BECKER'S
ASC REVIEW

Is your 503B outsourcing facility up to par? 17 vital questions for ASCs

In an effort to provide high-quality, cost-effective care, ASCs rely on outsourced human drug compounding to accommodate specific patient orders. Most centers don't possess the appropriate staffing or access to the most advanced technology for safe in-house compounding and search elsewhere for the service.

Compounded human drugs are combined, mixed or altered ingredients creating a medication for a specific patient's needs. A licensed pharmacist or licensed physician compounds the drugs; in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist is allowed to compound drugs. Outsourcing facilities can be used to fill the gap between traditional pharmacy compounding and industrial manufacturing when compounded products are needed for patient care at healthcare facilities.

For years, few federal regulations bound compounding facilities to deliver high-quality products. In 2013, Congress passed the Compounding Quality Act as part of the Drug Quality and Security Act, which armed the FDA with more oversight of compounding pharmacies and created section 503B to define outsourcing facilities.

The FDA defines outsourcing facilities as those compounding drugs via provider requests without patient-specific prescriptions. Outsourcing facilities are also required to compound drugs in compliance with the FDA's Current Good Manufacturing Practice regulations. The law establishes the annual registration requirement for outsourcing facilities and biannual reporting of the products they have compounded during the past six months.

While the FDA has made strides in boosting patient safety among compounders, it falls upon providers to determine whether their outsourcing facility is practicing high-quality processes. The question keeping ASC administrators up at night: How can you ensure your compounding pharmacy will deliver superior results?

Leiters knows how challenging the process can be to research and audit outsourcing facilities. The company strives to bring "health to outsourcing" by focusing on three key pillars: people, place and product.

"[Quality] starts with a different perspective — prioritizing what matters most, putting the patient at the center of everything we do and defining a source for greater accountability," says Paul Yamamoto, RPh, corporate pharmacist and general manager at one of Leiters' San Jose locations. "Before you know it, the need for greater quality becomes the opportunity to make the world a healthier place to live."

He suggests ASCs ask outsourcing facilities 17 questions covering key compliance issues, quality control and best-practice validation.

Compliance

To select a quality compounding facility, keep your finger on the pulse of compounding outsourcing regulations and how suppliers are performing within these guidelines.

"The risks associated with using a facility that is not bound to cGMP are too high and can compromise patient safety," warns Mr. Yamamoto. ASCs can use local compounding pharmacies, but they often comply with the less-stringent standards of the United States Pharmacopeia <797> Chapter, which can put their products at risk.

"As has been seen recently, 503A compounding pharmacies can lack the resources and expertise to consistently provide safe, quality medications. Unfortunately, this has led to instances where patients are harmed," Mr. Yamamoto says.

Six key compliance questions to ask a potential outsourcing partner are:

1. How do you qualify your suppliers/vendors?
2. How do you appropriately procure and test materials?
3. How do you ensure you have the appropriate environmental controls to produce sterile products?
4. How do you ensure use of an accredited outside vendor to certify the compounding space and hoods, including adequate airflow studies under dynamic conditions (e.g. in-sight smoke study)?
5. How do you monitor disinfectant efficacy and ensure that you have appropriate cleaning supplies that are sterile and adhere to appropriate contact times?
6. How do you monitor for nonviable particles and viable microorganisms?

"I would encourage facilities looking to enter into the outsourcing space to really do due diligence in assessing any potential 503B facility before purchasing products from them," says William Churchill, MS, RPh, former chief pharmacy officer at Boston-based Brigham and Women's Hospital. "This is a hugely important decision and requires thoughtful assessment of any potential vendor."

Mr. Yamamoto agrees, noting many facilities lack the "tools, expertise and leadership to correctly follow Current Good Manufacturing Practices." Medication production leaves no

room for error, and providers must ensure they are purchasing quality and safe products for patients.

Quality control

In a competitive landscape, some compounders are looking to cut costs, which can lower quality if organizations aren't careful. Although it is tempting to choose an outsourcing facility with lower prices, ASCs should be aware of the risks associated with poor-quality compounding processes. If quality is overlooked in an outsourcing facility, ASCs may receive contaminated products with sterility, potency and endotoxin issues.

"Cost is important, but it should be measured as but one factor in deciding on your outsourcer," says Mr. Yamamoto.

With the following eight key questions, you can determine whether the compounding facility maintains a quality assurance program:

1. What are your compounding processes, and do you use all sterile supplies?
2. What studies or processes do you have that illustrate your practices around preventing cross contamination?
3. If you produce beta lactams, how do you conform to the requirements to do so?
4. If equipment is used, how do you qualify it to perform those activities?
5. How do you ensure you have adequate aseptic training and how do you conduct employee qualifications, such as passing at least three successful, successive media fill simulations designed to verify the adequacy of their technique and behavior?
6. What is your process to ensure your products have full validation studies, container closure integrity studies and shipping studies?
7. What is your process to visually inspect each unit with the proper training and qualified equipment?
8. What is your process to keep products quarantined until release? How do you submit samples? Is it based on USP <71> standards and is the analytical lab using validated methods?

The outsourcing compounder should have a strong grasp of the FDA regulations to achieve optimal quality control. The FDA's "Outsourcing Facilities" website offers a variety of online resources for customers selecting a compounder, including information regarding facilities' inspection outcomes. Local Boards of Pharmacy also provide an online record of the facility's status as well as any disciplinary actions.

Best practices

|Still a relatively new industry, the 503B landscape is continuously evolving to ensure best practices for patient safety. There are best practices every reliable facility adheres to, and ASCs that conduct a rigorous audit reinforce the demand for safe medications.

Here are three key questions to determine whether compounding facilities follow industry best practices:

1. Does the quality department have the authority to release and reject products, and what is the process?
2. How does the quality department collect and review all the appropriate data before a product is released or rejected? (Be sure the outsourcer is doing a review of the raw data collected by the lab for chemistry and microbiology.) Do you review both the environmental and personnel data associated with the compounding of the product? Have you ever released a batch that was outside of your specifications and if yes, why?
3. How often do you report adverse events and recalls? Do you report them all? What is your customer notification process?

Brigham and Women's initially built an in-house compounding program, but then decided to outsource. Mr. Churchill worked with several colleagues to research compounding facilities, investigating via the state Boards of Pharmacy and department of public health. His team identified regulatory actions or sanctions against facilities and leveraged a customized survey tool to analyze the facility's compliance and quality systems. Their audit included:

- Licensure reviews
- Records review from external audits
- Compounding records
- Training records
- Equipment certification and validation records

"Only after satisfactorily passing all of these areas would the 503B facility be eligible for potential contracting and partnership with our institution." Mr. Churchill says.

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Leiters is a FDA-registered 503B outsourcing provider of high quality ophthalmology and hospital-based services. We are committed to providing healthcare professionals and their patients with high quality medications. Our team of experts in sterile pharmaceutical manufacturing, repackaging, and compounding provide a sophisticated understanding of what it takes to elevate quality and consistency of supply in outsourcing. We combine our team of experts, our robust processes and our state of the art manufacturing facilities to ensure the highest quality products and services. We believe the most important consumer of our products are patients, and patients have trusted Leiters with their health for nearly a century. For more on how we are elevating the standards in pharmaceutical outsourcing please visit www.leiters.com