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How Do Pharmacies Evaluate Cleanroom Automation Systems?

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How Do Pharmacies Evaluate Cleanroom Automation Systems?

Check Out These Pre- and Postimplementation Checklists, Which Also Help to Justify the Investment

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MANY PHARMACIES HAVE implemented or considered implementing cleanroom automation or compounding systems.[1]

Intravenous (IV) admixture automation is one of the newest areas of technology that has been applied to pharmacy workflow.

Manufacturers tout systems for reducing errors reaching patients.[2-4] Clinical literature supports that cleanroom technology can aid in patient safety.[5,6] Errors that occur during sterile product compounding can have significant consequences, from minor harm to the death of patients and expensive lawsuits.[7-9] Pharmacies have attempted to achieve the following goals as part of tech justification: reducing errors and improving accuracy, productivity, and workflow. Based on a justification for financial approval, here are pre- and postimplementation checklists for evaluating or upgrading existing automation in the cleanroom and for justifying the investment, including financial considerations, medication safety, productivity, and quality.

Preimplementation Assessment

Financial justification. Most facilities typically require some form of financial analysis and justification for capital expenditures. This information typically includes cost avoidance for medication errors, potential staffing adjustments, ability to handle growth, consumables for the automated systems, and potential reduction in outsourcing. Our previous study suggested productivity and safety were overriding reasons for implementation, but a large number of facilities still required financial analysis.[10] In addition, vendors often publicize that these systems reduce waste by creating more just-in-time dose preparation, decreasing lost and missing doses, and reducing rejected product and remakes.[2-4] Reporting tools for metrics and monitoring to document achievement of stated goals is also a consideration.

Medication safety. Most vendors project a reduction in medication errors pre-implementation. Error reduction can be achieved through automated calculations, barcode verification of ingredients, and use of standardized preparation steps.[11] It is important to identify upfront how one will measure medication safety pre- and post-implementation as it relates to the automation technology. A brief meeting with the chief financial officer can help firm up how savings will be counted on analysis of the project.

Promote dose preparation accuracy and safety. Cleanroom automation is advertised as highly accurate with automated calculations, standardized concentrations and preparation steps, which yields more consistently accurate results than the manual compounding process.[2-4] Pharmacists evaluating these systems should request evidence-based data supporting any accuracy claims made by vendors related to the technology and validate it with a currently installed client. Before implementation, pharmacies should evaluate any additional regulations or governing approvals that are required, including being compliant for USP Chapter <797>. Consideration should be given to identify quality control processes and additional required equipment.

Productivity. Pharmacy administrators must identify if staff workflow redesign is an implementation goal or part of the justification. The impact on pharmacist checking time is also a consideration, as many systems tout remote verification and suggest freed-up time. If increased volume is a concern, a metric should be identified to track any associated changes in staffing from baseline. Some vendors tout the reporting capabilities of their systems to allow analysis and trending of workloads and productivity.[2-4]

Additional items. Other matters to be addressed before implementation include compounding outside the automation, drug inventory storage, order entry and verification, policies and procedures for compounding sterile preparations in automated systems, preparation of source/bulk containers, product labeling and staff management, and workflow.[11,12]

Postimplementation Analysis

Facilities should report results and obtain a baseline for any metrics prior to implementation and associate reporting with the return on investment (ROI). Typically, results should be reported on an annual basis. Comparing annual metrics yields insight to improvements achieved with technology. Metrics to review include:

- **Accuracy.** Work with vendors to identify quality control procedures and measure accuracy at the recommended intervals and document results. If internal data exist, they should be compared with the automated systems.
- **Financial.** In our previous study, almost half the subjects indicated no savings were realized or documented related to IV room automation.[10] This issue is likely because a precise measurement tool was not adopted with baseline information before implementation. Also, including a parameter to monitor missing doses or product remakes could yield significant savings to identify impact on supply cost reduction.
- **Medication safety.** Any documented improvements should be made with a specified error rate reduction associated with IV compounding.
- **Productivity.** A baseline volume that accounts for seasonal variation for the cleanroom should be identified and used for comparison. This baseline should identify staffed hours, as well as a measurable volume.

Implications

IV room automation justification and analysis can be a complex process. Facilities that have implemented IV room automation have overwhelmingly indicated that there was not an ongoing assessment for justification of the achievement of the ROI.[10] Identifying the metrics that will be assessed before implementation and an associated reporting plan for the institution's specific goals with this technology are critical to justifying an ROI and documenting improvements of this technology. ■

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