By Noel C. Hodges, RPh, MBA

QA Practices for Bar Coded Unit Dose Packaging Operations

Photo courtesy of Medical Packaging Inc.

BY INVESTING IN BAR CODING SYSTEMS, HOSPITALS ARE MAKING STRIDES to improve patient safety and reduce medication errors at the point of administration. However, without incorporating stringent quality assurance (QA) measures into your pharmacy's unit dose packaging operations, you run the risk of shifting the potential for error from the point of administration to the pharmacy. After all, if your pharmacy is packaging large quantities of doses,

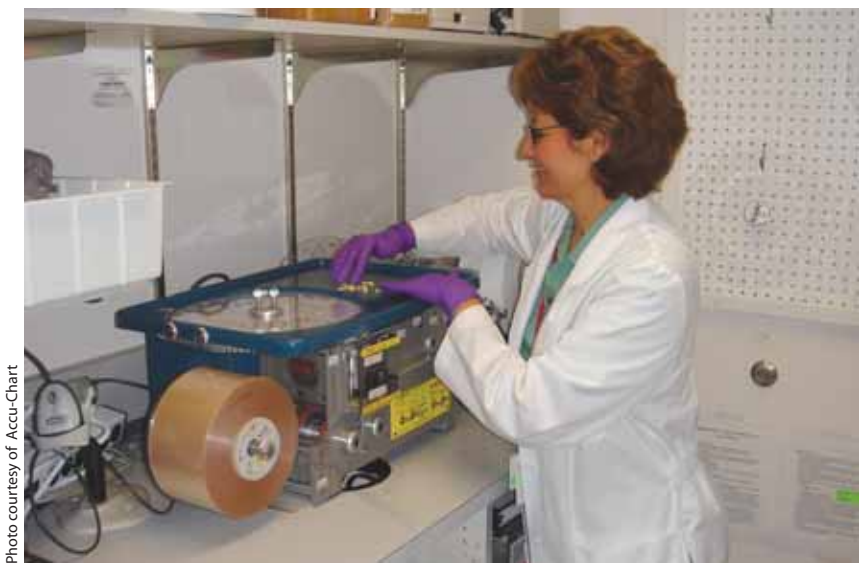

Photo courtesy of Accu-Chart

getting the right pill into the right packaging – labeled with the right bar code – can mean the difference between hundreds of accurately administered doses and hundreds of medication errors. It is important to note that as nurses become more comfortable with a bedside scanning system, they naturally become more confident that – unless their computers tell them otherwise – they are scanning the right dose. They may not take the time to inspect the tablet or capsule in the unit dose package to ensure it looks like the drug they are meant to administer. That is why it is critical to be vigilant in your packaging operations and to establish strict QA processes and continually reassess them.

Establishing Sound QA Policies and Procedures

From a patient safety standpoint, the most important part of a packaging operation is the QA program. The first step in establishing comprehensive QA policies is to examine all of the guidelines available for repackaging. Your state board of pharmacy's requirements for repackaging are a good place to start. State boards typically provide some form of guidance for these activities. ASHP also has some great documents on packaging processes, and the USP has established standards. In creating our packaging policies and procedures, the HCA Central Atlantic also looked at current Good Manufacturing Practices (GMPs), although it was never our goal to follow these standards exactly. Rather, our intention was to get as close as we could to the standards drug manufacturers and repackagers are held to for packaging. By visiting several GMP-compliant repackaging facilities, we were able to see these standards in action. At the end of the day, the aim is to establish the most stringent requirements possible for your facility. The state boards of pharmacy's regulations are typically less rigorous than GMPs. With this in mind, just meeting the intent of the state board will not lead to establishing the most robust QA processes possible and could, ultimately, adversely effect patient safety.

So what QA procedures must be built into your program? The most essential is the terminal check, which occurs before releasing doses from the pharmacy to the nursing unit. In the terminal check, a pharmacist must verify that the packages contain the right drug and the right dosage strength, and are appropriately labeled with the correct drug information and bar code. You should also scan the packages to make sure the bar code is associated with the proper medication in your hospital's information systems. If the bar code does not match a drug in your information system, your nurses will not be able to scan the dose at the bedside. Worse yet, if the bar code matches the wrong drug in your information system, an adverse drug event may ensue. In addition, this check provides the further benefit of reducing the amount of drugs returned to the pharmacy due to scanning problems.

