

# M5.1 — Compounding Pharmacy Quality Audit Checklist

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## Compounding Pharmacy Quality Audit Checklist

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**Use:** Before sending a single patient to a compounding pharmacy for semaglutide, tirzepatide, or any other peptide preparation. **Companion to:** M5.1 video lesson, §6 Compounded Section **Print:** Two pages, clinician operational reference

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### Why this matters

The molecule (semaglutide, tirzepatide) is FDA-approved for marketing claims; what varies between compounding sources is the **preparation pathway**. A high-quality 503A or 503B pharmacy meets every line below. A pharmacy that can't produce documentation for any of these should not be in your referral pathway.

Walk through this checklist on a phone call or via email with the pharmacy's compliance officer **before sending your first patient**. Re-audit every 12 months and any time the pharmacy's leadership or facility changes.

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### Section A — Regulatory pathway

#### A1. Pharmacy type

- ☐ **503A** (state-licensed traditional compounding pharmacy — patient-specific prescriptions)
- ☐ **503B** (FDA-registered outsourcing facility — can prepare non-patient-specific stock for office use)
- ☐ Other (specify): \_\_\_\_\_

For weight-loss peptides post-shortage (as of 2025), **prescribing path depends on the molecule's FDA shortage status at time of prescription**. Re-check the current FDA Drug Shortages list for semaglutide, tirzepatide, etc. before each prescription cycle.

## A2. State licensure

- ☐ Pharmacy licensed in the state where YOUR patient resides (not just where pharmacy operates)
- ☐ License number provided: \_\_\_\_\_
- ☐ License verified on state board of pharmacy website (URL): \_\_\_\_\_
- ☐ License expiration date: \_\_\_\_\_
- ☐ No active disciplinary actions or violations within last 24 months

## A3. FDA registration (503B only)

- ☐ FDA registration number provided: \_\_\_\_\_
- ☐ Verified on FDA Outsourcing Facility Registration list
- ☐ Last FDA inspection date: \_\_\_\_\_
- ☐ Inspection outcome (NAI / VAI / OAI): \_\_\_\_\_
- ☐ Any open 483 observations or warning letters

## A4. Active pharmacist-in-charge (PIC)

- ☐ PIC name: \_\_\_\_\_
- ☐ PIC license verified
- ☐ PIC reachable by phone within one business day

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## Section B — Facility & sterility standards

### B1. USP <797> compliance (sterile compounding)

- ☐ Written SOPs for sterile compounding on file
- ☐ ISO Class 5 primary engineering control (PEC) — laminar airflow hood or isolator
- ☐ ISO Class 7 buffer area surrounding the PEC
- ☐ Documented environmental monitoring: air, surfaces, personnel
- ☐ Garbing and hand-hygiene protocols documented
- ☐ Media-fill testing for compounding personnel — last completed: \_\_\_\_\_

### B2. USP <800> compliance (hazardous drugs — relevant if facility also handles HD)

- ☐ Separate negative-pressure room for HD compounding
- ☐ Documented PPE protocol
- ☐ Closed-system transfer devices in use

- ☐ Spill kit on premises

### B3. Beyond-use dating (BUD)

- ☐ BUD policy follows USP <797> revised limits
  - ☐ BUD posted on each finished prep label
  - ☐ BUD studies performed in-house OR cited from peer-reviewed source
  - ☐ BUD for reconstituted peptide: \_\_\_\_\_ days at 2–8°C
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## Section C — Per-batch documentation

### C1. Certificate of Analysis (CoA)

For every batch, request a CoA showing:

- ☐ Peptide identity (HPLC chromatogram + mass spec confirmation)
- ☐ Peptide content / potency (within  $\pm 5\%$  of label claim)
- ☐ Purity ( $\geq 95\%$  typical; verify against active drug substance source)
- ☐ Residual solvents (USP <467> compliant)
- ☐ Heavy metals (USP <232>/<233>)
- ☐ Endotoxin (USP <85> — must be below threshold for parenteral)
- ☐ Sterility test result (USP <71>)
- ☐ Date of testing, lot number, expiration date

