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Financial Disclosures

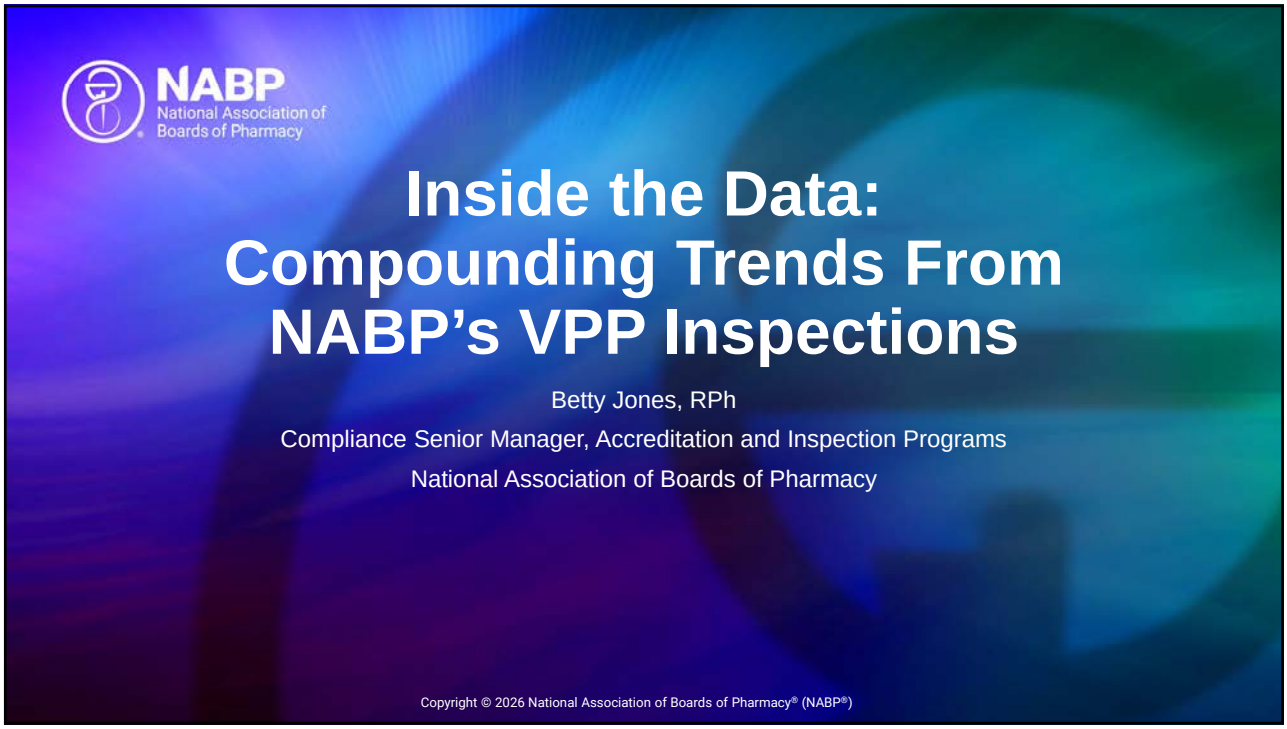
Our speaker declares that they do not have a current affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of this continuing pharmacy education (CPE) activity within the past 24 months.

Additionally, NABP staff involved in the planning of this activity do not have any current affiliation or financial arrangement with any ineligible companies that may have a direct interest in the subject matter of NABP's CPE program within the past 24 months.

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Learning Objectives

For this session:

1. Describe at least three of the inspection trends seen in compounding pharmacies.
2. Identify areas where educational efforts may improve compliance with compendially applicable USP compounding chapters.
3. Discuss current knowledge of USP compounding chapters against selected images from compounding pharmacies for compliance with the chapters.

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Pre-Assessment Questions

Question: According to data evaluated from NABP's Verified Pharmacy Program® (VPP®) inspection program, what are some of the topics where compliance with USP compounding chapters can be improved?

Answer Choices:

A. Training and competency assessment documentation
B. Master formulation records (MFRs) and compounding records (CRs) for nonsterile compounding
C. Aseptic technique for sterile compounding
D. Selecting a qualified designated person (DP)
E. A, B, and C

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Pre-Assessment Questions

Question: What are some recommendations to help improve employee training and competency assessment file review during an inspection?

Answer Choices:

A. Prepare employee files in advance of an inspection, ensuring they are organized and complete.
B. Conduct a mock inspection.
C. Designate a person to review the files with the inspector to help guide them through any paper or electronic files.
D. For paper training files, review at least one complete file with the inspector.
E. For electronic training files, have an employee navigate the system to demonstrate the location of each item.
F. Give the inspector a username and password into the electronic record and wish them luck.
G. A through E

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Pre-Assessment Questions

Question: Describe what is wrong with this photo.

Answer Choices:

A. Compounder's sterile gloves are not placed properly compared to the sleeves of their gown.
B. Compounder has too many items in PEC.
C. Compounder is blocking first air with hand placement.
D. All of the above



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About NABP

The National Association of Boards of Pharmacy® (NABP®) is a 501(c)(3) nonprofit organization that was founded in 1904. Working with our members – the state boards of pharmacy – we help support patient and prescription drug safety through examinations that assess pharmacist competency, pharmacist licensure transfer and verification services, and various pharmacy accreditation programs.

- Mission: NABP is the independent, international, and impartial Association that assists its member boards in protecting the public health.

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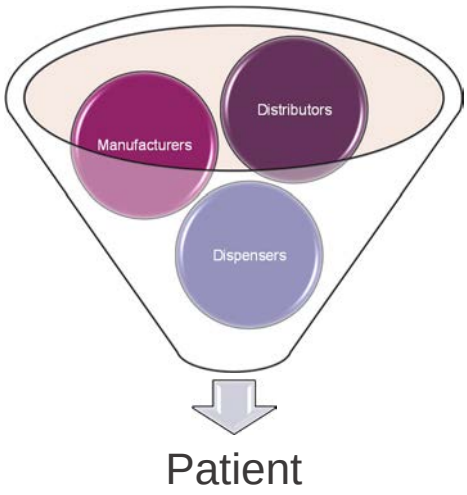
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Cornerstones of Compounding

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Supply Chain Considerations



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Compounding Is a Necessary Part of the US Drug Supply Chain!

Hospitals and Infusion Centers
(Dosage form requires the drug to be compounded)

Children

Allergies

Drug Shortage

Prescription Drug Is No Longer Commercially Available
(Not withdrawn for safety or efficacy)

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Cornerstones of Compounding

Majority of Compounding Pharmacies Do a Great Job With Patient Care, Every Day!





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What Is Compounding?

Definition of Compounding Under Federal , Drug, and Cosmetic Act (FD&C Act)

> **(d) [2] Definitions**
> In this section:
> (1) The term "compounding" includes the combining, admixing, mixing, diluting, pooling, reconstituting, or otherwise altering of a drug or bulk drug substance to create a drug.

FDA Guidance Footnote – Pharmacy Compounding of Human Drug Products Under Section 503A

Exceptions:

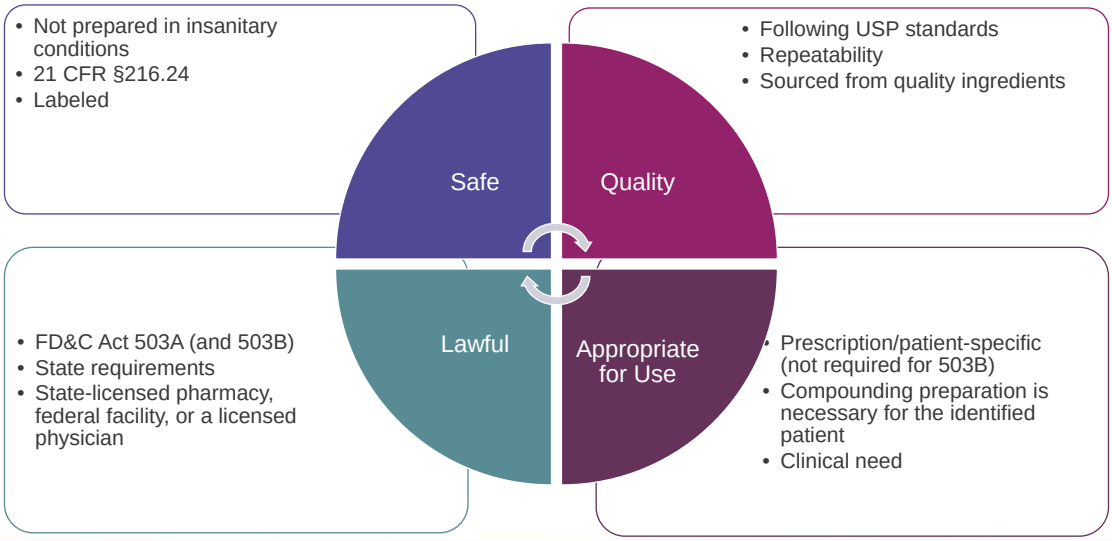
> [3] Section 503A of the FD&C Act and this guidance do not apply to positron emission tomography (PET) drugs as defined in section 201(ii) of the FD&C Act or radiopharmaceuticals (see section 503A(e) of the FD&C Act). Section 503A(e) specifically states that section 503A does not apply to radiopharmaceuticals or to PET drugs as defined in section 201(ii). PET drugs are subject to the current good manufacturing practice requirements of 21 CFR part 212. Section 503A also does not apply to drugs intended for use in animals. The statutory and regulatory provisions governing the compounding of human drug products differ from those governing the compounding of animal drug products. All relevant statutory and regulatory requirements relating to the compounding of animal drug products remain in effect, subject to the requirements of section 512 of the FD&C Act (21 U.S.C. 360b) and 21 CFR part 530.

