

PostScript

Ensuring Compounding Excellence: Quality Control or Quality Assurance?

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Today, there is a growing market for extemporaneously compounded pharmaceuticals and the pharmacies that produce them. The ability and willingness to compound those products can provide a unique niche for the independent pharmacy. With this special market, however, comes an extra measure of responsibility; the pharmacist must ensure that the acceptable strength, purity, identity, and quality of the desired product is delivered to the patient. To do that, a compounding pharmacy must have an effective quality control-quality assurance program. But what exactly is quality assurance (QA), and how does it differ from quality control (QC)?

QA Versus QC

QA examinations are used to evaluate a randomly chosen example of the final product, and QC measures should be part of the daily routine of a compounding pharmacy.

QA involves monitoring the identity, potency, sterility, and stability of the compounded product, and (in the case of injectable products) testing for pyrogen contamination. An effective QA program can be used to determine whether equipment and procedures fulfill their expected functions and ensures that personnel perform compounding procedures in an approved and reproducible method.

Some aspects of QA can be performed in the compounding pharmacy; however, an independent analytical laboratory can best perform more elaborate QA testing. That type of laboratory can provide an independent check of product potency, including the identity and purity of starting material, and can confirm the accuracy of technique and measurement used to compound the product. In an independent analytical laboratory, testing usually involves the use of high-performance liquid chromatography (HPLC), a technique not available in the typical independent pharmacy. The analytical laboratory can also determine the chemical, physical, and/or microbiologic stability of the compounded product. That information is essential to assigning an appropriate beyond-use date (BUD). An independent analytical service is particularly helpful when sterile-dosage forms must be prepared or when drugs with a potent or low-stability profile are used. In addition, that type of laboratory can provide a certificate of analysis that includes contact information about the laboratory and information about the sample (eg, the type of testing performed and the results). That documentation is valuable in the overall QC-QA program.

How often should QA evaluations be performed? No guidelines are "set in stone." However, routine testing may be prudent and will provide valuable assurance about the integrity of the compounded product. Investing in QA provides a multitude of long-term benefits.

QC begins with a daily assessment of all operations: the receipt of raw materials; product preparation, testing, and dispensing; and

documentation. The highest quality chemicals available must be used in the compounding of pharmaceuticals. Meticulous adherence to standard operating procedures prevents errors and ensures a reliable and reproducible product. All staff members involved in compounding should be carefully trained and tested before they are allowed to compound medications.

Product testing is an important part of a successful QC program. Such testing includes physical observations such as individual and average dosage unit weights, the total product weight, the pH, and other physical observations such as the appearance, taste, and smell of the compounded product. Documentation of all aspects of the compounding process (the identity of chemicals used, the name of the company from which those chemicals were obtained, the lot number and weights of the chemicals, the total product weight, individual unit weights, and comments about the physical appearance of the product) is essential.

The QA-QC Program: An Effective Combination

A successful QA-QC program is a powerful marketing tool that will build good rapport with patients, physicians, and the overall community. It ensures that the product extemporaneously compounded by the pharmacist has the correct concentration, identity, and purity and that intrathecal and parenteral injections are free from microbial or pyrogen contamination. It also provides a "paper trail" of supporting documentation on the quality of the compounded product.

In summary, it is imperative for a compounding pharmacy to have an effective QA-QC program to ensure the safety and effectiveness of the end product. When that type of program is not effective, disaster may occur.¹ The final product produced in a compounding pharmacy should be randomly tested as a part of an ongoing QA program, and compounding pharmacy owners should implement and follow a daily QC program that includes the use of high-quality materials, meticulous adherence to all standard operating procedures, product testing, and documentation. That testing can be performed in the pharmacy, or more extensive testing can be performed by an independent analytical laboratory. Pharmacists owe it to their patients to do everything possible to ensure their safety and the efficacy of their compounded medication.

Conclusion

A QA program involves the evaluation of product quality by an independent individual, agency, or group; day-to-day compounding operations are not evaluated. QC, the day-to-day monitoring of routine operational issues, ensures appropriate control of compounding procedures. Both programs are necessary to building the success of a compounding pharmacy and to ensuring that the highest quality products are made available to patients.

Reference

1. [No author listed.] Compounding errors: Lessons learned, never to be forgotten. *IJPC* 2001;5:408.

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