JAN. 2026

Alliance for Pharmacy Compounding

Compounding the Joy of Living

BEST PRACTICES FOR VENDOR VALIDATION IN COMPOUNDING PHARMACIES

Guidance applies to suppliers of prescription-only finished drugs, ingredients and compounding materials – including wholesalers, manufacturers, 503B outsourcing facilities, 3PLs, and others

INTRODUCTION

As compounding pharmacies face increasing regulatory scrutiny and patient safety expectations, establishing robust procedures for validating vendors – including 503B outsourcing facilities that distribute to 503A pharmacies, manufacturers, wholesalers, and others that supply prescription drugs and ingredients to pharmacies – is critical. This guide outlines best practices for selecting and maintaining relationships with vendors, ensuring compliance with regulatory standards, and maintaining the highest quality standards in the procurement active pharmaceutical ingredients (API) and finished drugs.

1. VENDOR LICENSING AND CREDENTIALING

- **State and Federal Registration:** Vendors of drugs must be registered with the FDA and, where required, licensed in their state of operation. However, licensing classifications vary widely by state. Before engaging with any vendor, verify your own state's specific licensing and distribution requirements, including whether your state requires a 503B outsourcing facility to hold a nonresident wholesaler or manufacturer license to ship compounded medications into your state. Documentation of this verification should be maintained as part of your vendor credentialing file. The following are key types of state licensing that may be required based on the vendor's business model. Please note that some definitions for these entity types may vary state by state.

    - **Wholesaler License:** Required for vendors that distribute medications in bulk to pharmacies or other healthcare facilities. This includes traditional wholesalers who handle, store, and ship medications, and wholesalers who furnish both finished drugs and API.

    - **Manufacturer License:** Required for vendors producing medications on a large scale, including 503B outsourcing facilities in some states.

    - **Third-Party Logistics (3PL) License:** Required for companies that coordinate the logistics, warehousing, and distribution of finished drugs but do not take ownership of the product. This applies to vendors managing the transport of drugs from manufacturers to pharmacies or healthcare facilities and does not include API repackaging and reselling.

    - **Virtual Manufacturer License:** Required for vendors that own and market finished drug products but outsource all actual manufacturing processes to third parties. These companies hold the NDA (New Drug Application) or ANDA (Abbreviated New Drug Application) for the drugs they market and does not include API repackaging and reselling.

    - **Virtual Wholesaler License:** Required for vendors that manage the sale and distribution of finished drugs but do not physically handle the product. This license applies to entities that operate primarily in a virtual environment and outsource warehousing and distribution to 3PLs and does not include API repackaging and reselling.

- **Interstate Licenses:** Vendors shipping drugs across state lines may require out-of-state wholesaler or other licenses. Wholesalers and 503B outsourcing facilities may have different requirements for shipping drugs interstate, check state specific requirements.

2. EVALUATION OF VENDORS AND 503B OUTSOURCING FACILITIES

- **Due Diligence:** Conduct comprehensive due diligence to evaluate the facility's operational, safety, and regulatory compliance standards, as outlined in vendor evaluation policies. Key areas to assess include:

    - **Facility Inspections:** Review FDA 483 reports and/or warning letters, recalls, and inspection histories for any violations. Request responses from the facility to 483s and/or warning letters to evaluate if the response to the observations or findings is adequate.
        - Compounding Actions found here: https://www.fda.gov/drugs/human-drug-compounding/compounding-inspections-recalls-and-other-actions
        - Warning Letters found here: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters
        - Recalls found here: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts

    - **In Person Audits:** Consider visiting the vendor and conducting an in-person audit of the facility. Check for cleanliness and organization, controlled environments, security, pest control, and flow of materials and personnel. See Attachment A: Sample Vendor Audit Checklist.

    - **Sterilization and Monitoring Processes:** Evaluate the vendor's environmental monitoring, sterilization methods, and adherence to Standard Operating Procedures (SOPs).