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Cornerstones of Compounding



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Cornerstones of Compounding – Safe Facility

Facility Minimum Requirements

- Clean (and cleanable), dry, sanitary, and orderly condition
- Well lit
- Temperature controlled and well ventilated
- Plumbing with hot and cold water
- Drugs are not prepared, stored, or held under insanitary conditions
- Separate area, equipment, and fixtures that are appropriate for compounding

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Cornerstones of Compounding – Safe Label (and Labeling)

Definitions

Label = immediate container

Labeling = any additional accompanying material

<< Previous TITLE 21 / CHAPTER 9 / SUBCHAPTER II / § 321 Next >>

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

Labeling violations *could* be considered misbranding – Section 502 of FD&C Act.

<< Previous TITLE 21 / CHAPTER 9 / SUBCHAPTER V / Part A / § 352

§352. Misbranded drugs and devices

A drug or device shall be deemed to be misbranded-

(a) False or misleading label

(1) If its labeling is false or misleading in any particular.

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Cornerstones of Compounding – Safe Label (and Labeling)

Pharmacy Label Challenges

Real estate on a label is limited.

Minimum requirements on pharmacy-dispensed labels (sidebar):

- May vary amongst states

Label vs Labeling:

- Label could interfere with some dosage forms (inhalers).
- Sealed manufacturer container (Pharmacy would need to "open" outer container to place the label on the inner container, which could affect the use-by date.)
- Labeling may be needed to supplement the label.

Abbreviations on pharmacy labels:

- Example: "Met" could mean metronidazole, metformin, or methylprednisolone.
- Litmus test for labels:
  - If an emergency room physician knows the contents inside the container

Minimum Requirements on Pharmacy-Dispensed Labels

- **Triad** – Pharmacy Name, Prescriber Name, Patient Name (addresses and contact information)
- **Drug** Prescribed (drug name, strength, dosage form, quantity, NDC, side effect statement)
  - Caution! Compounded drug(s) have varying quantities of active ingredients
- **Prescription and Dispensing** Information (date issued, Rx#, directions for use, refills, date of dispensing, beyond-use date)

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Cornerstones of Compounding – Quality USP Standards

USP Standards

USP compounding standards are a *minimum* standard.

USP compounding is mentioned under FD&C Act in 503A.

(b) Compounded drug

(1) Licensed pharmacist and licensed physician

A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician-

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations-

(i) that-

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c);

(ii) that are manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title); and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

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Cornerstones of Compounding – Lawful

Human Drug Compounding

Link to Food and Drug Administration (FDA) website for chart on right

If not *all* requirements of 503A (or 503B) are met, the applicable federal requirements are no longer exempt

. . . meaning, the facility has produced an unapproved drug.

These are in place to *protect* the drug approval process.

Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) specifically address human drug compounding, and reference other provisions of the FD&C Act. The following chart describes applicable FD&C Act requirements in different scenarios:

Scenario	Applicable Federal Requirements
Drugs compounded in accordance with all conditions of section 503A	Drugs subject to all provisions of the FD&C Act that apply to conventionally-manufactured drugs, except: • Current good manufacturing practice requirements (section 501(a)(2)(B)) • Labeling with adequate directions for use (section 502(f)(1)) • Premarket approval requirements (section 505)
Drugs compounded in accordance with all conditions of section 503B	Drugs subject to all provisions of the FD&C Act that apply to conventionally-manufactured drugs, except: • Labeling with adequate directions for use (section 502(f)(1)) • Premarket approval requirements (section 505) • Drug supply chain security requirements (section 582)
Drugs not compounded in accordance with conditions of sections 503A or 503B	Drugs subject to all provisions of the FD&C Act that apply to conventionally-manufactured drugs

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Compounding Federal Regulations – 503A (Pharmacy Compounding Guidance)

Types of Compounders (503A applies to)

- State-licensed pharmacy, federal facility, or physician (practitioner with prescriptive authority)

Patient-Specific Prescriptions

- FDA guidance
- Must be labeled with patient name before it leaves the compounding facility

Bulk Drug Substances (BDS)

- Valid COA and FDA-registered drug establishment
- Comply with:
  - USP chapter on pharmacy compounding; and
  - USP/NF monograph, if exists, or
  - be component of an FDA-approved drug; or
  - be on the BDS list (21 CFR §216.23)
- FDA Interim Policy – Nominations found in Category 1 may be compounded.

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Compounding Federal Regulations – 503A (Pharmacy Compounding Guidance)

Drugs Withdrawn or Removed From the Market

- Withdrawn for Safety or Efficacy List in 21 CFR §216.24

Drugs Presenting Demonstrable Difficulties for Compounding

- Proposed rule

Drugs That Are Essential Copies (of a Commercially Available Drug Product)

- Regularly or in inordinate amounts of essential copies
- FDA guidance

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Cornerstones of Compounding – Appropriate for Use, FDA

FDA Compounding

FD&C Act – Law

§353a. Pharmacy compounding

(a) In general

Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding-

(1) is by-

(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

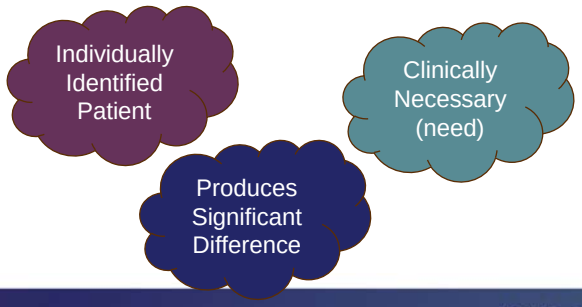
(B) a licensed physician,

(2) Definition

For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

Prescription Requirement Guidance:

In general, when a compounded drug product is clinically necessary for a patient, a prescriber writes a prescription for a compounded drug product, and the patient brings the prescription to a pharmacy, where a licensed pharmacist fills the prescription. In an inpatient setting, such as in a hospital, a prescriber may write an order for a compounded drug product on a patient's health record (e.g., chart). In an office setting, a physician may make an entry or order in a patient's health record that the physician compounded a drug in the office for administration to his or her patient after the patient presents at the physician's office with a clinical need for the compounded drug.



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Concerns Observed With Compounding

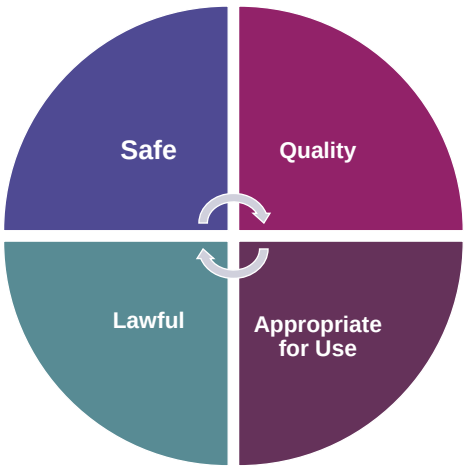
Unusual (Rare) Examples Seen in the Field

Why Minimum Standards Are Needed

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Cornerstones of Compounding



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Nonsterile Compounding Facility Concerns – Examples







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Sterile Compounding Facility Concerns – Examples







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Facility Concerns – Pets and Pests





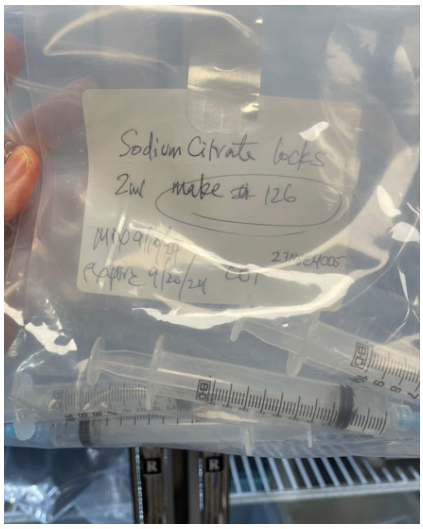


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Label Concerns







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Compounding Label Concerns – Question From DEA

Drug Enforcement Administration (DEA) Reached Out to NABP About a Compounded Testosterone Cream Complaint.

Question Posed: "We received a complaint from a patient who was unaware that amphetamines had been added to his (testosterone) cream and his [sic] tested positive for methamphetamine."

Follow Up From DEA: "I wanted to let you know also that our lab analyzed the cream and the substances identified were 17β-Hydroxyandrost-4-en-3-one (Testosterone) and methamphetamine."

Evaluation:

- Likely not a contaminant
  - Two FDA-registered drug establishments that have registered methamphetamine as an active pharmaceutical ingredient (API)/unfinished drug product
  - When cross-referenced, manufacturers of testosterone (again, as an unfinished drug product/API) said there was no cross-over in the 263 listed items (so, cross contamination of API substances is ostensibly ruled out).
  - Double-checked this with each of the listed labelers and did not see testosterone listed as one of their products listed

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Sourcing of Ingredient – Quality Concerns

Ln	Order	Customer Order#	Part Description	Batch	Exp Date	Storage Temp:	Quantity	UOM	Caution Statemer
1			Semaglutide	C005A-D240601	06/25/2027	Store frozen (-20°C)	0.025	KG	FOR RESEARCH AI TESTING PURPOSI ONLY. NOT FOR MANUFACTURING, COMPOUNDING OI RESALE.
TOTAL									0.0

Invoice

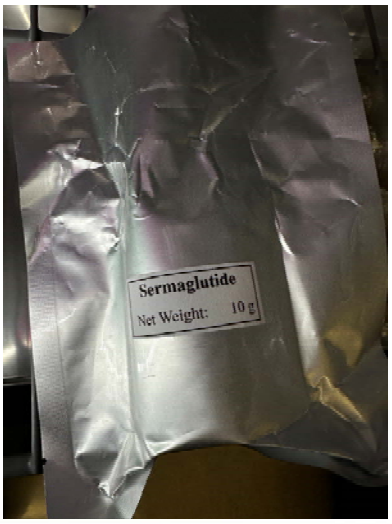
10	Semaglutide	Quantity	0.001
		Unit	KG
	CAS #: 910463-68-2	Unit Price	$0.00
	HTS #: 2937.19.00.00	Extended Price	$0.00
	Duty:0%%, Status:-		
	Chinese Duty:0%		
	FDA #: [redacted]		
	NDC #: [redacted]-05		
	Manufacturer: [redacted]		
	Caution: For - R&D Use Only.		

