Clinic owner or manager

Build a clearer understanding of the information moving through a clinic: product descriptions, pharmacy relationships, supplier documents and patient materials. Learn what each document can establish and how to keep claims and revisions traceable.



Marcus / fictional visitor

YOUR LEARNING JOURNEY

Produce a review record for patient-facing material, with a named owner, clear sources and a realistic update process. Keep revisions traceable over time.

Understand the product pathway, read the supporting report, then practice reviewing a patient handout.

A branded handout does not establish clinical or legal review. Staff review should address the actual services, jurisdiction and claims; adding a disclaimer does not fix misleading content.

Open the current online guide

Sources and related guides remain accessible on the website. All role paths are open to every reader.

Portrait: fictional illustration, not a real patient, professional reviewer or endorsement. This handbook provides education, not individual medical or legal advice.

Contents

Read in order for a foundation, or use the linked contents to find a specific topic. Page numbers refer to this edition.

SUGGESTED START

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Continue with the reading path and books, then record your findings in the learning worksheet.

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Know which product the evidence describes

A molecule name is a starting point, not a complete product description. Record the active ingredient, chemical form, formulation, route, manufacturer or compounder and the document date. Products using similar names may differ in ways that matter. A result for one preparation does not automatically establish the performance of another.

FDA approval concerns a particular drug product and its authorized labeling. A facility registration, product listing or National Drug Code does not mean FDA has approved the product. A company can have legitimate paperwork for one activity without every product or claim being authorized.

Compounded drugs are prepared under a different framework and are not FDA-approved. They can serve particular patient needs, but FDA does not review each compounded product for safety, effectiveness and quality before marketing in the way it reviews approved medicines. The 503A and 503B pathways have different conditions, explained below.

Investigational means a product or use is being studied; it does not mean success is established. Research-use labeling concerns a claimed purpose and cannot establish suitability for human use. Keep regulatory status, analytical quality and clinical evidence as three separate entries. None can substitute for the other two.

Build a simple comparison: what the paper studied, what the official label describes, and what the current document or service names. Mark missing information rather than filling it with a brand assumption. This comparison is useful for a patient preparing questions and for a professional reviewing a brochure.

Worked learning example

Two documents use the same ingredient name. One describes an approved finished medicine; the other describes bulk powder with a laboratory report. The shared name does not make the powder an approved medicine. Ask what each document actually establishes before carrying claims between them.

READ THE SOURCE

FDA - Is It Really FDA Approved?

FDA - Compounding and FDA: Questions and Answers

503A and 503B: understand the pathway before the product

Compounding means preparing a medicine for particular needs by combining, mixing or altering ingredients. In the United States, sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act establish different conditions for exemptions from certain federal requirements. They are not product-approval programs. A compounded medicine does not become FDA-approved because a pharmacy holds a license or an outsourcing facility appears in a registration database.

Section 503A concerns compounding by a licensed pharmacist in a state-licensed pharmacy or federal facility, or by a licensed physician. Its prescription condition concerns an identified individual patient. Limited anticipatory compounding can occur under specified conditions before a prescription arrives, but that is not unrestricted authority to supply unassigned office stock. When all applicable conditions are met, the product can qualify for exemptions from premarket approval, adequate-directions labeling and federal current good manufacturing practice requirements. Other requirements still apply.

Section 503B concerns outsourcing facilities, where compounding occurs by or under the direct supervision of a licensed pharmacist. These facilities remain subject to current good manufacturing practice, often abbreviated CGMP. They may obtain individual prescriptions or supply healthcare providers with office stock: medicine held before a particular patient needs it. FDA conducts risk-based inspections, and reporting obligations apply. Registration is not a guarantee that every preparation, practice or transaction complies.

Bulk ingredients have separate eligibility gates. Under 503A, FDA describes an applicable USP/NF monograph route; when no applicable monograph exists, a component-of-an-approved-drug route; or, when neither applies, inclusion on the 503A bulks list. Under 503B, a substance generally needs inclusion on the clinical-need bulks list, or the resulting drug must be on the shortage list at compounding, distribution and dispensing. A monograph is a published quality standard, not approval of every preparation made from the ingredient.