    - **Beyond-Use Date (BUD) Data:** Where required, ensure the vendor has supporting data for its BUDs and adheres to USP-compliant methods for testing and quality control, such as USP <71> and USP <85>.

    - **Staff Competency:** Verify staff credentials, ongoing competency assessments, and proficiency in compounding technique for 503B outsourcing facilities, as well as relevant certifications.

    - **Legal Compliance:** Verify all compounded preparations offered by a 503B outsourcing facility meet the legal criteria for use by the FDA. The drug must either appear as "currently in shortage" on the FDA's shortage list, or the API must appear on the interim or final 503B bulks list.

3. COMPONENT AND INGREDIENT VALIDATION

- **Bulk Drug Substances:** For API to be used in a compounded preparation, it must meet one the 3 criteria (be a component of an FDA approved drug, have a USP or NF monograph, or appear on the interim or final bulks list). Use the FDA's "Know Your Bulks and Excipients Suppliers" framework to validate the legitimacy of excipients and bulk substances.

- COA: The API must be accompanied by a valid certificate of analysis.

- If ordering API from a new or unfamiliar wholesaler or manufacturer, it is best practice to send a sample of the API to a third-party testing facility to verify the accuracy of the COA.

- Audit the wholesaler's product offerings to ensure that all API meet FDA criteria for use in compounding. If non-compliant or questionable substances are identified, the pharmacy should re-evaluate its relationship with that wholesaler. Pharmacies should evaluate the labeling of the vendor's chemicals to determine the suitability for its intended use. Further, labels should be reviewed for qualifying statements such as "veterinary use only," or "research grade," which should not be used in human compounds.

4. RECOGNIZING RED FLAGS FOR COUNTERFEIT OR ILLEGITIMATE PRODUCTS

Compounding pharmacies must remain alert to potential counterfeit, diverted or otherwise illegitimate drug products entering the supply chain. The FDA and NABP have documented a significant rise in counterfeit products sold through unauthorized channels.

General Principle: If an offer seems too good to be true, it probably is. Products sold at an unusually low cost, in unorthodox packaging, or through unverified channels should be treated as suspect until verified through formal documentation and laboratory analysis.

- Indicators of Possible Counterfeits or Illegitimate Products
    - Unusually low pricing or bulk "discount" offers on branded or shortage drugs (e.g., heavily discounted "Ozempic" or "Mounjaro" boxes).
    - Packaging that differs from manufacturer labeling (foreign language, missing lot numbers, altered logos, or typographical errors).
    - Missing or incomplete Certificates of Analysis (COA).
    - Finished drug vendors unable to produce FDA registration, state licensure, or transaction documentation required under DSCSA.
    - Shipping or return addresses inconsistent with the company's registered address or business license.
    - Requests for payment via nontraditional or unverifiable means (wire transfer, cryptocurrency, personal checks, etc.).

- **Best Practice Actions:**
    - Verify every new source against the FDA's Drug Establishments Current Registration Site (DECRS), the National Association of Boards of Pharmacy (NABP) e-Profile, other state license lookups or the FDA's List of 503B facilites.
    - Report suspicious offers or products to the FDA's Office of Criminal Investigations (OCI) or the NABP's "Report a Suspicious Site."
    - Quarantine suspect product immediately and document your investigation under your pharmacy's Quality Assurance or Purchasing SOP.
    - **5. Quality Assurance Programs**

- **Quality Assurance and Control:** For vendors that are manufacturing or compounding on site, confirm that the vendor has a robust quality assurance program, including:
    - **Process Validation:** Vendors should provide clear documentation on how they validate their repackaging, sterilization and compounding processes.
    - **Environmental Monitoring:** Review their environmental monitoring reports and corrective actions taken to address any detected contamination risks.
    - **Incident Reporting:** Ensure that the vendor maintains a responsive incident reporting system for product recalls or contamination events and can demonstrate steps taken to mitigate future risks.

