

Practice Spotlight: Compounding Pharmacy

Gentès & Bolduc Pharmacists
Sterile and nonsterile compounding
Saint-Hyacinthe, Quebec

It's a fact that many pharmacy graduates are less attracted to compounding and sterile-product preparation than to other areas of pharmacy practice. The strong emphasis on clinical training in our pharmacy educational programs encourages pharmacists to play a larger clinical role, with improvements in patient outcomes as the main goal. However, with pharmaceutical companies continually reducing their product ranges (particularly for older molecules) while simultaneously introducing newly developed products, primarily for parenteral administration, the importance of the pharmacist's role in compounding is increasing.

Gentès & Bolduc Pharmacists, based in Saint-Hyacinthe, Quebec, is a privately owned pharmacy that is fully dedicated to nonsterile and sterile compounding. The pharmacy has 70 employees and prepares both nonsterile and sterile compounded products for over 175 hospitals in 8 provinces across Canada.

All medications are dispensed to individual patients through their own community or hospital pharmacists, which allows complete follow-up through analysis of patients' medication lists. For community pharmacists who do not wish to offer compounding services, the option of obtaining compounded products through a specialized facility, without having to refer patients to another professional, is a big advantage. For hospital pharmacy departments, outsourcing the preparation of these products allows for easier inventory management, as well as improved quality and stability of the products.

At Gentès & Bolduc, pharmacists rotate through 3 positions: customer service, central IV admixture, and nonsterile compounding.

CUSTOMER SERVICE

During the customer service rotation, a pharmacist spends about 50% of the time doing initial verification of prescriptions. This first screening is essential to catch any errors that might have occurred during transcription of orders into the

computer system. On the rare occasions when a prescription seems out of the ordinary, the customer service pharmacist contacts the original pharmacist to warn of the potential problem. Another 25% of the customer service pharmacist's time is devoted to answering drug information questions related to compounding. The remaining time is split between 2 activities: assisting the pharmacist in the nonsterile laboratory and overseeing the shipment of specialty products.

CENTRAL IV ADMIXTURE

Gentès & Bolduc is equipped with 8 aseptic rooms with laminar flow hoods (meeting ISO [International Organization for Standardization] 5 standards), all with buffer areas meeting ISO 6 or 7 standards. Two of the rooms have negative-pressure capability and are equipped with isolators for the preparation of sterile products for oncology.

Various parenteral products are prepared daily for ambulatory patients, for dispensing through community pharmacies. For hospitals, Gentès & Bolduc provides a variety of products such as prefilled syringes (including syringes prefilled with narcotics for patient-controlled analgesia), high-risk compounded preparations, and oncology products.

The central IV admixture pharmacist schedules and manages the preparation of these products in the admixture centre, checks and analyzes the results of sterility testing performed by technicians and releases batches accordingly, and controls the quality of compounded preparations through supervision of pharmacy technicians and verification of preparations in relation to current regulations.

NONSTERILE COMPOUNDING

The nonsterile compounding pharmacist is the final gatekeeper before release of nonsterile preparations from the facility. Pharmacists in this position review the compounding records to ensure that the pharmacy technicians have documented all of the important details about every preparation, including lot number and expiry date of the raw materials used, weighing information and weight verification by a second technician, identification number of the scale used for weighing, and confirmation that the compounding instructions were followed. The pharmacist's verification process includes check-

ing every raw material that was used, followed by a visual and textural check of the compounded product before release. If a product is deemed to be nonconforming, a nonconformity record is issued and analyzed to evaluate the source of the problem. If a product is deemed to conform with required criteria, it is released for shipping.

ENVIRONMENTAL CONTROL AND QUALITY ASSURANCE

Gentès & Bolduc Pharmacy has been certified to ISO 9001 standards since 2001 and is also compliant with standards such as USP (United States Pharmacopeia) <795> and <797>, provincial regulations, and Health Canada's Good Manufacturing Practices. Standard operating procedures are key to the quality of the company's products, as they allow standardization of work. Continual revision of these procedures is mandatory to correct any weaknesses discovered through audits or to address any problems that may have occurred.

Besides a good quality control system and well-trained staff, installations and equipment are also important for quality assurance. To ensure the cleanliness of the environment in which preparations are compounded, Gentès & Bolduc follows a strict maintenance and cleaning schedule. Also, a full-time microbiology technician performs daily particle counts and microbiological testing in the clean rooms.

Recently, Gentès & Bolduc acquired new technology for rapid microbiological testing. This technology is now used for in-process monitoring of sterile production, which reduces the delay for sterility testing from 14 days to less than 6 hours. Beyond-use dates can now be based on physical and chemical stability data for the product.

EXPANSION AND FUTURE DIRECTIONS

Numerous pharmacies across Canada can provide high-quality compounding services and sterile products to patients and other pharmacies, but few have exclusively focused their practice on this aspect of pharmacy. Because Gentès & Bolduc's practice is limited to the preparation of nonsterile and sterile products, its pharmacists and technical staff have strong expertise in this area, which can be of benefit to pharmacist colleagues in both hospital and community settings. Regular investments in dedicated equipment and new technologies help to improve product quality. Nonetheless, regular communication between compounding pharmacists and their clinical colleagues remains vital to improving the quality of patient care in the context of customized therapeutic solutions.

The Practice Spotlight series highlights the accomplishments of Canadian pharmacists with unique practices in hospitals and related health care settings. If you have a unique or innovative practice, or you know someone else who should be profiled, please submit your contact information to Mary Ensom, Editor of *CJHP* (cjhpedit@cshp.ca), and one of our Associate Editors will be in touch with you.