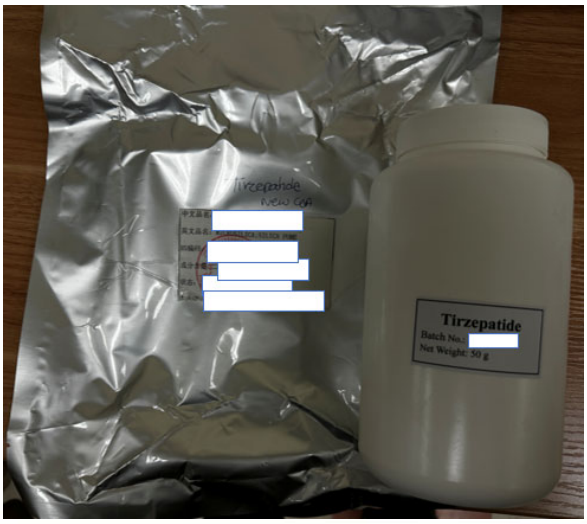
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Sourcing of Ingredient – Quality Concerns





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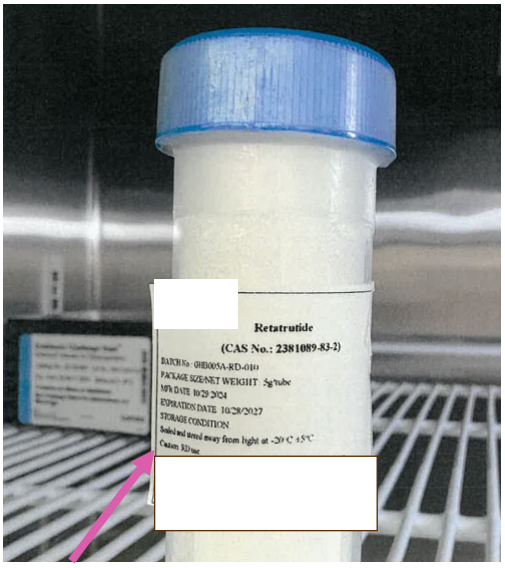
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Concerns of Lawfulness

Retatrutide and cagrilintide cannot be used in compounding

Retatrutide and cagrilintide cannot be used in compounding under federal law. Additionally, these are not components of FDA-approved drugs and have not been found safe and effective for any condition.

Source: *https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss*



See "Caution: R&D use" on label

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Concerns of Lawfulness (and Lack of Label)



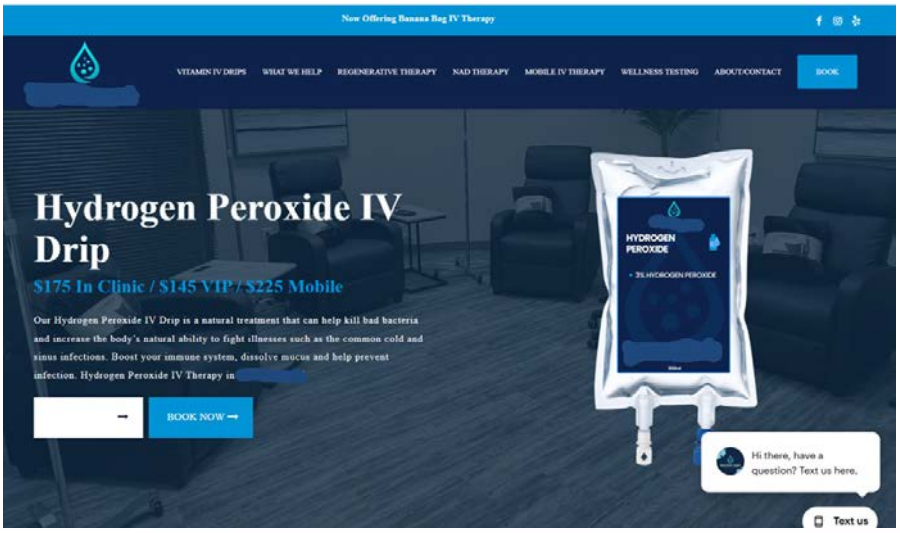


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Appropriate for Use (Medically Necessary) and Safety Concerns



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NABP Accreditation and Inspection Programs

Pharmacy Programs	Distributor Programs	Digital Health Program

• Inspections:
  • **VPP**
  • State inspection projects
• Accreditations:
  • Digital Pharmacy
  • DMEPOS Pharmacy
  • Community Pharmacy
  • Specialty Pharmacy
  • **Compounding Pharmacy**
  • **Home Infusion Therapy Pharmacy**
	• Inspections:
	  • **Supply Chain Inspection Program**
	• Accreditations:
	  • Drug Distributor
	  • OTC Medical Device Distributor
		• Healthcare Merchant Accreditation

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VPP Inspection

The most widely recognized multistate, uniform inspection program accepted by state boards of pharmacy across the nation.

If your pharmacy is seeking resident and/or nonresident licensure, NABP's Verified Pharmacy Program® (VPP®) allows state boards of pharmacy to request access your verified pharmacy licensure details, VPP inspection report, inspection responses, and other important data through the use of a secure information sharing network. The program equips the state boards of pharmacy with quality and timely data that can assist in decreasing the time it takes to make licensing decisions.

VPP is ideal for pharmacies that:

- Need a nonresident pharmacy inspection required by an out-of-state board of pharmacy for renewing or obtaining nonresident licensure.
- Want to pursue NABP Compounding Pharmacy Accreditation for which VPP is a prerequisite.

Applicants for VPP tend to be community pharmacies, mail order pharmacies, home infusion therapy pharmacies, specialty pharmacies, and compounding pharmacies.

NABP does ***not*** routinely inspect hospital inpatient pharmacies.

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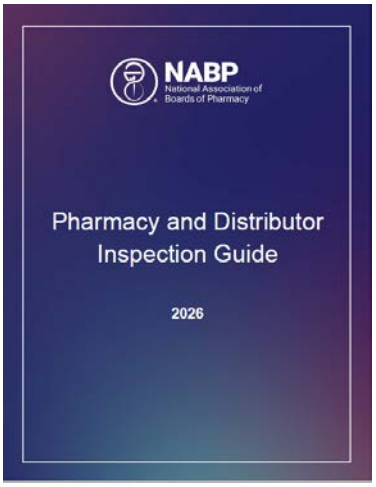
Preparation for a VPP Inspection

The NABP Inspections team will provide you a checklist of documents to have prepared for your on-site inspection.

NABP has a two-part blog article series: *Preparing for an Inspection or Accreditation Survey* (April 2024).

NABP has a free inspection guide for applicants.

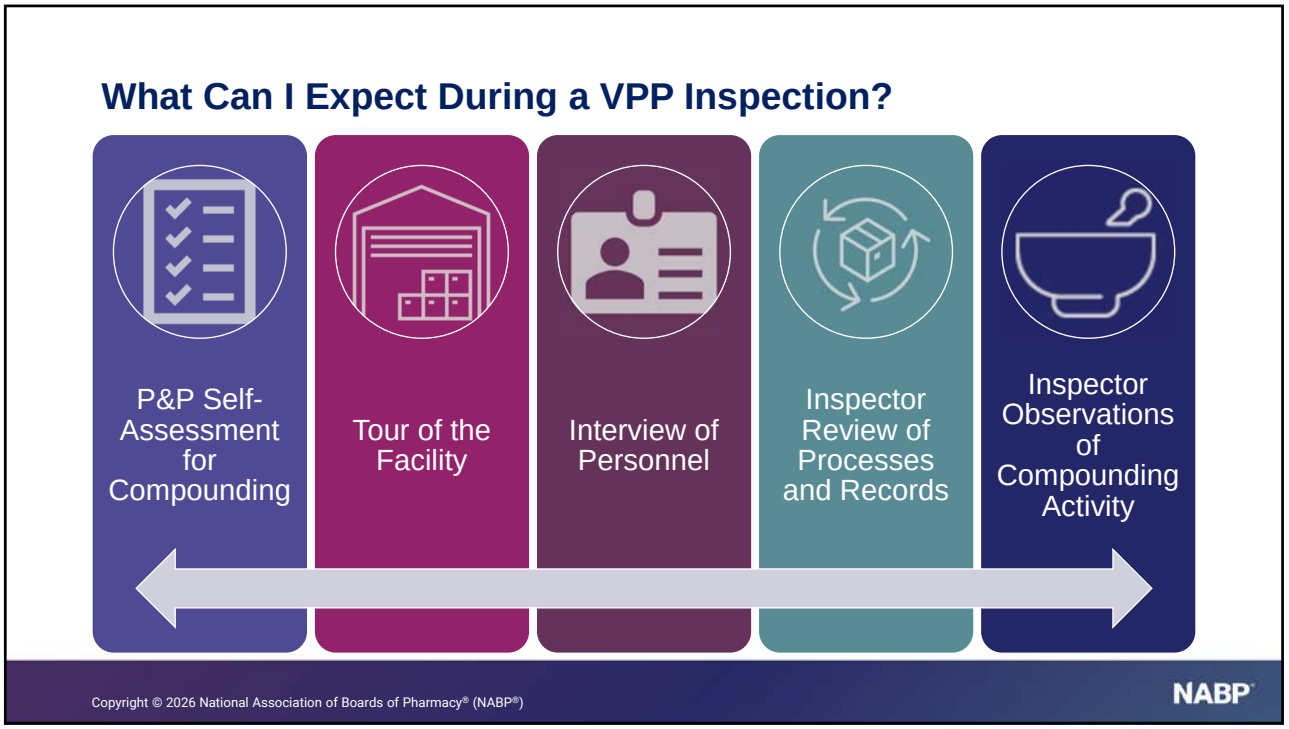
Other *NABP Blog* articles are also available.