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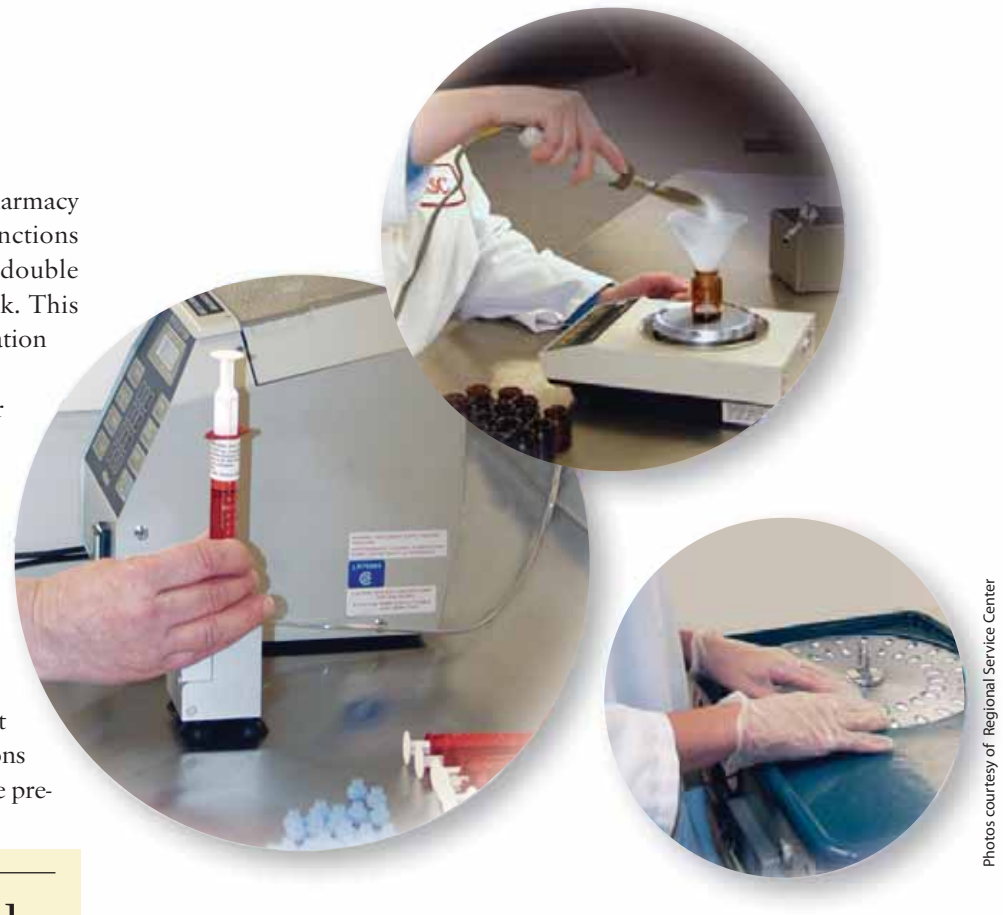
After establishing our terminal check procedures, HCA found it helpful to work backwards, identifying junctures in our packaging processes that presented opportunities for error. To prevent such errors from occurring, we established several QA procedures, such as evaluating equivalent generic products, quarantining the finished product before the terminal check, and utilizing tall-man lettering whenever possible. We found it helpful for one techni-

cian to perform all of the data entry for our packaging systems and pharmacy information system, another technician to perform the packaging functions (with both technicians responsible for performing the established double checks), and finally, one pharmacist to perform the terminal check. This method ensures that three independent sets of eyes review the information for each drug package that leaves the pharmacy.

Also be sure to factor expiration date and recall procedures into your packaging QA program. By tracking lot numbers in your hospital's information system, you can quickly identify which nursing units received the recalled products. At HCA, one of our criteria for selecting an outsourced repackaging vendor was a robust recall system. It is very important to track manufacturer recalls directly to your repackaged products. We looked for a vendor that could provide us this information in real time.

I would recommend designating one staff member to oversee and take ownership of all of the packaging QA processes. By establishing a point person to manage your QA protocol from end-to-end, you will not only increase productivity, but you will also decrease information deviations on your packaging labels; in other words, medication descriptions will be presented in the same way on every package. Once we assigned a single person to lead the QA processes, we found an immediate improvement in our packaging consistency; for instance, our labels no longer alternated between micrograms and milligrams. This consistency can ultimately improve efficiency and patient safety. Obviously you want to assign this responsibility to a detail-oriented person — someone who is consistent and methodical. Equally important, this person must be willing to take a strong stand and demand consistent quality at all times. Your QA person should not be afraid to reject a package if it does not meet protocol — even if it means throwing the product away — and should be able to identify ways to continually improve your packaging processes.

From a QA standpoint, it is ideal to purchase unit dose drugs directly from the manufacturer, as their QA processes are held to the higher GMP standards. However, that quality often comes at a price. It does not often make sense to pay a manufacturer $0.40 per dose, when — should you have a high level of confidence in your QA protocols — your pharmacy can buy the same drug in bulk and repackage it for $0.17 per dose. Once you determine your true packaging costs, including supplies, equipment, and QA procedures, it may be helpful to create a decision tree for determining the difference in cost between manufacturer-packaged doses and in-house packaged doses. Comparing these costs should make pharmaceutical purchasing decisions clearer.



Photos courtesy of Regional Service Center

When considering a service provider for your repackaging needs, be sure that **QA processes** have been factored into their cost estimates.

Outsourcing: Calculating the Costs of QA

Full transparency of your total costs is key to assessing any option for packaging your medications into unit dose — in-sourced (i.e., McKesson's PakPlus-Rx program), outsourced (i.e., Regional Service Center), or in-house. The first step is to establish your in-house total cost per unit, including QA costs. The most expensive component of your packaging QA program will be your staff's time, and it cannot be excluded from your packaging cost analysis. When considering a service provider for your repackaging needs, be sure that QA processes have been factored into their cost estimates. The repackaging service provider may not perform certain QA checks at their facility, in which case it falls to your staff to do so. In this instance, you need to understand how much time you will need to devote to QA and then equate it to a cost related to your pharmacists' and technicians' time. Then take a close look at the service providers' agreements. Are there any additional costs beyond the per-unit cost, such as rental fees, lot number change fees, shipping costs, and staff time charges? Be sure to ask outsourced repackaging service providers not just what their costs per unit are, but also what their QA processes are and how they handle product recalls. If your primary goal is to reduce distributive tasks and allocate your pharmacists' time to patient care activities, you may factor this consideration into your decision-making process as well.

Regardless of the repackaging method you choose, you need to focus on QA and assign resources to those practices. Incorporating QA measures into your packaging operations can have a profoundly positive effect on your patients' safety and the overall success of your bar coded medication administration initiative. ■

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