- Why an FDA-approved product may not meet the patient's needs
- Documentation of formulation, strength, dosage form, route, and quantity
- Pharmacist review before preparation

Key point to emphasize: **Nothing happens until a prescriber has determined that a patient needs a compounded medication.**

3. **API sourcing and supplier qualification**

Walk the visitor through how active pharmaceutical ingredients are ordered.

Cover:

- Use of qualified suppliers
- Review of certificates of analysis
- Verification of source, identity, lot number, expiration/retest date, and documentation
- Preference for FDA-registered or otherwise appropriately qualified supply-chain sources where applicable
- Why API provenance matters to patient safety
- What APIs can be used in compounded products
  - API that is part of an FDA-approved product
  - API that has a USP or NF monograph
  - API that appears on the interim or final 503A bulks list

Key point to emphasize: **Ingredient quality is the first patient-safety checkpoint.**

4. **Receipt, quarantine, and verification**

Show where ingredients and components are received and logged.

Cover:

- Receiving procedures
- Quarantine pending review
- Documentation checks
- Lot tracking
- Storage conditions
- Inventory controls
- Rejection or segregation of materials that do not meet requirements

Key point to emphasize: **A pharmacy does not simply receive an API and start compounding. Materials are reviewed, documented, and controlled before use.**

5. **Facility design and cleanroom controls**

Before entering or viewing the cleanroom, explain the facility investment and environmental controls.

Cover:

- Segregated compounding areas, cleanrooms, buffer rooms, ante rooms, and ISO-classified spaces, as applicable
- HEPA filtration and airflow principles
- Pressure differentials
- Temperature and humidity monitoring
- Cleaning and disinfection schedules
- Environmental monitoring

- Certification of primary and secondary engineering controls
- Restricted access
- Visual supervision of compounding personnel via windows/cameras

Key point to emphasize: **The cleanroom is not ordinary workspace. It is a controlled environment designed to reduce contamination risk.**

6. **Personnel garbing and Cleaning Procedures**

Before a compounded sterile medication can be prepared, every individual entering the cleanroom must follow a carefully designed process to minimize the risk of contamination. Show, if appropriate, where personnel garb and prepare to enter sterile areas.

Cover:

- Removal of jewelry and other items that could introduce contamination
- Hand hygiene
- Donning sterile personal protective equipment in prescribed order, including hair covers, beard covers (where applicable), shoe covers, gowns, masks, and sterile gloves.
- Final sanitization of sterile gloves before beginning compounding activities.
- Limits on who may enter the sterile compounding area

Key point to emphasize: **Sterile compounding depends not only on equipment, but on trained, qualified personnel following validated procedures every time.**

Describe the pharmacy's cleaning and environmental control program, including:

- Routine cleaning and disinfection of all cleanroom surfaces using validated procedures.
- Scheduled cleaning performed before, during, and after compounding activities.
- Environmental monitoring to evaluate the cleanliness of the compounding environment.
- Regular certification of engineering controls, including laminar airflow workbenches, biological safety cabinets, and cleanrooms.
- Continuous monitoring of critical environmental conditions such as temperature, humidity, air pressure, and airflow.

Sterile compounding begins long before ingredients are combined. By the time a prescription enters the cleanroom, both the personnel and environment have been carefully prepared to reduce contamination risk and protect patient safety.

7. **Formulation and preparation**

Walk through, without interrupting active work, how a sterile preparation is made.

Cover:

- Master formulation records
- Compounding records
- Weighing and measuring procedures
- Calculations and pharmacist checks

- Aseptic technique
- Use of laminar airflow workbenches, biological safety cabinets, or compounding aseptic isolators
- In-process checks
- Documentation at each step

Key point to emphasize: **The process is standardized, documented, and pharmacist-supervised – not improvised.**

8. **Beyond-use dating and batch size**

Explain how beyond-use dates and quantities are determined.

Cover:

- USP standards
- Sterility risk category considerations, as applicable
- Stability information
- Storage requirements
- Batch size limits based on prescriptions, anticipated need, and applicable law
- Why "batch" in a pharmacy context does not mean mass manufacturing

Key point to emphasize: **Beyond-use dates and quantities are not marketing decisions. They are governed by standards, evidence, and professional judgment.**

9. **Testing and quality assurance**

Show where samples or finished preparations are handled for testing, or explain the outside lab process.

Cover:

- Sterility testing, when required or appropriate
- Endotoxin testing, when applicable
- Potency testing
- Particulate inspection
- pH or other formulation-specific checks
- Use of independent laboratories
- Review of results before dispensing when required
- Corrective action processes

Key point to emphasize: **Quality assurance is built into the workflow, and testing is part of the safety system.**

10. **Labeling, packaging, and patient instructions**

Walk through the final preparation and release process.

Cover:

- Final pharmacist verification

- Label content
- Storage requirements
- Lot numbers and traceability
- Patient-specific information
- Auxiliary labels and warnings
- Packaging to preserve sterility and temperature requirements
- Patient counseling or prescriber communication

Key point to emphasize: **The finished preparation remains traceable from ingredient lot to patient.**

11. Dispensing or shipping

Explain how the preparation gets to the patient or prescriber.

Cover:

- Dispensing to the patient
- Shipping controls, if applicable
- Cold-chain packaging, if needed
- Delivery tracking
- Counseling
- Documentation of dispensing
- Follow-up procedures for recalls or adverse events

Key point to emphasize: **The pharmacy's responsibility does not end when the preparation leaves the cleanroom.**

12. Compliance and oversight

Close the tour by explaining the layers of accountability.

Cover:

- State board of pharmacy licensure and inspections
- USP compliance
- FDA authority under Section 503A
- DEA oversight, if controlled substances are involved
- Internal quality systems
- Standard operating procedures
- Complaint handling
- Adverse event reporting
- Recall procedures

Key point to emphasize: **Sterile compounding pharmacies operate within a defined legal and regulatory framework, with multiple layers of oversight.**

13. Closing conversation

End with a short discussion, not a lecture.

Suggested closing points:

- Pharmacy compounding exists to meet patient needs that FDA-approved drugs do not meet.
- Sterile compounding requires substantial investment, documentation, training, and quality systems.
- Bad actors should be addressed, but policy should distinguish between illicit activity and lawful, compliant pharmacy practice.
- Legislators should be cautious about proposals that sound simple but may disrupt access for patients whose prescribers rely on sterile compounded medications.

Suggested closing question for the guest:

“Having seen the process from prescription to ingredient sourcing to cleanroom preparation to final dispensing, what concerns or questions do you still have about how sterile compounding is practiced and regulated?”