M5.1 — Compounding Pharmacy Quality Audit Checklist

Compounding Pharmacy Quality Audit Checklist

Use: Before sending a single patient to a compounding pharmacy for semaglutide, tirzepatide, or any other peptide preparation. **Companion to:** the M5.1 video lesson — 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.

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

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

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 ± 5% of label claim)
- [ ] Purity (≥ 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

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

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

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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