



Advancing 503B Forward:

A Guide to Choosing the Right Supplier

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Introduction

In the world of healthcare, 503B compounding pharmacies play a crucial role in providing safe and high-quality medications to patients. These pharmacies adhere to strict regulations set by the FDA to ensure quality and consistency in the compounding process.

Choosing the right 503B supplier is essential for healthcare facilities looking to provide the best care for their patients. In this eBook, we will explore the key factors to consider when identifying and engaging a 503B compounding pharmacy supplier, as well as how to navigate and understand FDA Form 483.

Understanding 503B Compounding Pharmacies



What is a 503B Compounding Pharmacy?

A 503B compounding pharmacy, also known as a 503B outsourcing facility, compounds and distributes medications for healthcare facilities without patient-specific prescriptions. They are registered with the United States Food and Drug Administration (FDA) and regulated under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

How 503B Pharmacies Differ from Insourcing within a Hospital Pharmacy

Hospital pharmacies can compound medications in-house, also known as insourcing, or outsource to a 503B pharmacy that will compound their medications for them.

Insourcing requires staffing, purchasing, and maintaining expensive equipment. This investment can be reduced through outsourcing. A 503B pharmacy can also provide expert strategy and guidance, improve the reliability and regulatory compliance of your drug supply, and reduce labor costs for drug prep and end-product testing.

Regulations and Requirements for 503B Pharmacies Set By the FDA



Quality Assurance & Testing: 503B pharmacies are required to adhere to the stringent current Good Manufacturing Practices (cGMP) of the FDA, offering another level of quality above USP<797>. Outsourcing minimizes medication errors through customized standards and processes that include specialized labeling with linear and 2D barcoding. All SCA Pharma's end product batches are tested for sterility, endotoxin, potency, and identity, and pass a check for environmental and personnel monitoring.



Inspections: 503B pharmacies are regularly inspected to confirm their compliance with regulations and requirements, and to confirm that their medications are safe.



Reporting: 503B pharmacies are required to report the medications they produce to state boards of pharmacy and other regulatory agencies, as well as reporting on compliance, adverse events, inspections, and registration.

Engaging a 503B Compounding Pharmacy



The Importance of Clear Communication with a 503B Supplier

It's essential to have clear communication when engaging a 503B supplier. With clear communication, the 503B supplier should be able to answer your questions and determine whether the partnership would be a good fit. Confirm they can meet your expected delivery dates, and packing, labeling and special handling instructions.

Developing a Strong Partnership for Ongoing Medication Needs

When engaging with a 503B supplier, it's important to get to know each other to develop a strong partnership. You should establish a primary point of contact for both parties, agree on response times, and outline a clear process for addressing any inquiries. This will build a strong foundation for the 503B supplier to meet your ongoing medication needs timely and efficiently.

Ensuring Compliance with Regulations and Guidelines

To ensure you are engaging with a 503B supplier who compounds high-quality and safe medications, you must have a good understanding of the current regulatory environment, and dedicate sufficient time and resources to evaluate them. Two essential steps are ensuring that the 503B is licensed as required to ship to your state(s) and is in good standing with state, and confirming the supplier's compliance with FDA regulations.

