QA and QC Techniques for Tabletop Unit Dose Packaging Machines

Available from several vendors, tabletop unit dose packaging machines have proven to be a reliable technology for packaging oral solid medications in bar coded unit dose. Relatively easy to use, the machines require little mechanical oversight and can produce 60 to 120 packages per minute, depending on manufacturer and model. However, in order to ensure the accuracy of your bar coded unit doses, it is important to build quality assurance and quality control measures into your packaging process.

Initiating the Packaging Run
When starting a packaging run, the technician should bring the bulk bottle to be packaged to the pharmacy’s designated packaging area. It is advisable to bring only one product into the packaging area at a time, in order to avoid inadvertent mixups between drug products. The technician can either scan the bulk bottle’s bar code or manually select the drug to be packaged from a menu in the packaging machine’s software. The technician is then responsible for entering the bulk bottle’s lot number and expiration date, as well as the quantity of doses to be packaged. Keep in mind that bulk bottles of the same drug that have a different lot number or expiration date should not be packaged as part of the same run and should be segregated until a pharmacist verifies the accuracy of the unit dose packages. Prior to initiating the packaging run, the technician should then carefully confirm that each piece of information has been entered correctly in the software. While feeding tablets and capsules into the packaging machine, the technician should work without interruption or distraction until the completion of the packaging run.

Package Accuracy
Once the packaging run has been completed, the technician should verify that the first and last dose packaged have been accurately labeled. Specifically, he or she should compare the drug name, strength, NDC number, lot number, and expiration date from the bulk bottle to those detailed on the unit dose packages. The technician can then set the empty bulk bottle aside with the packaged doses so a pharmacist can verify the same information for both the first and last doses. It is fair to assume that, in a batch of 100 doses, if the first and last doses are consistent, the 98 doses in between will be as well. The verifying pharmacist should also perform a visual check of all of the doses to ensure that no tablets or capsules have been crushed during packaging and that each package has been filled and heat-sealed. Any empty packages or crushed doses should be taken out of inventory.

Bar Code Quality
To ensure the quality of the bar codes printed by your tabletop packaging machine, scan one of the packages’ bar codes to ensure it will be recognized by both your pharmacy information system and the bar coded medication administration platform your nurses use at the bedside. You may also consider installing a bar code verifier, which grades the quality of a bar code based on established criteria from the American National Standards Institute (ANSI), in the vicinity of your packaging machine to further ensure the quality and ultimate readability of your bar codes.

Tall-Man Lettering
The Institute for Safe Medication Practices (ISMP) recommends the use of tall-man lettering, when appropriate, on drug labels and provides a list of FDA-approved uses of this safety tool on www.ismp.org. To ensure the consistent use of tall-man lettering across your institution, copy this suggested lettering into your packaging machine’s database, as well as the databases for your hospital’s other information systems.

Policies and Procedures
Food and drink should be prohibited in the packaging area. Technicians should wear gloves when handling drugs and, at a minimum, should change their gloves after handling and packaging products with high risk for patient allergies or that produce a visible amount of powder residue. Consider establishing a policy that requires technicians to change gloves after each packaging run, regardless of the drug being handled, to prevent cross contamination. At the conclusion of each packaging run, a technician should also wipe the surfaces that make contact with drug products with isopropyl alcohol to further reduce the risks of cross contamination and patient drug allergies.

Furthermore, certain drugs should not be run through the packaging machine at all. For instance, estrogen, antineoplastic agents, and some antiviral medications are not appropriate candidates for automated packaging. Should the machine inadvertently crush these drugs, the resulting risk to both your patients and staff negates any efficiency benefits you could derive from automated packaging. You can use ASHP’s list of hazardous drugs to develop a policy specific to your institution’s formulary. Also keep tablet and capsule size in mind when determining which drugs your
Tabletop unit dose packaging machines can handle. Though they are not common, very large pills may cause jams, crushed doses, and other issues during packaging.

Packaging Logs
It is important to maintain logs of your packaging activities as a quality assurance measure. While you can keep paper logs of your packaging activities, electronic logs may prove to be more efficient when searching for information on specific packaging runs or staff member activities. Furthermore, extensive paper logs can eat up storage room in space-constrained pharmacies. If you keep electronic logs, be sure to back them up on a redundant hard drive or server to preserve your data in the event of a system failure.

The verifying pharmacist can crosscheck information in the packaging log against the packages produced by your tabletop packaging machine to further verify the accuracy of your packages. In addition, logs can be helpful in resolving issues related to product recalls or product mix-ups that may have occurred during packaging. For instance, if you notice that one batch of unit dose medications have been inaccurately packaged, you can use your logs to check the other lots that were processed that day, and remove any other problematic batches from your inventory for repackaging.

Conclusion
Tabletop unit dose packaging machines are mechanically reliable devices that can aid pharmacies in efficiently packaging medications in bar coded unit dose. By implementing sound quality assurance and quality control measures into your packaging policies and procedures, you can help to ensure the safety of your patients and the success of your facility’s bar coded medication administration program.

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