SELECTING & EVALUATING COMPOUNDED MEDICATION

A step-by-step decision framework for determining when compounding is appropriate — and how to "vet" the pharmacy that prepares it.

01 Is Compounding Necessary?

FDA DECISION HIERARCHY

1st **Approved animal drug** — On-Label

↓ IF NOT APPROPRIATE

2nd **Approved animal or human drug** — Extra-Label

↓ IF NOT APPROPRIATE

3rd **Compound from an approved drug product** — Extra-Label

↓ IF NOT APPROPRIATE

4th **Compound from a bulk drug substance** — per GFI #256

Key Principles

Compounding should only be considered when approved options cannot meet the patient's needs.

Compounding should NOT be done for price or convenience alone.

02 Which Type of Compounding Facility?

503A COMPOUNDING PHARMACY	503B OUTSOURCING FACILITY
Patient-specific prescriptions	Office stock and patient-specific products
USP standards	cGMP standards
Testing may not be required	Potency / sterility testing required
Default Beyond-Use-Dates may be used	Stability-supported expiration dates

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03 Quick Pharmacy Screening

ASK THESE TWO QUESTIONS

Does the pharmacy compound products that duplicate commercially available drugs?

Does the pharmacy compound products that are not clinically appropriate?

If either answer is YES, investigate further.

EVALUATE THE PHARMACY

- Licensure in states where located and shipping
- State Board of Pharmacy and FDA inspection history
- PCAB accreditation
- Discussion with Pharmacist-in-Charge
- Facility tour (if feasible)

QUALITY INDICATORS

GREEN FLAGS	RED FLAGS
PCAB accredited	Missing or restricted licensure
Fully licensed in states where located and shipping	State restrictions or FDA warning letters, recalls, or Form 483s
Veterinary-trained staff	No veterinary-specific staff training
Pharmacist-led formulation review process	Limited clinical/formulation review
USP-compliant Beyond-Used-Dates	Unsupported Beyond-Used-Dates
Routine product quality testing	No routine product testing
Adverse event reporting process	No adverse event tracking process
Formal staff training program	Inadequate staff training or supervision
“No” to both screening questions	“Yes” to either screening question

DURING AN ON-SITE VISIT

LOOK FOR	BE CONCERNED BY
Clean, organized facility	Poor cleanliness or organization
Appropriate PPE use	Inconsistent PPE use
Current SOPs and policies	Missing procedures
Restricted sterile compounding areas	Weak sterile controls
Pharmacist oversight	Limited pharmacist oversight
Complete formulation and batch records	Incomplete records
Quality check throughout production	Few or no quality-control checkpoints