A valid certificate of analysis and manufacture by an FDA-registered establishment are additional bulk-substance conditions, not substitutes for eligibility. Interim enforcement policies are also distinct from the statutory lists: nomination or Category 1 status is not final list inclusion. Other limits, including restrictions involving essentially copies of available medicines, still need attention. Review the specific product, pathway and date rather than assuming that a familiar ingredient or a national shortage headline answers everything.

503A status as of October 31, 2026: interim Categories 1, 2 and 3 are not the final 503A bulks list. Category 1 concerns adequately supported nominations under evaluation; Category 2 identifies significant safety concerns; Category 3 concerns inadequate nomination support. Removal from Category 2 does not itself establish eligibility. An advisory-committee recommendation is nonbinding advice, not list inclusion. Addition to the final list requires FDA rulemaking; other 503A conditions still apply. Read the category record, committee record and final rule separately rather than treating one as a substitute for another.

Illustrative case: the clinic refrigerator

A clinic asks for unnamed-patient inventory. “Our supplier is a compounding pharmacy” does not resolve the office-stock question. The useful next questions concern the facility’s actual pathway, the exact preparation, the relevant federal conditions and applicable state rules. This example is a reading exercise, not clearance to obtain or administer stock.

Status-note sources checked October 31, 2026; this is not a claim that every retained source was re-reviewed.

READ THE SOURCE

FDA - Human Drug Compounding Laws

FDA - Provisions Applicable to Human Drug Compounding

FDA - 503A Bulk Drug Substances

FDA - 503B Bulk Drug Substances

FDA - Interim categories (PDF updated May 14, 2026)

FDA - July 23-24, 2026 PCAC meeting page

Federal Register - PCAC meeting notice, April 16, 2026

API provenance: trace the ingredient, not just the logo

An active pharmaceutical ingredient, or API, is the ingredient intended to provide a medicine’s pharmacological activity. An excipient serves another formulation role. A manufacturer makes material; a distributor moves it through commerce; a repackager transfers material into another container. One organization may perform several roles, but a reseller’s name does not identify the original manufacturing site. This distinction matters when interpreting records and investigating a quality problem.

FDA urges compounders to understand their API and excipient suppliers, the quality of the material and what testing has been performed. It also urges repackagers to identify the original API manufacturer clearly and maintain supply-chain transparency. The agency describes patient harm associated with component-quality problems. A useful document review therefore connects the chemical identity, original manufacturer, manufacturing site, intermediaries, batch identifiers and document dates instead of collecting unrelated certificates.

A certificate of analysis, or COA, reports specified test results for an identified sample or batch. Start by asking what was measured and how the report connects to the material. Identity, purity, content, microbial quality and other attributes answer different questions. A percentage without its method and meaning is easy to overinterpret. A purity result alone cannot establish sterility, clinical benefit, FDA approval or eligibility for a particular compounding use. Those are different conclusions requiring different evidence.

In its drug-manufacturing guidance, FDA discusses representative sampling, identity testing and establishing the reliability of supplier analyses. That context matters: a manufacturing quality system cannot be reduced to downloading a COA. Nor is every CGMP provision automatically a universal checklist for every research laboratory. The educational task is to recognize missing information and the applicable context, not to declare a batch released or independently certify a laboratory.

Keep three conclusions separate: what the organization says it does, what documents establish about this material, and what rules apply to the proposed use. Registration is not FDA approval. A sound provenance record can reveal unanswered questions without promising that a product is safe, legally eligible or appropriate for a patient.

Illustrative case: a report with no batch connection

A brochure displays a high-purity result but the report identifier cannot be linked to the item being discussed. The result may describe a tested sample; it does not establish that the item shares those results. Record the gap rather than filling it with an assumption about the entire supplier.

READ THE SOURCE

FDA - Know Your Bulks and Excipients Suppliers

FDA - CGMP Questions and Answers: Components, Containers and Closures

FDA - Is It Really FDA Approved?

Bachem - Vista Manufacturing Site

CordenPharma - API Manufacturing

Read a certificate of analysis without filling in the blanks

A certificate of analysis, or COA, records analytical findings for an identified material or sample. It is useful evidence only when its scope is understood. It is not interchangeable with a manufacturing history, clinical study, regulatory approval or guarantee about every item bearing a similar label. Begin with the identifiers rather than the biggest percentage on the page.