5. ONGOING VENDOR MONITORING

- **Routine Audits:** Establish a routine for re-evaluating vendors at least annually or biannually, ensuring they continue to meet compliance standards and best practices. This includes periodic review of licensure, SOPs, and the vendor's quality assurance data.
- **Contractual Obligations:** Incorporate clear terms into your contracts with outsourcing facilities regarding expectations for product quality, delivery timelines, and recall procedures.

6. DRUG SUPPLY CHAIN SECURITY ACT (DSCSA) COMPLIANCE

Verification and Traceability Requirements: Pharmacies must ensure that other trading partners from which they obtain finished drugs – manufacturers, wholesalers, 3PLs, and others – comply with DSCSA requirements for product tracing, verification, and authorized trading partner (ATP) status for finished drug products. Vendors should be able to provide transaction information (TI), transaction history (TH), and transaction statements (TS) for applicable finished prescription drugs.

- **Authorized Trading Partners:** Before purchasing from any vendor selling finished drugs, confirm they are an authorized trading parter (ATP) under DCSCA.
    - Pharmacies must purchase only from entities that can provide valid, serialized transaction documentation when required.
- **Exemptions and Applicability:** Drugs compounded at 503B facilities, active pharmaceutical ingredients (APIs) and bulk excipients are not subject to DSCSA serialization or transaction data requirements, but the vendors distributing finished drugs are.

7. CONTROLLED SUBSTANCES COMPLIANCE

Compounding pharmacies and their vendors must adhere to all federal and state requirements for handling controlled substances under the Controlled Substances Act (CSA) and DEA regulations (21 CFR Parts 1300–1321).

Verification Requirements:

- Confirm that both the vendor and pharmacy hold current DEA registrations and statecontrolled substance permits, where required.
- Verify vendor registration using the DEA Diversion Control Division's CSA Validation Tool.
- Maintain DEA Form 222 or CSOS documentation for Schedule II substances, and invoicesfor Schedule III–V substances.

Compounding Limitations:

- 503A pharmacies may compound controlled substances pursuant to patient-specific prescriptions.
- 503B outsourcing facilities must hold DEA registration and state authorization to compound and distribute controlled substances for office use.

Controlled substances may be procured only from DEA-registered and state-licensed suppliers. Any anomalies in ordering patterns, vendor licensing, or pricing should trigger an internal compliance review.

8.REGULATORY COMPLIANCE AND DOCUMENTATION

- **Regulatory Adherence:** All vendors must comply with federal, state, and local lawsgoverning drugs, including specific guidance for labeling, packaging, and drug distribution.
- **Documentation Review:** Regularly review critical documentation such as licenses,insurance, staff training records, and quality assurance logs.

9.RISK MANAGEMENT AND CONTINGENCY PLANNING

- **Failure Mode and Effects Analysis (FMEA):** Use FMEA as a tool to proactively identifypotential risks in a 503B outsourcing facility's compounding processes and to addressthose risks through corrective action before they affect patient care.
- **Product Recall Procedures**: Ensure the vendor has a transparent process for handlingrecalls and can provide detailed reports on any past recalls.
- **Redundant Sources:** Ensure 503A pharmacies have at least a primary and secondarysource for key items to ensure patient continuation of care. Pharmacies should be awarethat secondary sourcing may have implications for the BUDs of their compounds.

Attachment A: Sample Vendor Audit Checklist

VENDOR AUDIT CHECKLIST

Purpose: To evaluate compliance, quality systems, and reliability of all entities supplying prescription-only drugs, APIs, or compounding materials.