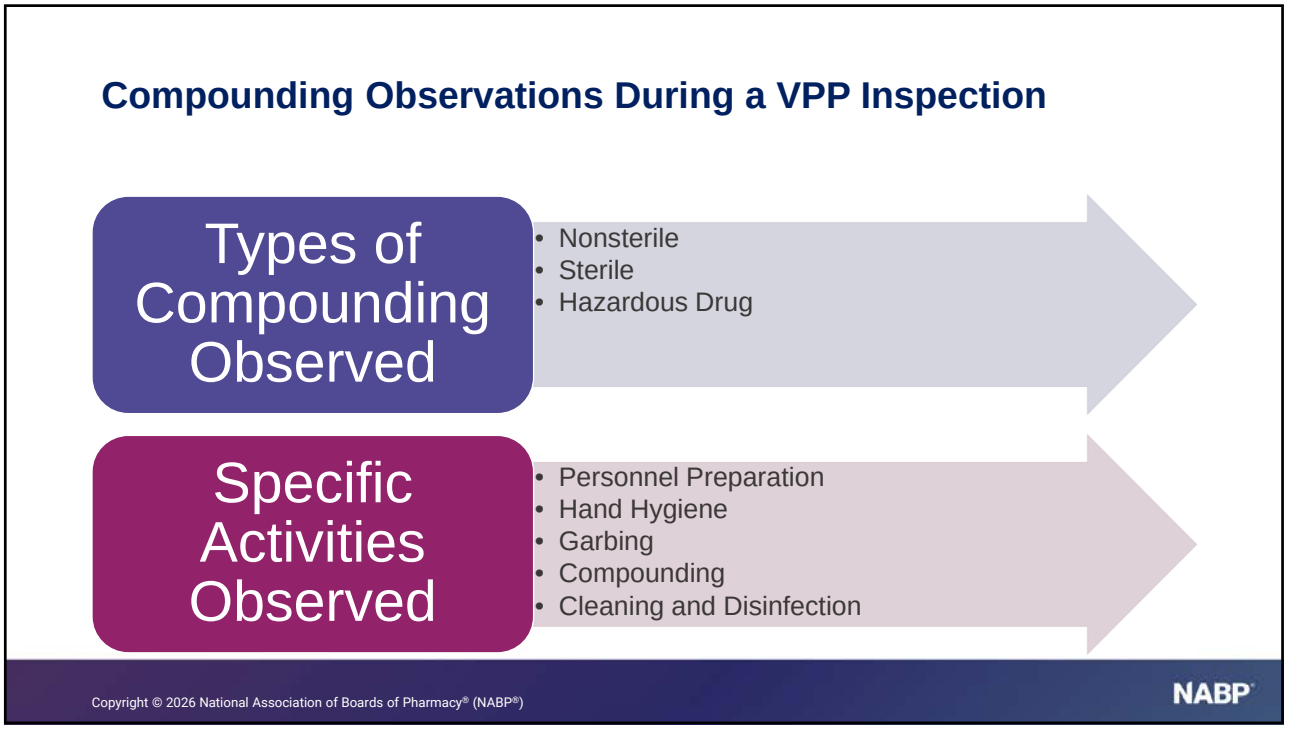
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What Can I Expect During a VPP Inspection?
P&P Self-Assessment for Compounding
Tour of the Facility
Interview of Personnel
Inspector Review of Processes and Records
Inspector Observations of Compounding Activity
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Compounding Observations During a VPP Inspection
Types of Compounding Observed
Nonsterile
Sterile
Hazardous Drug
Specific Activities Observed
Personnel Preparation
Hand Hygiene
Garbing
Compounding
Cleaning and Disinfection
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Recommendation!

Designate a Person

- PIC, DP, and/or another person familiar with training files
- Individual should ask inspector to let them know if something appears to be missing (so individual can track it down, in case it is in HR record or another system).
- Conduct a mock inspection.

Paper

- Make sure files are organized, complete, and ready for review.
- Walk inspector through one complete training file (before inspector does any independent review).

Electronic

- Have this person navigate the training record system following inspector's instructions ("show me" method).

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VPP Inspection Report

Read the Entire Report

- VPP is **not** a pass/fail inspection; it contains on-site observations and descriptions.
- Compounding (USP <795> and <797>) questions are in the affirmative and in a parent/child format.

Focused Information

- This gives the reader a summary of items (eg, sections, topics, or questions) to review.
- These are the items for which the pharmacy is encouraged to provide a response.

Inspector Notes

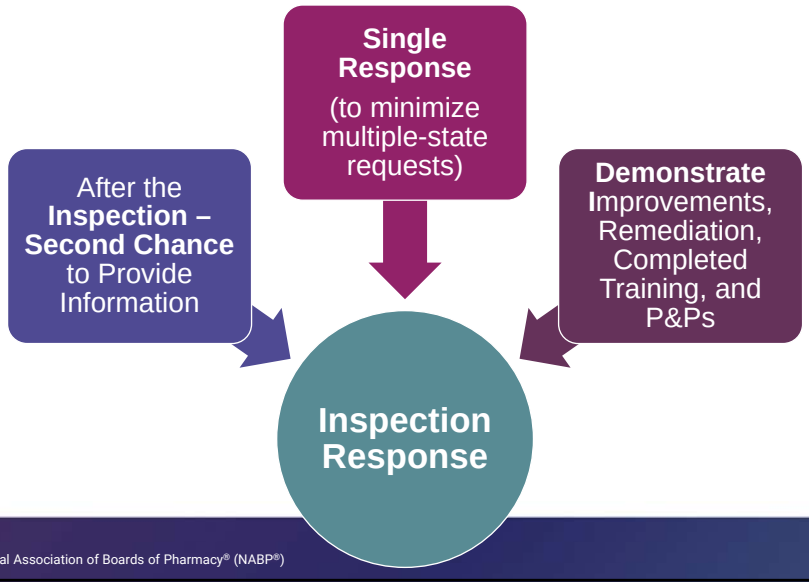
- Inspector notes, under the licensing section, may include a summary of the inspection (business models, licensing, or questions that aren't asked elsewhere in the report).
- Inspector notes throughout should describe details to support a "yes" or "no" answer.

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VPP Inspection Response



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VPP Inspection Response – Fully Supported Response

Description of Scenario Found During Inspection	Incomplete Response	Full Response
Cleaning log had blanks showing the task was not performed	- Copy of revised cleaning log	- Revised P&P documenting cleaning frequency - Revised cleaning log - Training materials - Evidence to support training was completed - Evidence to show cleaning is being performed at the correct frequency
Prescription drugs found on concrete floor	- Explanation that drugs were removed from the floor and placed on a shelf	- Revised receiving procedure - Photograph of drug storage location - Training materials - Evidence to support training was completed
Alarm settings for refrigerator were outside the expected range (30° F, instead of 36° F)	- Explanation that the temperature was changed to 36° F	- Revised procedure specifying the correct temperature range for alarm settings - Image or photograph of 36° F for the low alert

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Overview of Compounding Trends From VPP Inspections

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VPP Inspections – Overview

By the Numbers
- VPP Inspections conducted between 7/1/25-6/30/26
- 299 total number of inspections
  - Not all inspections included compounding.
  - Does not include nuclear pharmacies

Compounding Specific
- 163 Nonsterile Compounding activity
- 156 Sterile Compounding activity
- 120 Nonsterile Hazardous Drug Compounding activity
- 62 Sterile Hazardous Drug Compounding activity

Assessment
- Overall compliance is assessed for the parent topic (question).
- Individual compliance is the area of focus (child statement).
  - Child statement below 90% is considered an educational opportunity.

Data Limitations
- If a standard did not apply, it was counted as a "yes" for statistical purposes.
- *When high volume of N/A*, will provide a secondary compliance statistic.

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Top 5 Opportunities for Improvement – Nonsterile

Training/Competency Assessment	• Overall compliance is 62%. • Records Review: Initial training (69%); direct oversight personnel (70%); and ongoing assessment (68%)
Facility/Storage	• Overall compliance for storage requirements is 77%. • Temperature monitoring devices annually verified for accuracy (85%)
Cleaning	• Overall compliance for cleaning is 75%. • Frequency not following Table 1 (range of 89-92%)
MFR	• Overall compliance is 74%. • Physical description (88%) and supporting references (89%) continue to be outliers.
CR	• Overall compliance is 73%. • Physical description (87%) and QC procedures (88%) continue to be outliers.

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Top 5 Opportunities for Improvement – Sterile

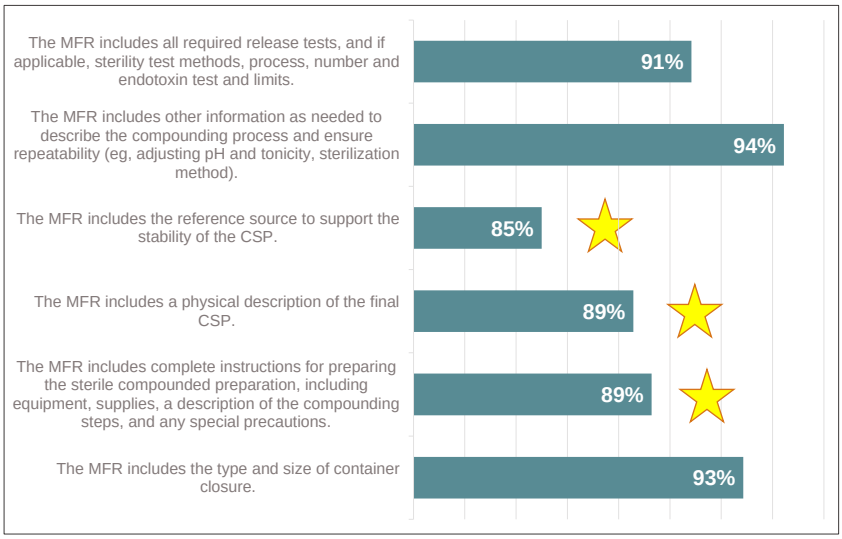
Training/Competency Assessment	•Hand hygiene and garbing competency assessments (87%) •Aseptic manipulation assessment (87%) •Training program and ongoing competency assessment (92%)
Live Compounding Observations	•Overall compliance for hand hygiene is 90% (fingernails cleaned with nail pick is 94%). •Overall compliance for garbing is 81% ("all personnel entering are garbed" is 91%). •Overall compliance for compounding processes is 78% (aseptic technique is 85%).
Vial Assembly	•Stoppered vials moved outside primary engineering control (PEC) before vial crimping step completed •Observed 8 times in reporting period
MFR/CR	•MFR overall compliance is 74% (reference source is 85%; complete instructions is 89%; and physical description is 89%). •CR overall compliance is 81% (QC process is 91%).
Category 3 BUD	•Limited observations •91% overall compliance (when excluding N/A, overall compliance is 68%) •Particulate matter testing (<788>) is 94% (when excluding N/A, compliance is 79%). •Container closure (<1207>) and compounded sterile preparation (CSP) BUD supported by a stability indicating assay is 95% (when excluding N/A, overall compliance is 80-83%).