**Red flag:** Pharmacy cannot produce a CoA for the batch your patient will receive.

### C2. Active pharmaceutical ingredient (API) source

- ☐ API supplier name (e.g., Beijing Strong-Bio, Cangzhou Bond, etc.)
- ☐ API supplier is FDA-registered or DMF-filed (verify on FDA database)
- ☐ API CoA on file for each lot used in compounding
- ☐ **No “research-grade” API used for human compounding** — full pharma-grade only

### C3. Excipients

- ☐ Bacteriostatic water for injection: USP grade, source documented
  - ☐ Mannitol / disodium phosphate (sema/tirz formulation buffers): pharmaceutical grade
  - ☐ No undisclosed excipients
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## Section D — Cold-chain & shipping

- ☐ Lyophilized vials shipped at controlled room temperature with temperature logger included
  - ☐ OR reconstituted preparations shipped at 2–8°C with continuous temp monitoring
  - ☐ Temperature excursion policy documented (what they do, what they tell you)
  - ☐ Shipping carrier qualified for pharmaceutical shipments
  - ☐ Tracking number provided per shipment
  - ☐ Patient instructions included for safe receipt + immediate refrigeration
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## Section E — Patient-side documentation

- ☐ Each prep ships with: patient name, Rx number, prescribing clinician, dose, BUD, storage instructions, reconstitution instructions if lyophilized
  - ☐ Patient information leaflet provided (includes contraindications, common side effects, when to call clinician)
  - ☐ Lot number traceable from patient label back to batch CoA
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## Section F — Communication & response

- ☐ Defined point-of-contact for clinical questions: name + phone + email
  - ☐ Adverse event reporting pathway documented (who patient/clinician calls, how the event is logged, MedWatch reporting policy)
  - ☐ Recall procedure documented
  - ☐ Time-to-response SLA for clinical questions: \_\_\_\_ business days
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## Audit summary










Section	Pass / Conditional / Fail	Notes
A — Regulatory pathway		
B — Facility & sterility		
C — Per-batch documentation		
D — Cold-chain & shipping		
E — Patient-side documentation		

Section	Pass / Conditional / Fail	Notes
F — Communication & response		

**Overall recommendation:** - ☐ Approved for referral pathway - ☐ Conditional (specify gaps + remediation deadline): \_\_\_\_\_ - ☐ Not approved (do not refer patients)

**Auditor:** \_\_\_\_\_ **Date:** \_\_\_\_\_ **Next re-audit due:** \_\_\_\_\_

## Red flags that should stop the audit immediately

-  Cannot produce a CoA on request
-  Won't disclose API source
-  Markets "research-grade" or "not for human consumption" peptides
-  Active state-board disciplinary action
-  Refuses to provide PIC contact
-  FDA 483 observations unresolved more than 12 months
-  No documented sterility testing on parenteral preps
-  Markets peptides directly to consumers (DTC) without prescription
-  Promotes peptides under FDA-approved brand names (Wegovy, Ozempic, Mounjaro, Zepbound) — that's a trademark/marketing violation, distinct from the molecule being compounded

## References

- USP General Chapter <797> Pharmaceutical Compounding — Sterile Preparations (2023 revision)
- USP General Chapter <800> Hazardous Drugs — Handling in Healthcare Settings
- USP General Chapters <71> Sterility, <85> Endotoxin, <232>/<233> Heavy Metals, <467> Residual Solvents
- FDA Compounding Quality Center for Excellence resources
- FD&C Act §503A and §503B
- M5.1 video lesson — Compounded Section §6

**Doc status:** Draft v1, 2026-05-26. Not yet reviewed. **Reviewers needed:** Dr. Gross (clinical signal red flags), Daria (formatting), optionally an operations / pharmacy-side advisor.