Match the laboratory name, report number, sample identifier and stated lot or batch. Check receipt, testing and issue dates, and whether the report was revised. Establish who selected and submitted the sample and what material the laboratory actually received. A report cannot establish the history of material it never handled. A seller’s screenshot may omit pages, qualifications or revisions; report authenticity can be checked through independently located contact details for the issuing laboratory.

For each result, read four things together: the property measured, the method, the units and the acceptance criterion. A specification describes tests and criteria used to judge the material. A pass means the reported finding met that stated criterion; it does not make unmeasured properties pass too. The appropriateness of the criterion is a separate question. If the report does not explain its basis, ask what standard or specification was used.

Read purity and content separately. Chromatographic peak-area purity describes signals separated by a particular analytical method. A content assay measures an amount using its own method and calculation basis. A product can have a high chromatographic percentage while containing less target substance than its stated claim. Water, counterions and other components are reasons that the mass of powder and the mass of target peptide are not necessarily identical.

Not tested means no result for that question; it is neither a pass nor a demonstrated failure. Not detected means the method did not detect the substance under its conditions and detection capability; it does not necessarily mean zero. A result below a quantification limit cannot automatically be treated as a precise amount. When relevant, ask about method suitability, the reference standard and measurement uncertainty rather than comparing bare numbers across unlike methods.

Keep the conclusion as narrow as the evidence. A chemical report without microbiological testing cannot establish sterility or endotoxin status. A single test date does not establish shelf life. A certificate for one submitted sample also does not show that a treatment works in humans. The practical reading question is: which test, on which sample, against which criterion, and what remains unknown?

Invented COA exercise: high purity, failed amount

This is an invented learning example, not a real product or report. Teaching Material A, lot EDU-001: identity is consistent with the stated sequence under the named method. HPLC purity is 99.2% area against an invented criterion of at least 98.0%, so that criterion passes. Content is 8.1 mg per container against a nominal 10.0 mg claim and an invented acceptance range of 9.0-11.0 mg, so content fails: 8.1 divided by 10.0 equals 81% of the claim. Biological potency, sterility and endotoxin were not tested; no stability study was supplied. Those questions remain unanswered. All limits here are fictional educational values, not product standards or use instructions.

READ THE SOURCE

USP authors: Peptide reference standards, purity and content

NIST: Reference materials and certified values

NIST: Traceability and uncertainty

FDA: Expiration Dates-Questions and Answers

Explain a claim with its evidence attached

A reader receives a message from the complete presentation: headline, image, testimonial, spoken words and qualifications. Write down the actual impression before judging the evidence. A document titled “education” can still communicate a product benefit or sales claim.

Keep a claim ledger with the exact wording, intended audience, primary source and relevant limits. Record the population, product, outcome and date. Attach a decision: supported as written, needs narrowing, or unanswered. This makes review repeatable when a sentence moves from a website to a printed handout.

Use plain language without removing uncertainty. Explain an unfamiliar term when it first appears. Put a consequential limitation beside the claim it qualifies. A small disclaimer elsewhere cannot repair an unsupported headline. Separate community reports from controlled evidence and company statements from independently established findings.

Give each document a content owner, version and review date. Preserve sources and consequential limitations when adapting it for another audience. Keep a change record so later readers can identify which claim changed and why.

Worked learning example

An illustrated handout combines a vial photograph with “clinically proven recovery” while its citation is an animal experiment. The evidence does not support that human claim. A useful revision describes the animal study and its limits directly, and removes the unsupported promise.

Changed claims about presentation checked against FTC guidance October 31, 2026.

READ THE SOURCE

FTC - Health Products Compliance Guidance

Where to report a problem and how to check a pharmacy

FDA MedWatch accepts reports of adverse events and product-quality problems. Record the product name, manufacturer or compounder, lot if available, dates, what happened and relevant packaging or photographs; distinguish what you observed from what you suspect caused it. A report communicates a concern and does not itself prove causation.