Considerations When Choosing a 503B Supplier

Quality and Safety Measures in Place at the 503B Pharmacy

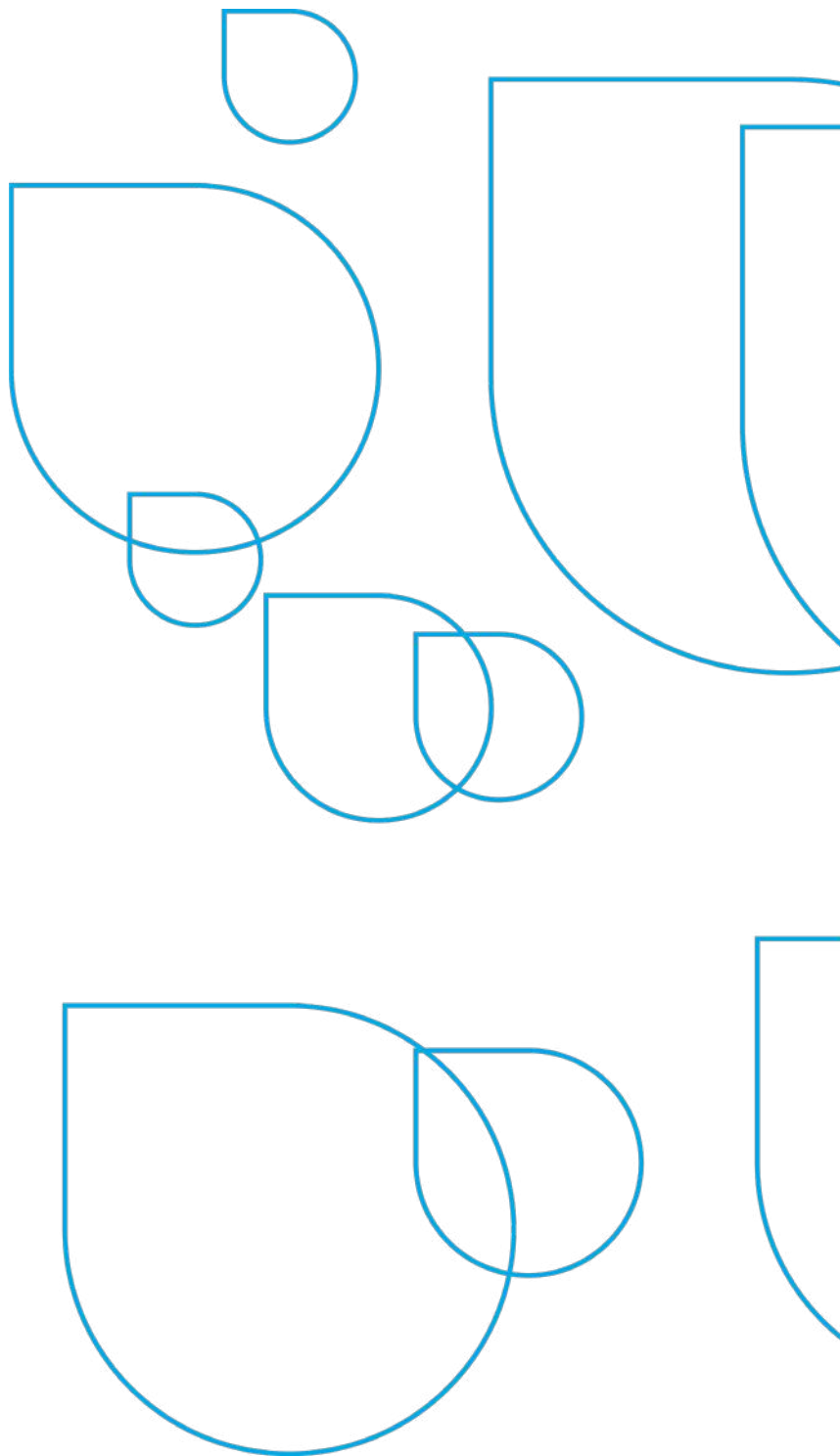
Partnering with a supplier that prioritizes quality and safety is essential for your patients. The supplier should diligently follow the most up-to-date regulations, guidelines, and industry standards. Another factor to access is how the quality department is structured. Utilizing an independent quality department highlights a dedication to patient safety and best practices.

Range of Services Offered by the 503B Pharmacy

Partner with a 503B pharmacy that offers a range of services to your hospital pharmacy. In addition to sterile compounding, they should offer expert consultation and support, effective inventory tracking and control, and flexible shipping methods. Most suppliers also compound specialized medications, providing you with access to a broader range of medications.

Reputation and Track Record of the 503B Pharmacy

Additional key factors to consider in a supplier are reputation and transparency. Two ways to determine if a supplier is transparent is whether they share thorough documentation of their compounding processes, and whether they promptly provide important reports and notifications. These can include quarterly reports, and updates on order status and product availability.



Reading and Understanding FDA Form 483

What is FDA Form 483 and Why is it Important?

FDA Form 483, titled “Notice of Inspectional Observations”, may be issued at the end of an on-site inspection of a company by the FDA investigator. It notifies the company’s management of any observations that need to be responded to and resolved with a corrective action plan. The form is important because it holds 503B suppliers accountable and upholds public health. Observations can be for minor procedural issues or more serious findings.