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Sterile – MFR
74% Full Compliance



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MFR Trends

- 13 items for inspector's review
- MFR overall compliance is 74% (reference source is 85%; complete instructions is 89%; and physical description is 89%).
- Additional Observations
  - Container closure not documented
  - Storage requirements missing
  - One amber vs clear container not listed
  - One no mention of stock solution use
  - One USP BUD limits used but was refreezing after initial thaw
  - One pH adjusters not listed
  - One steps missing for how to re-filter

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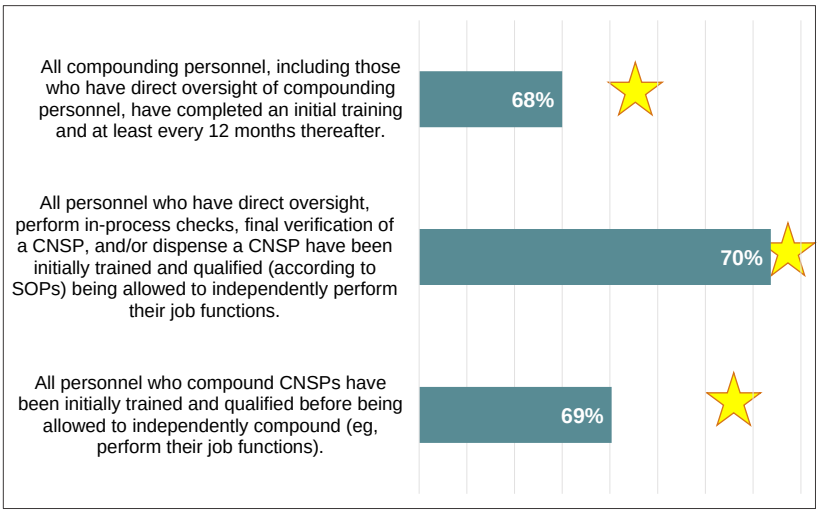
Nonsterile Compounding Trends and Other Observations

Opportunities for Improved Compliance With USP Compounding Chapters

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Nonsterile –Training and Competency Assessment Records Review, 62% Full Compliance



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Training and Competency Assessment Trends

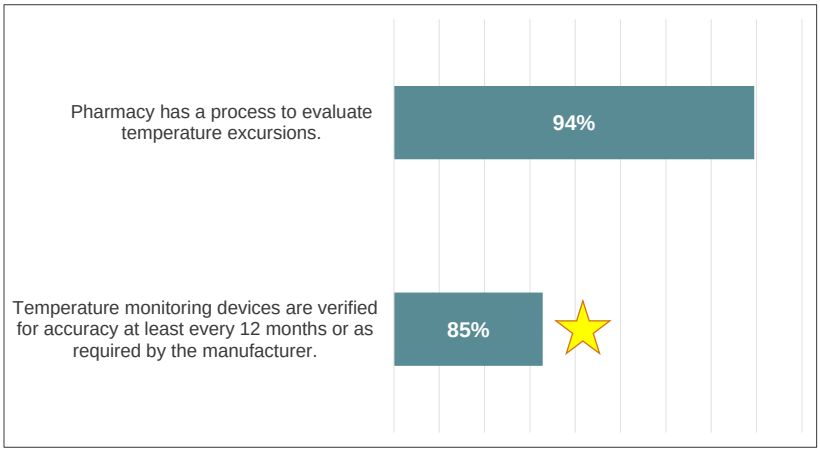
- Annually
  - Saw some N/A since it was not time for annual review
  - Missed deadlines for annual
- Additional Observations
  - Read and understand, not demonstrated
  - Compounding equipment training missing
  - No written documentation
  - One had no assessment since revision (2023)

76% compliance with **USP recommendation** – designated person(s) should monitor and observe compounding activities

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Nonsterile – Facility/Storage 77% Full Compliance



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Pharmacy's Storage Areas Trends

- 7 items for inspector's review
- Temperature monitoring devices verified for accuracy is 85%

Additional Observations

- Observed better temperature monitoring for refrigerator than for controlled room temperature (CRT) storage areas
- Not all areas where compounding was performed were monitored (general pharmacy and lab monitored but not HD room).

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Facility Storage (Occasional) Observations – Recommendation for Walk-Through





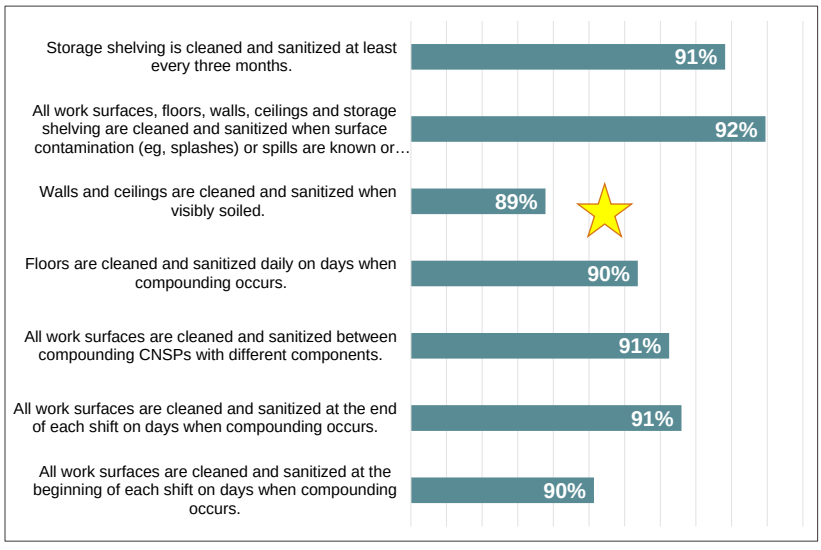


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Nonsterile – Cleaning and Sanitizing Activities 75% Full Compliance



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Pharmacy's Nonsterile Cleaning and Sanitizing Trends

- 7 items for inspector's review
- "Walls and ceilings are cleaned and sanitized" is 89%.
- Documentation was #1 issue.
  - Done, but not documented
  - Incomplete documentation
  - No logs found
- Frequencies not following Table 1

USP Recommendation

Are floors in the compounding area easily cleanable, non-porous, and non-particle generating?

- 97% compliance

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Sinks in Nonsterile Compounding Areas – Recommendation for Walk-Through

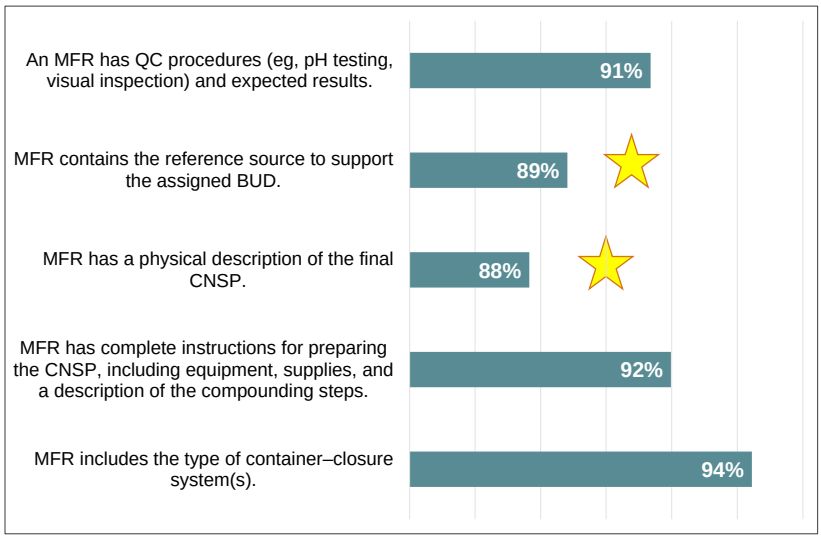


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Nonsterile – Master Formulation Record 74% Full Compliance



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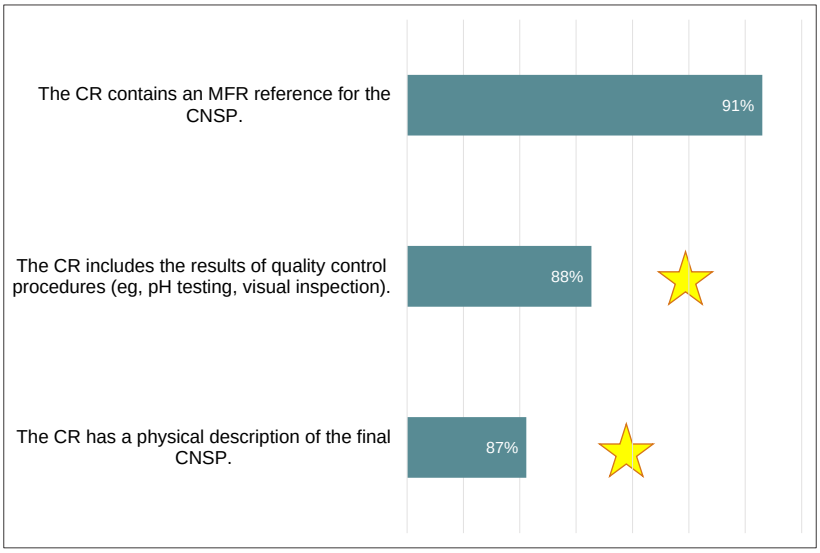
MFR Trends