Applies to: 503B Outsourcing Facilities • Manufacturers • Wholesalers • 3PLs • Any Rx-only Supplier

Vendor Name: _____ Date: _____

Auditor(s): _____ Vendor Contact: _____

Vendor Type: ☐ 503B ☐ Manufacturer ☐ Wholesaler ☐ 3PL ☐ Other: _____

Product Category: ☐ Sterile ☐ Non-sterile ☐ API ☐ Finished Drug ☐ Packaging/Devices

1. FACILITY AND ENVIRONMENT

Item	Yes/No	Notes
Facility is clean, organized, and free of clutter	☐	
Adequate lighting, ventilation, and pest control	☐	
Controlled access to storage/processing areas	☐	
Storage areas meet temperature/humidity requirements	☐	
Design prevents mix-ups or cross-contamination	☐	
For sterile vendors: certified cleanrooms and environmental monitoring	☐	

2. LICENSING AND REGULATORY STATUS

Item	Yes/No	Notes
FDA registration current and verifiable	☐	
State licenses current (manufacturer, wholesaler, 3PL, 503B, etc.)	☐	
DEA registration current (if handling controlled substances)	☐	
Inspection history reviewed (FDA/state)	☐	
No unresolved warning letters, consent decrees, or enforcement actions	☐	
Recall and complaint procedures documented	☐	
Verification of DSCSA compliance (serialization, tracing, T3 data)	☐	
Documentation of drug distributor or manufacturer licenses where applicable	☐	

3. QUALITY SYSTEMS

Item	Yes/No	Notes
FDA registration current and verifiable	☐	
Written Quality Management System (QMS) in place	☐	
Documented SOPs for all relevant processes	☐	
Change control, deviation, and CAPA processes active	☐	
Training records maintained and current	☐	
Supplier qualification program documented	☐	
Internal audits conducted regularly	☐	
Recall procedures defined with timelines and documentation	☐	
Evidence of culture of quality among staff	☐	

4. MATERIAL HANDLING AND DOCUMENTATION

Item	Yes/No	Notes
Clear procedures for receiving, quarantine, and release	☐	
Materials labeled accurately with lot/batch control	☐	
Temperature-controlled storage and shipment verified	☐	
DSCSA transaction history, information, and statement maintained	☐	
Certificates of Analysis (COA) retained and verified	☐	
Return, complaint, and recall processes documented	☐	

5. PRODUCT INTEGRITY

Item	Yes/No	Notes
APIs sourced from qualified, FDA-registered manufacturers	☐	
Identity testing or third-party verification of COAs performed	☐	
Packaging tamper-evident and labeled properly	☐	
For 503Bs: compliant with CGMP and distributing finished drugs only	☐	
For wholesalers/3PLs: no repackaging or relabeling beyond license	☐	
Product sterility, potency, and endotoxin testing reviewed as applicable	☐	

6. PERSONNEL AND TRAINING

Item	Yes/No	Notes
Key staff trained in GDP/GMP and regulatory compliance	☐	
Ongoing training documented and competency assessed	☐	
Quality or compliance officer designated	☐	
Staff able to describe QA and recall procedures	☐	
Training includes handling of suspect/illegitimate product per DSCSA	☐	

7. RED FLAGS / OBSERVATIONS

Item	Yes/No	Notes
Refusal to allow document or facility review	☐	
Incomplete or inconsistent documentation	☐	
Evidence of unlicensed distribution or mislabeling	☐	
Prices or products that appear "too good to be true"	☐	
Selling items outside license authority	☐	
Recent enforcement actions or recall history without documented	☐	

8. RISK ASSESSMENT AND FOLLOW-UP

Item	Yes/No	Notes
Vendor risk rating assigned (Low / Moderate / High)	☐	
Follow-up required for moderate/high risk vendors	☐	
Re-evaluation frequency: Annual for high-risk, Biennial for low-risk	☐	
Documented corrective actions from	☐	

9. SUMMARY

Overall Impression: ☐ Satisfactory ☐ Conditional Approval ☐ Unsatisfactory

Follow-Up Actions Required: _____

Vendor Risk Rating: ☐ Low ☐ Moderate ☐ High

Auditor Signature: _____ Date: _____