By Nicole Kruger, PharmD

Grifols' Gri-fill System 3.0

SENTARA HEALTHCARE IS A COMMUNITY, not-for-profit health care organization serving more than two million residents in southeastern Virginia and northeastern North Carolina. Sentara operates more than 87 care-giving sites, including seven acute-care hospitals with a total of more than 1700 beds. As a clinical pharmacist at the Sentara CarePlex Hospital located in Hampton, Virginia, I first became interested in the Gri-fill automated compounding device as a possible solution to our USP <797> compliance needs.

The CarePlex pharmacy stocks a number of high-demand compounded sterile preparations, including narcotics such as morphine PCAs, various concentrations of fentanyl and bupivacaine epidurals, and 2-g bags of magnesium sulfate and calcium gluconate. These preparations are not available commercially, so we prepare them ahead of time to ensure they can be dispensed as needed.

For sterility reasons, USP Chapter <797> requirements indicate that batch narcotics can only remain on the shelf for seven days – less if not refrigerated. Given that short shelf life, there is an argument for making the products each day as the orders come into the pharmacy. But that can cause delays in therapy while the order is entered, processed, and delivered up to the nursing floor. So we began looking for a way to meet <797>'s sterility standards and keep product on the shelf longer. The Gri-fill System 3.0 from Grifols USA helps us to do just that.

System Selection

I first learned about the Gri-fill 3.0 System for automated compounding at the 2005 ASHP Summer meeting. At the time, we were investigating several options to achieve USP <797> compliance. We examined our current processes (time, labor, materials, and waste), the impact of shorter expiration dates, and costs associated with the device. The numbers told us it made sense to implement the Gri-fill system. Nonetheless, price was not the only factor in our decision-making process. Quality, safety, and the ability to control our product output were equally important.

Sentara has a culture of safety and a focus on quality, and we strive to promote both through innovation and the use of advanced technology. The Gri-fill was a good match because it supported our safety philosophy and our compliance and goals. The Gri-fill System is ideal for standardizing a compounding practice. Furthermore the system ensures that every preparation coming out of the pharmacy is sterile, thereby helping to reduce the incidence of bloodstream infections. And with the Gri-fill, we are not dependent on outsourcing for preparations required on a daily basis.

So in the fall of 2005, we decided to implement one device in the CarePlex pharmacy. The Grifols representative trained our technicians in a couple of hours. After a few weeks, we conducted a demonstration for all other Sentara hospital managers. In less than two months, the decision was made to implement the Gri-fill in six Sentara hospitals.

System Features and Benefits

The Gri-fill System is an automated compounding device that can extend the shelf life of compounded preparations up to 60 days (provided, of course, this is not beyond the chemical stability period). The system uses a terminal sterilization process. It filters each dose and then tests and documents the integrity of the filter so product sterility and, hence, extended shelf life are assured.

The Gri-fill System automatically reconstitutes solutions and withdraws volumes in a closed and controlled system. The device draws up the dose and pushes it into bags with 0.22-micron filters in the filling ports. The Gri-fill system documents the exact measure of each admixture component and the results of the filter integrity test. We are in the process of installing optional system software that will give us even more documentation capabilities such as the ability to print more detailed labels, track lot numbers, and organize our compounding procedures, all of which support USP <797> compliance.

Future Applications

Implementing the Gri-fill System 3.0 at Sentara was not difficult, and from my perspective, it did not require a big leap of faith. While the device may be relatively new on the market, the 0.22-micron filtration technology it uses has long been proven. We also had a great deal of confidence in our Grifols representative. She was extremely knowledgeable and responsive, providing implementation support and information every step of the way.

Going forward, I think the Gri-fill will have additional applications at Sentara. At CarePlex, we started out using the Gri-fill for batch specialty compounding. We have now expanded it to epidurals. We have even used the device to extend the beyond-use date for IVIG. In one instance, we prepared an IVIG that only had a few hours' shelf life when manually compounded. However, the patient's therapy was unexpectedly delayed, which, had we prepared the IVIG maually, would have lead to us wasting the preparation – and several thousand dollars. But by compounding the IVIG through the Gri-fill, we were able to extend its shelf life so it could be administered to the patient. Down the road, I can envision using the Gri-fill for hazardous solutions. The device fits easily in a hood, biological safety cabinet, or isolator. So it would be ideal for oxytocin and other preparations that require additional protection per NIOSH. The device's flexibility meets our current compounding needs and will likely meet additional needs in the future. ■

Nicole Kruger, Pharm D, has been a clinical pharmacist at the Sentara CarePlex Hospital since the facility opened in 2002.

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