- 10 items for inspector's review
- Physical description (88%) and supporting references (89%) continue to be outliers.
- Small improvement in QC procedures
- "Complete instructions" is still an area for further review.
- Other Observations
  - One templates not completed (troche) or no specification (cream directions were all the same)
  - Equipment needed was missing.
  - Label missing quantity of each active ingredient

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Nonsterile – Compounding Record 73% Full Compliance



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CR Trends

- 16 items for inspector's review
- Physical description (87%) and QC procedures (88%) continue to be outliers.
- Additional Observations
  - Strength/ concentration missing
  - No storage conditions
  - Mixing directions missing

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Nonsterile – Inspector Observations for Compounding Activities

Personnel Preparation
- 93% Full Compliance
  - Examples: Nose ring accommodation not documented; head scarf accommodation not documented

Hand Hygiene
- 95% Full Compliance
  - Examples: Did not wash hands for 30 seconds; another said, "Performed in rest room prior to starting garbing."

Garbing
- 96% Full Compliance
  - Examples: Not fully garbed (simulated compounding observed); no face mask

Compounding
- 84% Full Compliance
  - 94% compliance – appropriately garbed for the type of CNSP prepared

Cleaning and Disinfection
- 90% Full Compliance
  - 93% compliance for cleaning prior to compounding and in between compounds



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Nonsterile Compounding Photos





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Nonsterile – Statistics to Share

- 23% of pharmacies compound using at least one USP monograph.
- 90% of pharmacies compound a CNSP using APIs.
- 85% of pharmacies are using a closed system processing device (eg, CVE).
- 35% of pharmacies are compounding preparations outside of Table 4 limits.

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Nonsterile – Statistics to Share
Be on the lookout!

MFR was created for each unique formulation.	APIs used for CNSPs were manufactured by an FDA-registered facility.	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.
• 92% compliance	• 91% compliance	• 95% compliance

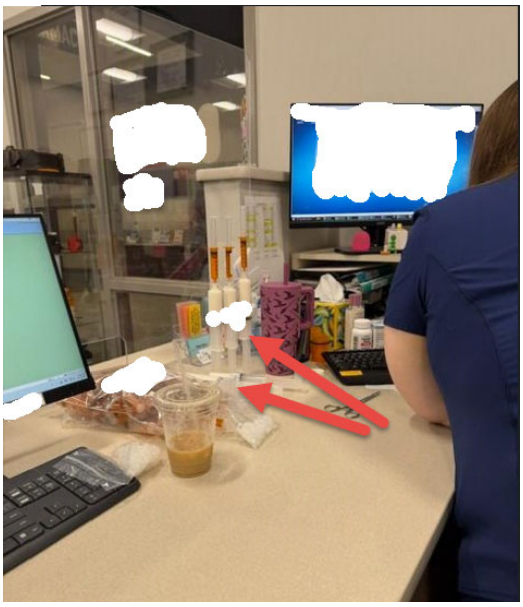
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Facility – Compounding Area





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Nonsterile – Statistics to Share
Policies Needed at the Ready (and Are Present)

Complaints Related to CNSPs

- 42% of pharmacies reported a complaint had been filed.
- 94-99% compliance on this process

Recalls Related to CNSPs Within Past 2 Years

- Only 4% of pharmacies reported.
- 96-99% compliance on these processes
- 93% of pharmacies comply with USP recommendation to immediately notify prescriber with out of specification (OOS) results.

Chemical Hazard, Spill Management, and Disposal Information Program

- 88% overall compliance
  - 94% annual document training on spills

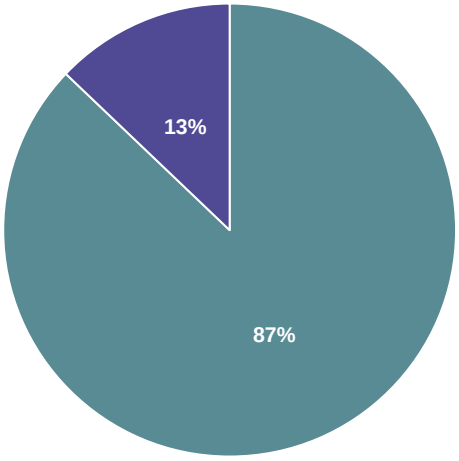
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Nonsterile – Designated Person
87% Full Compliance

Does the pharmacy have a designated person(s) (DP) who meets the requirements in USP <795> standards?



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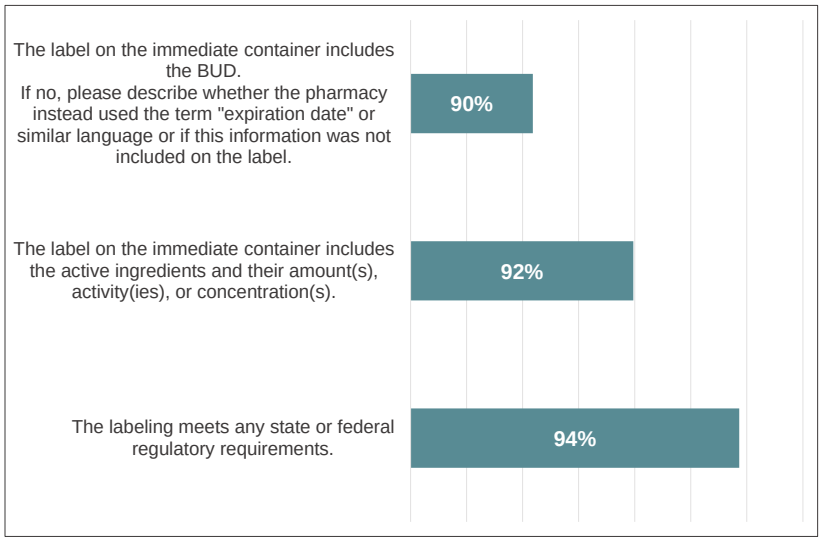
Designated Person Trends

- 7 items for inspector's review
- 93% of the time, the DP has the training, experience, responsibility, and authority to perform the duties required of them.
  - One example, the pharmacy named a DP who was not registered with the state as a technician (or pharmacist) when it was required for compounding.
  - DP had not completed training since before 2023.
  - DP had no annual documented training.
- 93% of the time, the DP reviews the facility SOPs at least every 12 months to ensure that they reflect current practice and that such review is documented.

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Nonsterile – Label/Labeling
83% Full Compliance



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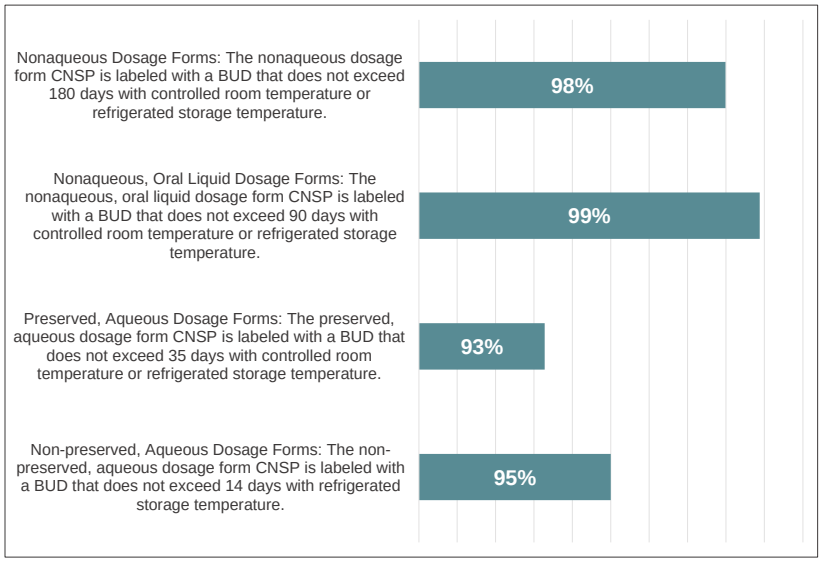
Label/Labeling Trends

- 8 items for inspector's review
- The label on the immediate container including the BUD is 90%.
- Additional Observations
  - Not all active ingredients listed on label
  - One pharmacy phone number missing
  - Bulk container found without complete labeling tied to a specific batch
  - Listed "Expiration Date"

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Nonsterile – BUD Compliance With Table 4
92% Overall Compliance



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BUD (Table 4) Trends

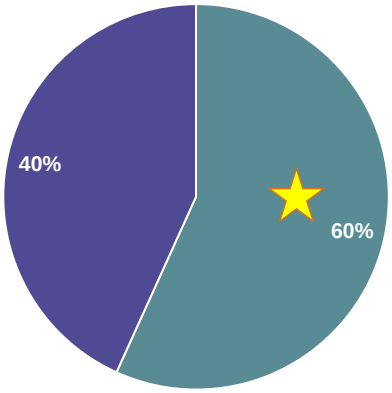
- Preserved, Aqueous Dosage form is at 93% compliance
- Additional Observations
  - One not following bracketed (high/low concentrations)
  - Assigned 12 months
  - One preserved, aqueous assigned 60 days without support
- One was for allergenic extract set for 12 months

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Excess After Weighing
60% Compliance With USP Recommendation

When components are removed from the original container and not used in compounding (eg, excess after weighing), they are discarded and not returned to the original container (to minimize risk of contamination).