Use FDA BeSafeRx to learn how to evaluate an online pharmacy, then follow FDA's state-pharmacy directory to the relevant board's license lookup. Match the legal name and address, check the current license record and contact the board when an entry is unclear. A license lookup and a product-approval record answer different questions.

Worked learning example - fictional

A package names a dispensing pharmacy different from the website brand. Look up the pharmacy's legal name and address, not just the platform name. If reporting a damaged container, retain its lot number and describe the damage without assuming which organization caused it.

Sources for this addition checked October 31, 2026.

READ THE SOURCE

FDA - Reporting serious problems

FDA - BeSafeRx

FDA - State pharmacy license lookup directory

Worked review: a fictional patient handout

Read the headline, image and body copy together, then enter each implied claim in the ledger. In this fictional exercise, the source packet contains an animal study, a sample COA with identity and purity results, and an establishment registration record. None is invented clinical testimony or a professional endorsement.

Give the handout an accountable content owner and version. Clinic customization must preserve sources and limitations; changing a logo does not create medical review. Name a professional reviewer only after an actual completed review.

Claim in draft	Evidence supplied	Review and replacement
“Proven recovery in people”	Animal experiment only	Human claim unsupported. Replace with: “An animal experiment measured this outcome; human benefit is not established by it.”
“Tested sterile”	Identity and purity COA only	No sterility result supplied. Describe only the reported identity and purity tests.
“FDA-approved clinic formula”	Establishment registration	Registration is not product approval. Remove the approval claim; state the documented product category.

Sources for this addition checked October 31, 2026.

READ THE SOURCE

FTC - Health Products Compliance Guidance

FDA - Is It Really FDA Approved?

Reading path and books

1. Audit the wording

Find the precise claim behind phrases such as recovery, wellness or optimization.

2. Check product descriptions

Separate the identities of clinician, pharmacy, manufacturer and product.

3. Check investigational boundaries

Make uncertainty and product status visible beside attractive claims.

Continue in the Church Library

Choose the level that fits your background. Book links lead to the Library, where reading options and any affiliate disclosures are shown.

Testing Treatments - Evans, Thornton, Chalmers and Glasziou

Start with fair comparisons and uncertainty. The library entry includes an official free reading option. Published in 2011; use current official sources for regulatory questions.

The Art of Statistics - David Spiegelhalter

Go deeper into denominators, uncertainty and interpreting data. Read alongside the actual study rather than using a statistical slogan as a verdict.

Bottle of Lies - Katherine Eban

Investigative cases provide context for manufacturing oversight and documentation. The book is not a current supplier assessment or a conclusion about every generic medicine.

Browse all Library rooms

Examples in practice

These examples identify published resources and their uses; they are not evaluated services.

Intertek - peptide characterization

Analytical example: provider-published descriptions of identity, impurity analysis, stability and biological activity assays. Read to compare the questions different methods answer; this is not an endorsement or independent accreditation verification.

Eurofins - peptide characterization and development

Analytical example: describes complementary separation, structural, impurity and stability methods. Published capabilities do not guarantee acceptance of a particular sample or suitability for a particular project.

Bachem - Vista peptide API manufacturing

Company-described example of clinical-to-commercial peptide API manufacturing in Vista, California. The page lists GMP and non-GMP capabilities, illustrating why a company name alone does not establish a specific item’s grade. Reviewed October 31, 2026; not an endorsement, current inspection assessment, purchase direction or finding of compounding eligibility.

CordenPharma - API manufacturing and peptide services

Company-described example of peptide API development, cGMP manufacturing, analytical services and clinical/commercial supply. Reviewed October 31, 2026. This illustrates an industry role; it does not establish availability, approval, suitability or legal eligibility of a particular product or transaction.

Questions and explanations

What would a reasonable patient understand this sentence to promise?

Read the sentence together with its headline, picture and placement, because patients receive the overall message. A technically cautious paragraph may still imply a guaranteed benefit when paired with a confident promise above it. For example, “research is ongoing” in small print does not turn “proven injury recovery” into a supported human claim when the source is an animal experiment. Record the likely patient interpretation and revise the prominent claim to fit the evidence.

