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The Essential Elements of a 503B Outsourcing Facility

What your surgery center should look for in a high-quality, reliable partner.

From strict quality and safety standards to mitigation against drug shortages, the benefits of 503B outsourcing facilities are well documented — and a major selling point for surgery centers everywhere.

"Outpatient facilities rely on 503B compounding facilities because these organizations meet rigorous quality standards," says Sheldon Sones, RPh, FASCP, president of Sheldon S. Sones and Associates, a pharmacy and accreditation consulting firm based in Newington, Conn. "They can be a surgery center's best option because they have developed a federally licensed pharmacy provider that has met a strict list of criteria enabling it to manufacture sterile products, as well as non-sterile products, and provide them to the end user."

Of course, not all 503B facilities are created equal, and finding the right partner for your center's unique needs requires a thorough understanding of what a 503B is — and what it isn't.

Defining 503Bs

The basic definition of a registered 503B — an outsourcing facility that provides healthcare facilities with access to a broad spectrum of CGMP-compliant compounded preparations — only scratches the surface of how meticulously 503Bs operate. To fully understand the safety requirements and stringent oversight required of 503Bs, you need to go back more than a decade to a tragedy that served as the catalyst for the Drug Quality and Security Act (DQSA) of 2013 and created Section 503B to establish "outsourcing facilities" with higher regulatory standards.

"This evolved from the events at the New England Compounding Center in 2012, where a fungal meningitis outbreak resulted in the contamination of methylprednisolone acetate injections and subsequent illness in hundreds of patients across 20 states," says Mr. Sones. "The outbreak led to the deaths of more than 100 people and was the largest public health crisis caused by a contaminated drug."

Enter 503Bs. These facilities are required by law to register with the FDA, comply with the Current Good Manufacturing Practices (CGMP) and meet quality requirements, which include reporting adverse events to the FDA and providing the agency with information about the products they compound. They also rely heavily on the American Society of Health-System Pharmacists (ASHP).

"A 503B outsourcing facility is not a big drug company, but it is a 'mini' drug manufacturer," says Mr. Sones. "To perform those functions, it must meet very strict criteria, which is outlined by the ASHP in response to regulatory stipulations. This group considers 503B outsourcing facilities essential for a robust compounding framework, but also acknowledges their limitations in meeting all healthcare system needs."

Mr. Sones says it's important to understand the distinction between a 503B and a 503A. "A 503A pharmacy dispenses medications on a single patient-specific prescription by an authorized prescriber," he says. Specifically, Mr. Sones advises facility leaders to pay careful attention to the key aspects of 503B standards outlined by the ASHP when selecting an outsourcing facility:

- **CGMP compliance.** Facilities must adhere to the same standards applied to pharmaceutical manufac-

turers, including rigorous testing for sterility, potency and endotoxins.

• **Federal and state oversight.** Facilities are subject to FDA inspections and must comply with federal and state regulations.

• **Quality management.** Facilities are required to maintain a robust quality management system, including validated processes and thorough testing of each medication batch before release.

• **Documentation.** ASHP guidelines on outsourcing recommend that healthcare organizations conduct a thorough assessment with key stakeholders in the decision-making process before outsourcing.

• **Product labeling.** Medications from 503B facilities must be clearly labeled as such, including the facility's contact information, lot number, date of compounding, expiration date and storage instructions.

USP 797 also comes into play with 503Bs.

"The United States Pharmacopeia (USP) General Chapter 797 [Pharmaceutical Compounding — Sterile Preparations] sets standards for preparing sterile medications and outlines requirements for facilities, personnel and procedures to ensure the safety and quality of compounded sterile preparations," notes Mr. Sones. "The USP Compounding Expert Committee makes sure a facility complies with USP 797, which governs a wide range of factors that ensure compounded drugs are prepared in a compliant, dedicated space by specially trained pharmacists who follow strict quality controls and do all their mixing under proper environment and equipment utilization," he says.

Choosing the right partner

Making sure the 503B you partner with is current on the dizzying array of safety and compliance standards 503Bs are required to meet can seem daunting, if not overwhelming, to facility leaders, particularly newer administrators. Luckily, there are plenty of simple, cost-free resources to help.

The best place to start is the updated list of FDA-registered outsourcing facilities (**osmag.net/FDAlist**). The list provides contact names and phone numbers for each facility. Mr. Sones also recommends the FDA report card, which is generated by online surveys, as well the ASHP Research and Education Foundation's Outsourcing Sterile Products Preparation Vendor Assessment Tool. Created in 2021, the tool offers a host of invaluable information as well as a long list of questions to ask potential 503B partners. By using questionnaires, Mr. Sones says healthcare providers can make informed decisions about which 503B facilities to partner with, ensuring they are receiving compliant, high-quality compounded medications.

Finally, consultants can play a valuable role in helping outpatient facilities with 503B issues — especially if a problem arises with a current partner.

"If an outsourcing facility is cited for something serious like poor sterile record-keeping or it doesn't have adequately trained personnel that have been educated and can demonstrate competence, my job as a consultant would be to help evaluate the findings for degree of significance and trail the facility's action plan for resolution," says Mr. Sones. "If an unanticipated outcome occurs, a reasonable question would be, 'How did you choose that vendor?'"

In these cases, Mr. Sones recommends facility leaders research online content and the FDA website, and then bring all that information to medical staff leadership with the help of a consultant. "It's a collaboration and shared responsibility at the facility between the administrator, the medical staff, leadership, the consultant pharmacist and the nurse director," he says.

When it comes to selecting the right 503B partner, Mr. Sones advises facilities to allow research and a simple rule to guide them in making the right choice.

"We make the best choices on selecting a 503B outsourcing facility by practicing due diligence, as if it were you or a family member on the table," he says. "I would want my research to include all elements of performance. And I'd want to make sure that it was a collaborative decision by the leadership team and not a single person. The key to this is getting that collaborative decision." OSM

Watch for the next article in this series supported by Leiters in the October *Special Edition: Staff & Patient Safety* of *Outpatient Surgery Magazine*.