Mike Morsch | OSM Contributor

This three-part article series is supported by

Leiters Health
QUALITY COMPOUNDING FOR LIFE™

Audit Your 503B Outsourcing Facility the Right Way

Regularly evaluate whether your partner is the best fit and the safest option.

Are you using the right 503B outsourcing facility for your needs? It's a multilayered question that ASCs and HOPDs should return to regularly.

Each 503B outsourcing facility is unique, notes Kevin Hansen, PharmD, MS, BCSCP, senior director of pharmacy compounding services for Premier Inc., a healthcare performance improvement company and group purchasing organization for 4,350 hospitals and hundreds of thousands of additional sites of care.

They're not commercial manufacturers; they're not the traditional state-licensed 503A pharmacies; they're somewhere in the middle, says Dr. Hansen. Plus, FDA-registered 503Bs must comply with Current Good Manufacturing Practices (CGMP) that are still being defined by the FDA and have been in draft form since 2020.

These factors can make it difficult for facility leaders to properly evaluate whether they are using the right 503B partner. "We're still in those growing pains of an industry that's only been around for 11 years," says Dr. Hansen, whose organization provides comprehensive 503B evaluations and is active in educating pharmacies on interpreting and applying that information to drive patient safety.

On paper, the benefits of 503Bs are undeniable. They include:

- **High-quality sterile preparations.** 503B outsourcing facilities are required by the FDA to follow rigorous testing standards for sterility, potency and endotoxins. 503Bs also provide longer Beyond Use Dates due to the extensive testing that is performed.
- **Cost efficiency.** Because sterile preparations are produced at high volumes, the time savings and associated costs of compounding, documenting and wasting products translate to savings for the customer.
- **Accessibility.** 503Bs give outpatient facilities access to the Ready-to-Use sterile preparations and medications they need — when they need them. They also produce medications that are on the FDA Drug Shortage list.

All about safety

Even if you're happy with your current 503B outsourcing facility, it's essential to audit and evaluate it regularly — and do it the right way. This often means enlisting the services of an outside, independent auditor.

From asking the key questions to analyzing and acting upon the data, it's up to facility leaders to ensure their 503B is not only the right fit, but also the safest option for their patients. "It's crucial that all facilities adhere to the highest standards to ensure patient safety," says Dr. Hansen. "Healthcare facilities need to look at quality documents, review their operations and physically go on site where the drugs are prepared."

Dr. Hansen notes that CMS and the accreditation agencies have requirements for evaluating 503B outsourcing facilities and for any contracted outsourced service that is provided in the patient care health system. This requires facilities to evaluate and ensure that services provided by their chosen 503B are performed from start to finish in the safest, most effective manner.

Assess these areas

According to Dr. Hansen, a proper audit of a 503B outsourcing facility should include an assessment of at least the following areas:

- quality assurance and culture

- regulatory compliance history
- preparation methods and sterilization
- patient safety
- supply reliability
- cost efficiency
- risk management
- documentation and transparency
- customization and flexibility
- partnership and support
- contracting terms and conditions
- physical assessment (onsite).

Audits will uncover any potential problems or red flags. "We need to be as comfortable and confident with these preparations as if we were compounding them ourselves," says Dr. Hansen.

Best practices on labeling

503Bs don't need to meet the same requirements as commercial manufacturers for labeling. Because it's not required, some organizations simply won't do it.

Dr. Hansen suggests finding a partner that goes beyond the bare minimum. "While these labeling practices may not be required, we ensure to highlight these gaps for our members, as they are ultimately responsible for the safety of the patients," he says. "We provide detailed labeling recommendations to our partners, and many have implemented them, showing a commitment for patient safety."

Your 503B should follow labeling recommendations such as tall man letters and standardized font sizes put forth by trusted organizations. The Institute of Safe Medication Practices, the leading medication safety organization in the nation, has been very active in highlighting adverse events based off poor 503B labeling. There's also the United States Pharmacopeia(USP), which also offers valuable guidance in General Chapter <7> on Labeling (**osmag.net/chapter7**).

Check the ingredients

An audit of a 503B outsourcing facility should also evaluate the sourcing of its ingredients. "The FDA has a list of requirements for 503B outsourcing facilities, especially when sourcing and using 'bulk drug substances,' or an 'active pharmaceutical ingredient (API),'" says Dr. Hansen. "It needs to come from an FDA-registered facility. It can't just come from any API manufacturer. The 503B must be currently registered with the FDA, regardless of its source country."

Further, the FDA has a restrictive list of the bulk drug substances that can be used by 503B outsourcing facilities.

"There is a dynamic nature to the market because there are drug shortages, which allows 503Bs some more flexibility in what they can compound," says Dr. Hansen. "Look at some of those dynamics. What is currently on shortage today? What are they actively making? How do they respond when the shortage ends? Do they follow the FDA requirements?"

Spotlight on organizational culture

Audits should also examine subjective areas of the 503B, such as its organizational culture.

Specifically, find out how a 503B responds to the FDA when there's some type of action. Audits can uncover a lot through interviews with front-line staff all the way down to those who mix the drugs.

"Interview them one-on-one to learn more about how they are getting the resources they need. If they saw an issue, could they stop the line and escalate the concern?" says Dr. Hansen. "These types of interviews have been extremely valuable."

Finally, evaluate the 503B's response letters from regulatory bodies, which aren't always available publicly but can be requested. Dr. Hansen says the culture of the organization can be quickly gleaned from these letters.

"We've learned that if you're outright arguing with the FDA and telling them you don't have a problem, generally that's not a good approach," says Dr. Hansen. "It really starts at the top of the organization, from the C-suite down. That's a key area I think is often overlooked: 'What happens when things go wrong? And what's your resiliency plan to address that?' It all starts with culture." OSM

Watch for the next article in this series supported by Leiters in the October issue of *Outpatient Surgery Magazine*.