Read the source: health products compliance guidance

Does this material clearly identify who does what without implying FDA endorsement?

The material should distinguish the clinic, prescriber, dispensing pharmacy, compounder or manufacturer and any testing laboratory. Registration, inspection history or a logo should not be presented as FDA approval of the clinic or every preparation it discusses. For example, “prepared by Pharmacy X” identifies a role, whereas “FDA-approved clinic formula” makes a very different claim that cannot be inferred from registration. Check each credential against the organization and activity it actually concerns.

Read the source: it really fda approved

Could the layout make an investigational compound look like an approved treatment?

Yes: placement, badges and visual repetition can imply equivalence even when the words do not state it directly. Keep the product's investigational status and evidence stage beside its description rather than relying on a distant disclaimer. For example, placing an emerging compound inside an "approved treatments" grid can mislead readers despite a research note at the bottom of the page. Move it into a clearly labeled research section and explain what has and has not been established.

Read the source: health products compliance guidance

Read the source: it really fda approved

Who originally manufactured this material, and how does this report connect to this batch?

A clinic's record should identify the original manufacturing organization and site, any distributor or repackager, and the batch identifiers connecting the material to the report. A reseller's logo is not a substitute for that chain. For example, a report for lot A cannot substantiate the contents of inventory labeled lot B merely because both came through the same supplier. Mark the connection unresolved until the relevant documents establish it; the clinic should not describe the material as verified on that basis.

Read the source: fda compounders know your bulks and excipients suppliers

Which attributes were not tested?

Review the report's actual methods and results rather than assuming that a "pass" covers every attribute. Identity, content, biological activity, sterility, endotoxin and stability are separate questions, with testing needs depending on the material and context. For example, a report containing identity and chromatographic purity results but no microbial results cannot support a clinic handout saying "tested sterile." List the missing attributes explicitly and keep the patient-facing description within the report's scope.

Glossary

Comparator
The reference group or intervention against which an outcome is compared, such as placebo or another treatment.

Endpoint
An outcome defined for a study. A biological measurement and a patient-important outcome are not necessarily the same thing.

Formulation
The composition and presentation of a product, including ingredients beyond the active substance.

Adverse event
An unwanted medical occurrence during observation; occurrence does not itself establish a causal connection to treatment.

Investigational
Under investigation. This describes research status, not proof of safety or benefit.

COA
Certificate of analysis: a report of specified tests and results for an identified material or sample. Its meaning depends on scope and provenance.

Identity
Whether a material matches the named substance within the methods and comparisons used.

Purity
A method-dependent assessment of detected components; chromatographic peak-area purity is not automatically total mass purity.

Assay / content
A measurement of the amount of a specified substance, stated with units and a defined basis.

Potency
Biological activity assessed by a specified assay; the term is sometimes used differently, so inspect the report’s definition.

Sterility
The absence of viable microorganisms; interpreting a sterility-test result requires its sampling and method context.

Endotoxin
A component of certain bacteria that can provoke inflammatory reactions. Endotoxin testing is distinct from sterility testing.

Traceability
A documented connection to an origin or reference. Measurement traceability and supply-chain provenance are related but different questions.

API
Active pharmaceutical ingredient: the substance intended to provide a medicine’s pharmacological activity. An API is not the same as a finished medicine.

503A / 503B
Different U.S. statutory pathways for qualifying compounded drugs. Neither makes a compounded drug FDA-approved.

CGMP
Current good manufacturing practice: requirements for manufacturing controls and quality. The applicable framework depends on the activity and product.

Learning worksheet

Patient-material review

Use these prompts to record what you understand, what remains uncertain and which source could answer the question.

Learning prompt	Filled-in fictional example
Patient-material review	Fictional example: Draft claim: “tested sterile.” Supplied evidence: identity and purity COA only. Decision: remove the sterility claim; record the missing test and assign the content owner to resolve it.

List the document, version, intended audience and accountable reviewer.

Pair every benefit or safety claim with a source and its relevant limitations.

Check that approval, compounding and investigational status are described accurately.

Set a review date and a process for replacing outdated printed and digital copies.

Educational information, not individualized medical or legal advice.

Explore another perspective in the Community Center