How to Interpret the Findings on a Form 483

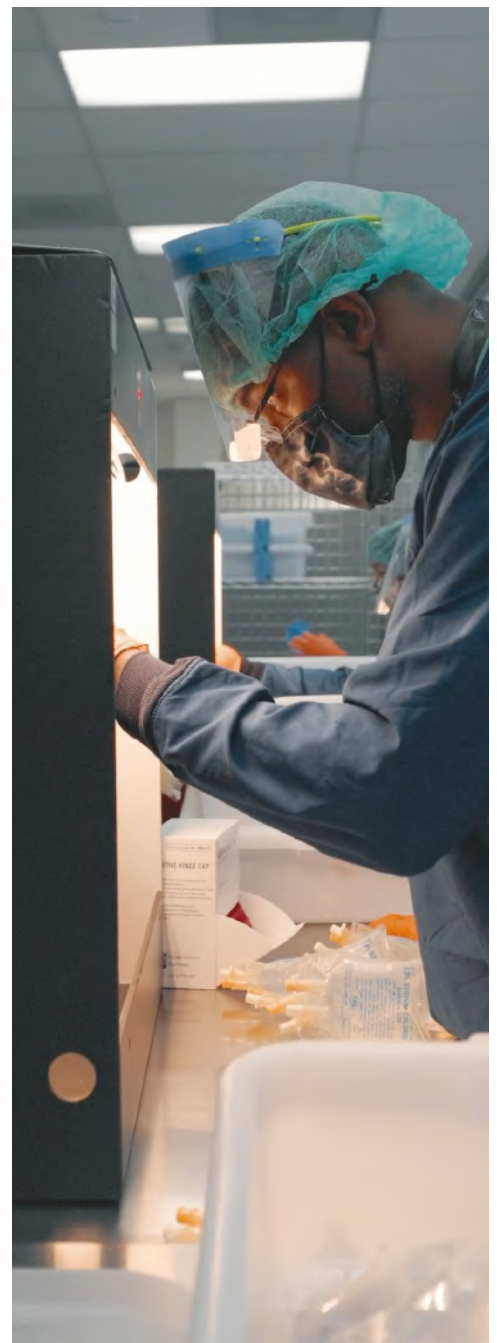
Begin interpreting the findings on the Form 483 by thoroughly reading each observation and understanding the relevant regulatory requirements for each. This will allow you to assess whether the impact of the observations is minor or severe. A minor observation could be documentation errors, procedural deviations, and facility maintenance issues. Severe observations can entail data integrity issues and critical equipment malfunctions. The 503B should take the lead in communicating with their customers when a Form 483 is issued. A typical response is offering a summary and arranging follow-up discussion with the quality team, however, they may provide a full response. The 503B should also develop and execute a corrective action plan, and establish measures to prevent recurrence.

Steps to Take if Issues are Identified on a Form 483

A 503B supplier should follow these steps if issues are identified on a Form 483:

1. Review the observations
2. Understand the regulatory context
3. Assess the impact of the observations
4. Identify the root causes
5. Executive a corrective action plan
6. Communicate with the FDA
7. Continue to monitor compliance

SCA Pharma is committed to facilitating smoother FDA inspections by providing compliance documents including Quarterly Quality Reports and Certificates of Conformance with every lot.



Innovations in 503B Pharmacies

Optimization in Production

Innovations will continue to make it easier for 503B pharmacies to provide your orders on time and in full. One of these innovations is optimizations in the production process to be more efficient and reliable. Examples include implementing an improved workflow and a semi-automated sanitization procedure to expedite bag production.

Improvements in Order Management and Inventory Optimization Capabilities

Many 503B suppliers are also making improvements with their order management and inventory optimization capabilities, including SCA. Our updated ordering process saves our customers time and offers more control over order management, resulting in improved reliability and consistency in order deliveries. Some examples include:



Ability to Edit, Modify, or Cancel Orders in the Online Customer Portal



Shorter Lead Times & Accelerated Delivery



Predictable Product Delivery



Designated Short-Dated Products



Choosing the Right 503B Compounding Pharmacy Supplier is a Crucial Decision for Healthcare Facilities

SCA is committed to advancing the 503B industry forward. By understanding the key factors to consider when engaging a 503B supplier and how to read and interpret FDA Form 483, healthcare providers can ensure that they are partnering with a reliable and innovative 503B pharmacy.

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