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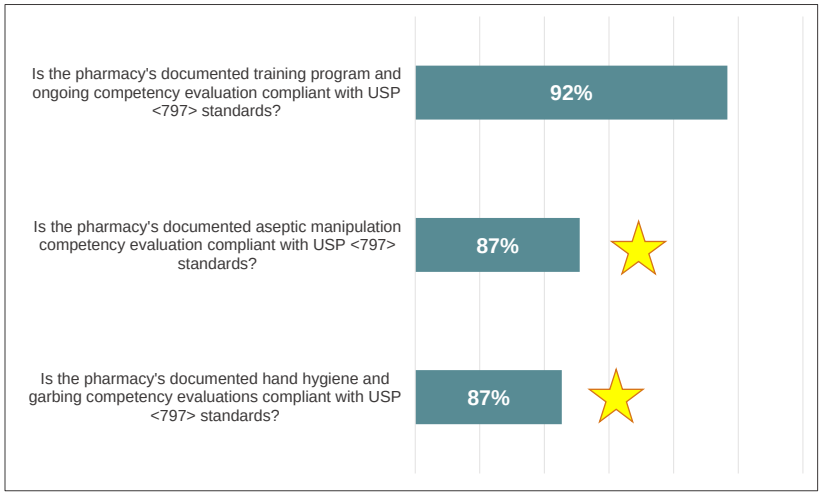
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Sterile – Training/Competency Assessment, Records Review



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Training and Competency Assessment for Sterile Compounding Trends

- Training program and ongoing competency assessment (92%)
  - Training on equipment missing
  - Supervisor/direct oversight staff missing
- Aseptic manipulation assessment (87%)
  - DP missing
  - One consultant performed, no documentation on site available
- Hand hygiene and garbing competency assessments (87%)
  - One incubated for less than 48 hours (no vs missing)
  - 2 GFT only

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Sterile – Compounding Activities Observed During the Inspection

Personnel Preparation

- 88% overall compliance
  - 90% compliance – Eyeglasses, if worn, are wiped.

Hand Hygiene Compliance

- 90% overall compliance
  - 94% compliance – Fingernails are cleaned under warm running water using a disposable nail cleaner (eg, nail pick).

Garbing Compliance

- 81% overall compliance
  - 91% compliance – All personnel entering compounding area are fully garbed.
  - 92% compliance – Garbing is done in order to minimize contamination.

Compounding Processes

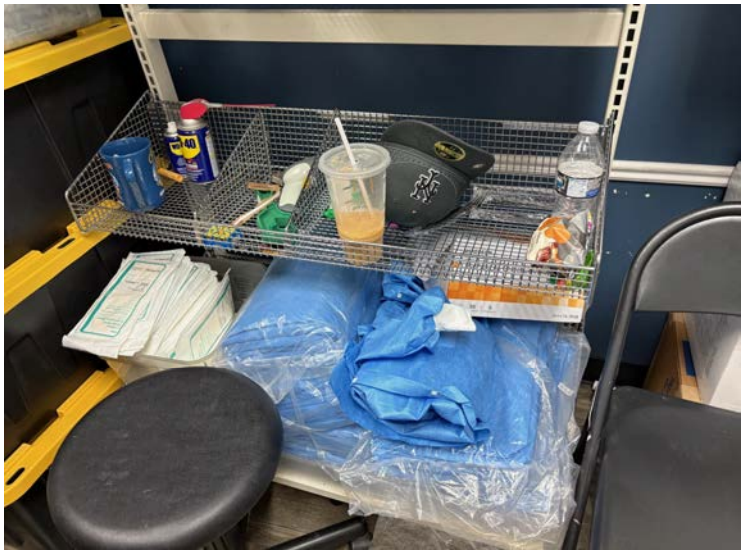
- 78% overall compliance
  - 85% compliance – Aseptic technique
  - 92% compliance – Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.

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Personnel Preparation

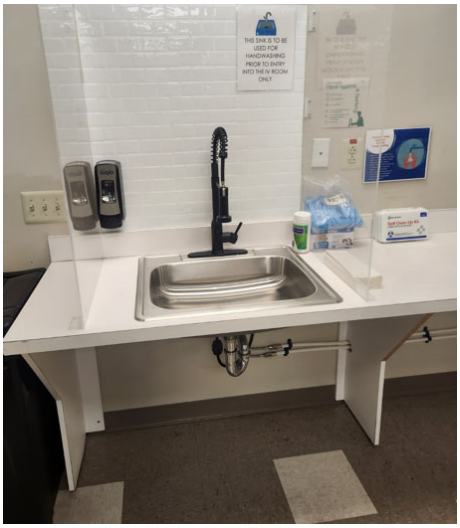


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Sinks/Hand Hygiene for Sterile Compounding Areas





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Aseptic Technique Examples





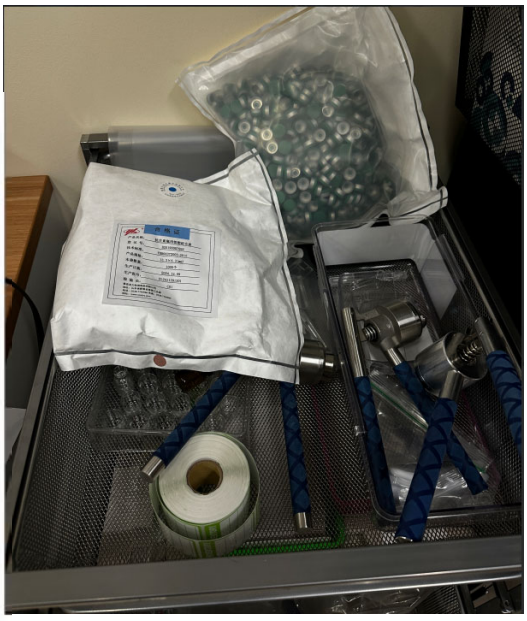
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Vial Assembly



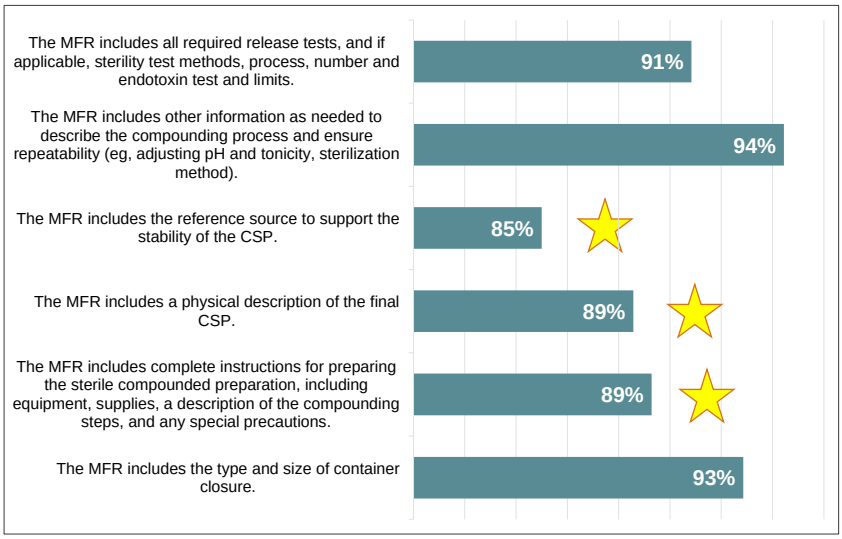


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Sterile – Master Formulation Record
74% Full Compliance



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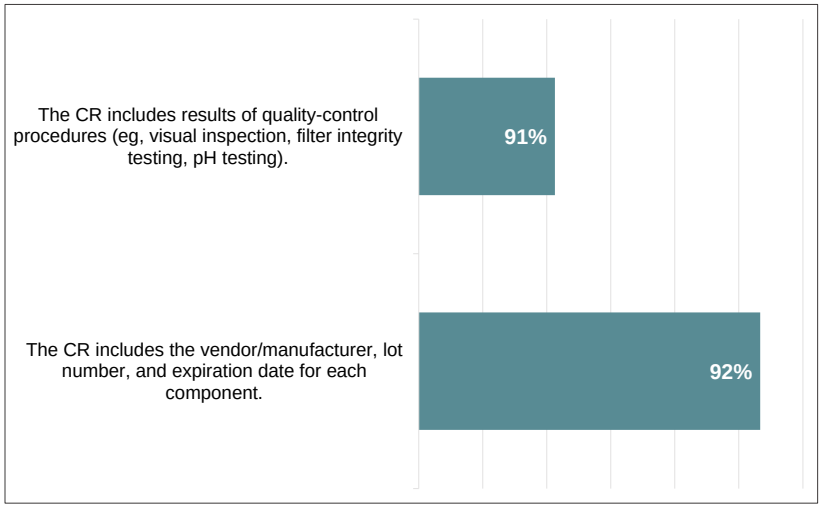
MFR Trends

- 13 items for inspector's review
- MFR overall compliance is 74% (reference source is 85%; complete instructions is 89%; and physical description is 89%).
- Additional Observations
  - Container closure not documented
  - Storage requirements missing
  - One amber vs clear container not listed
  - One no mention of stock solution use
  - One USP BUD limits used but was refreezing after initial thaw
  - One pH adjusters not listed
  - One steps missing for how to re-filter

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Sterile – CR
81% Full Compliance



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CR Trends

- 17 items for inspector's review
- CR overall compliance is 81% (QC process is 91%).
- Additional Observations
  - One QC is "visual check points" without a detailed description.
  - Visual inspection not documented on CR
  - Physical description of final preparation (one yellow)
  - One pH adjuster not listed and pH adjustment step unclear
  - Storage conditions missing

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Sterile – Statistics to Share

- 32% of pharmacies were garbing for Category 3 activities.
- 92% of pharmacies limited batch sizes to 250 units (when sterility testing is required).
- 56% of pharmacies prepared Category 2 and/or Category 3 preparations from nonsterile ingredients.
- 91% of pharmacies evaluated API for use in sterile preparation (eg, not dietary or research use only).

