5 Critical Quality Questions to Ask Your Outsourced Repackaging Provider

White Paper

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Section 1

Executive Summary

The past few years in pharmacy have been among the most difficult from a practice perspective. Drug shortages, reimbursement challenges and, more recently, the tragedies surrounding pharmacy sterile compounding have all created a resource challenge for hospital and long-term care pharmacies. The response from many pharmacies has been to look at outsourcing non-sterile medication repackaging as more sterile compounding and packaging comes back into the pharmacy. Outsourcing of the non-sterile packaging burden can be a valuable alternative and can provide a resource pool inside the pharmacy to address sterile compounding challenges. For those pharmacies that have not outsourced their non-sterile packaging in the past, many have questions about the potential providers and the quality procedures that those providers employ in their operations. This white paper addresses the five key questions that each pharmacy should ask of their potential packaging partner.

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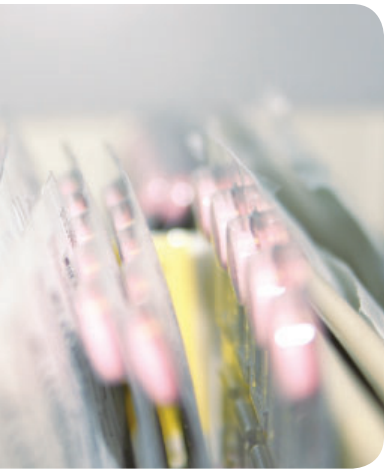

The Five Key Questions to Ask Your Service Provider

1. How many years have you been in business?
2. Can you describe your quality organization and are pharmacists a key component?
   a. Describe your overall quality program.
   b. Describe your compliance to 21 CFR, FDA guidances, and applicable sections of the current version of USP.
3. Have you had any FDA warning letters or has the firm had any recalls?
4. Can you describe your supply chain presence and process?
5. Can you provide references from hospitals or long-term care pharmacies in my area?

Section 2

How many years have you been in the business?

Experience is important. The complexity of repackaging, including understanding the unique requirements of hospitals and long-term care pharmacies, requires years of experience. The more, the better. Of course, the quality and experience of individuals in the firm are also important. Ensure the key resources in your partner organization have the experience and dedication to deliver a quality service to your facility. Having this experience will also help the firm comply with the myriad of FDA and state regulations that apply to the industry.

Can you describe your quality organization/process and are pharmacists a key component?

Ensure that pharmacists are not only on staff, but deeply involved in all aspects of quality.

A repackaging firm should be able to readily describe the quality organization. If they use terms such as "we have a person" it might be a signal that the quality organization does not have the staffing resources to fully implement an FDA-level quality program. Also, while pharmacists are not required by the FDA, the expertise they bring to the packaging process, the science and analytics of testing, and the exposure to hospitals and pharmacies are all valuable components of a good quality program. Ensure that pharmacists are not only on staff, but deeply involved and hold leadership roles in all aspects of quality.

A firm's description of their quality program can also meaningfully point to the comprehensive nature of their quality efforts. Descriptions of cGMP ("current good manufacturing practices") and a formal quality organization is not enough. The firm should be able to describe in detail their operating procedures, the testing they perform for cleaning and for packaging components, and their disciplines around the training and competency testing of employees. Understanding their adherence to the firm's procedures, and also what happens when those procedures are violated, will tell you a great deal about the firm's disciplines.

Finally, the firm should be able to provide the details of their compliance with 21 CFR, FDA guidances, and relevant sections of the current version of USP. These are the critical regulations that determine a firm's compliance with cGMP requirements for oral, non-sterile packaging. While these specific points may be difficult for a sales representative to communicate, the firm should have documentation in written form that describes their compliance and have resources available for you to ask more detailed questions, if desired.

Ask detailed questions. If you don't get detailed answers, you should have concerns about the depth of the quality team.

Have you had any FDA warning letters or has the firm had any recalls?

Many in the health care marketplace become immune to pronouncements from the FDA or pharmaceutical firms that issue recalls as it seems that dozens are issued each day. Recalls and other communications from the FDA from firms may not necessarily be a warning sign, but they might be of concern. Ask about the content of the warning letter or recall and understand the fundamental reasons for the communication. Look for patterns in multiple warning letters or for issues surrounding manufacturing processes that might seem to be basic fundamentals of manufacturing. The description of the reasons for the warning letters or recalls could signal issues in the firm's quality department or a lack of investment in the resources required to provide a quality product. Warning letters can be searched at the following FDA link:

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm

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Can you describe your supply chain presence and process?

While turnaround time is certainly important, what is most important is the ability to hit agreed upon turn times on a consistent basis without compromising quality. Ask the firm to supply data over the past year of their actual turn time and quality performance and confirm the data provided with other customers in your geographic area. Consistent turn times combined with setting the appropriate par levels and order replenishment protocol in your pharmacy will ensure you have what you need on hand to serve patients. Ultimately, the proven quality and consistency of your packaging provider are what will matter most to your pharmacy.

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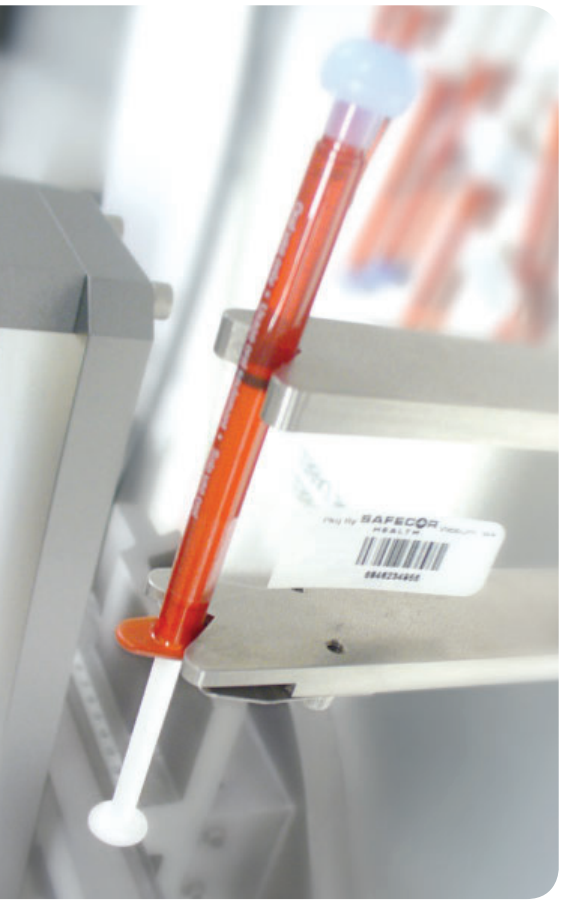
In addition to distribution, be certain that your packaging firm has all of the right relationships with your wholesaler, your group purchasing organization, or your regional buying group. The firm should be able to describe electronic order connections with wholesalers and contracts that are currently in place with the GPOs. Not having those relationships could create a number of headaches for your buying staff. Most GPOs have programs to audit suppliers. Ask if your GPO has toured the firm's facility and check with your GPO about the firm if you have any questions.



Can you provide references from hospitals or long-term care pharmacies in my area?

References are the final step. Ask your pharmacy colleagues in the area about their experience with packaging firms. The firm should be able to readily provide a list of customers in the region with whom they do business. If a firm has difficulty providing references, it may be a sign that the firm has not penetrated the market near you or they simply don't want to share that information. Great firms will readily provide references. Check at least three references, but ask for more if the firm will provide them.