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Sterile – Statistics to Share

- 3 pharmacies were using robotic enclosure.



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Sterile – Statistics to Share

5% of pharmacies had an integrated vertical laminar flow zone design in cleanroom suite.



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Sterile – Statistics to Share, Policies Needed at the Ready (and Are Present)

Policy is in place to cease compounding when the pharmacy is unable to maintain positive pressure differentials.

- 95% of pharmacies followed this process (*not required by USP*).
- 70% had an alarm (*not required by USP*).

Procedures for complaint handling, adverse events, and recalls that include corrective action, investigation, reporting, and documentation requirements

- 99% compliance (only one pharmacy)

If a CSP is dispensed or administered before the results of release testing are known, the pharmacy ensures procedures for recalls, and OOS notifications are conducted and documented.

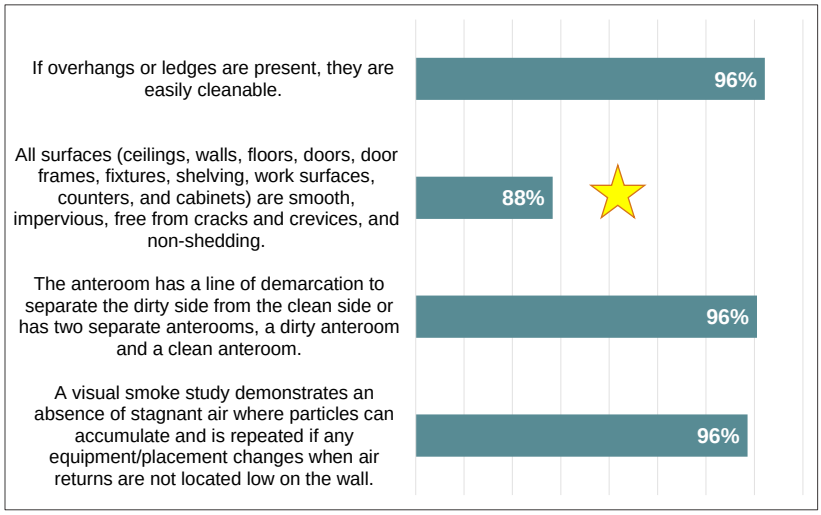
- 98% compliance

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Sterile – Cleanroom Suite
77% Full Compliance



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Cleanroom Suite Trends

- 24 items for inspector's review
- "All surfaces are smooth, impervious, free from cracks and crevices, and non-shedding (eg, cleanable)" was 88%.

Additional Observations

- Evidence of rust on equipment and surfaces
- One HD compounding done in positive pressure room
- One not all personnel garbed when entering compounding suite (while inspector on site)

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Walk Through Recommended – Review if Rust on Surfaces and Equipment







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Walk Through Recommended – Ensure Cleanroom Suite Meets Facility Requirements



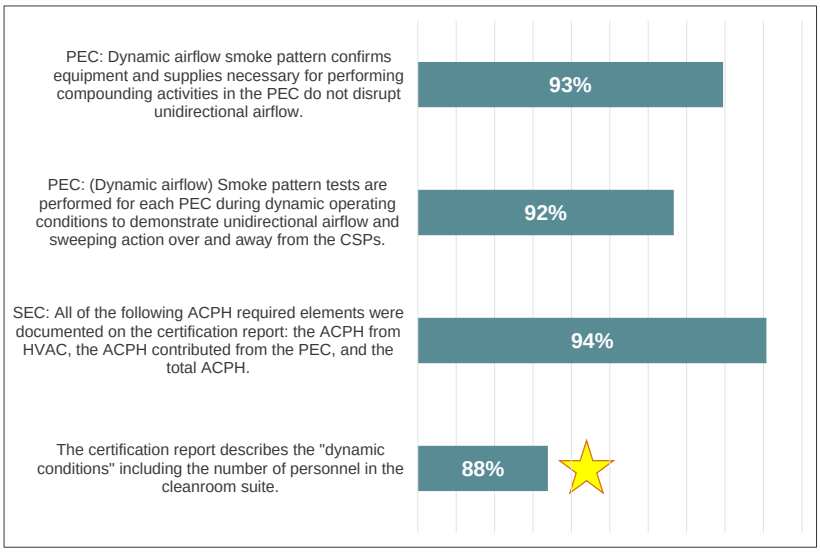


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Sterile – Certification Reports 79% Full Compliance



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Question: *Does the certification report(s) received by the pharmacy have all required elements documented for the pharmacy's designated person(s) to make an informed decision related to functionality of PEC and SEC environments?*

- 18 items for inspector's review
- Certification report describing "dynamic conditions" including number of personnel is at 88%.
- Compounding staff was not involved in creating dynamic conditions.
- Number of personnel present in the SEC was missing on the certification report.

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Sterile – Environmental Monitoring Program

Formal Environmental Monitoring Program	Viable Air Sampling	Viable Surface Sampling
• Overall compliance is 88%. • Viable air and surface performed by trained individual is 91%.	• Overall compliance is 91%. • One device (2 different temperature incubation method) is 97%, following Box 5. • Two device method was 99%.	• Overall compliance is 84%. • Sampling at correct frequency and within each classified area is 93%.

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Sterile – Cleaning and Disinfection

Supplies and Equipment	Cleaning Activities in Table 10	Sporicidal Use	Inspector Observations
• Overall compliance is 88%. • Labeled with expiration dates (not expired) is 92%.	• Overall compliance is 94%. • "Sinks used for hand hygiene are cleaned and disinfected on each day of use" is 95%.	• Overall compliance is 96%.	• Ranges were from 96-99% for 10 items observed. • 96% compliance for "Compounding personnel are using the appropriate cleaning and disinfecting procedures and techniques within the PEC."

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Sterile – Operate and Maintain Records for All Equipment Used for Compounding, 87% Full Compliance

Equipment are periodically inspected and calibrated.	Incubators are placed in a location outside of the sterile compounding area and calibrated.	Incubators are monitored for temperature during incubation periods.
• 94% compliance • Monitoring equipment, autoclaves, ovens • Calibration yearly, unless different by manufacturer specifications	• 90% compliance • Incubators used for environmental and personnel monitoring	• 95% compliance • Incubators used for environmental and personnel monitoring • Temperature monitored manually or by use of a continuous recording device

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Sterile – Presterilization Procedures 85% Full Compliance

Presterilization procedures, such as weighing and mixing, are completed in an ISO Class 8 or better environment (eg, anteroom or buffer room).

- 97% compliance

Presterilization procedures, such as weighing and mixing, are performed in a single-use containment glove bag, CVE, BSC, or CACI to minimize the risk of airborne contamination.

- 88% compliance 

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Sterile – Sterilization Methods

***High volume of N/A; % if N/A excluded**

Filter Sterilization

- Overall compliance is 92%.
  - "Filters used have enough capacity to filter the required volumes" is 93%.

Steam Sterilization

- Overall compliance is 96%.*
  - *High volume (without N/A, compliance is 79% for those who autoclave compounded preparations)
  - "The pharmacy has evaluated if steam sterilization would cause degradation of the drug" is 81%.

Dry Heat Sterilization

- Overall compliance is 98%.*
  - *High volume of N/A
  - Only one topic had one pharmacy noncompliant: Calibrated data recorder or chart is used to monitor each cycle, and the data is reviewed to identify cycle irregularities (eg, deviations in temperature or exposure time), with results documented on the CR.

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Sterile – Beyond Use Dates

***High volume of N/A; % if N/A excluded**

Category 1 (Table 12)

- 100% compliance
  - 2 pharmacies total

Category 2 (Table 13)

- Filtration/no sterility testing is 97%.
- Filtration with sterility testing is 95%.
- Terminally sterilized was 100% compliance.

Category 3 (Table 14)

- Overall compliance is 91%.*
  - High volume of N/A (without N/A, compliance is 68%)
- Particulate matter testing (<788>) is 94% for those who perform Category 3 compounding for injections or ophthalmics (once per formula)
  - High volume of N/A (without N/A, compliance is 79%)
- Container closure (<1207>) and CSP BUD supported by a stability indicating assay is 95%
  - High volume of N/A (without N/A, compliance ranged from 80-83%)

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Sterile – Statistics to Share, Beyond the USP Chapter

Facility defines "the most difficult and challenging procedures" and the rationale for how they are the most challenging.	Compounding label identifies the CSP as a "compounded preparation."	Surface sampling is performed after compounding.
• 78% compliance • Best practice	• 84% compliance • USP recommendation	• 92% compliance • USP recommendation

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Post-Assessment Questions

Question: According to data evaluated from NABP's VPP inspection program, what are some of the topics where compliance with USP compounding chapters can be improved?

Answer Choices:

A. Training and competency assessment documentation
B. Master formulation records (MFRs) and compounding records (CRs) for nonsterile compounding
C. Aseptic technique for sterile compounding
D. Selecting a qualified designated person (DP)
E. A, B, and C

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Post-Assessment Questions

Question: What are some recommendations to help improve employee training and competency assessment file review during an inspection?

Answer Choices:

A. Prepare employee files in advance of an inspection, ensuring they are organized and complete.
B. Conduct a mock inspection.
C. Designate a person to review the files with the inspector to help guide them through any paper or electronic files.
D. For paper training files, review at least one complete file with the inspector.
E. For electronic training files, have an employee navigate the system to demonstrate the location of each item.
F. Give the inspector a username and password into the electronic record and wish them luck.
G. A through E.

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Post-Assessment Questions

Question: Describe what is wrong with this photo.

Answer Choices:

A. Compounder's sterile gloves are not placed properly compared to the sleeves of their gown.
B. Compounder has too many items in PEC.
C. Compounder is blocking first air with hand placement.
D. All of the above.



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Thank you!

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