

White Paper

STERILE COMPOUNDING MORE COMPLEX THAN JUST MIXING: MARKET TRENDS OF STERILE COMPOUNDING FOR HOSPITALS

Mary Nazzal, Pharm.D., Clinical IQ, LLC, Eric S. Kastango, MBA, RPh, FASHP, Principal-CEO, Clinical IQ, LLC & CriticalPoint, LLC

There are basically two options to consider when it comes to compounding sterile medications for your facility. Medication of specific strengths, specific ingredients and administration routes that are commercially not available can be compounded whenever required.¹ You can choose to either compound necessary medications in your facility or have an outsourcing pharmacy compound fulfill your needs. Preferably a 503B registered facility would be used for the latter. Many facilities use a combination of both, utilizing an outsourcing agency to compound medications needed in large quantities or to compound medications they do not have experience with compounding. Other facilities take on all compounding themselves.

What is the best approach? The following will discuss the pros and cons and the current market trends.

Let's start with facilities who take on all the compounding themselves. Many have lost trust in outsourcing pharmacies due to many reasons including the New England Compounding Center tragedies, FDA 483's and warning letters issued to these facilities and recalls issued for these facilities. Hospitals are at risk if they do not ensure the quality of their sterile compounded preparations given to patients and therefore often feel that if they do the job they can better ensure the quality.

Hospitals may be at risk

if they do not ensure the quality of their sterile compounded preparations.

Facilities that decide to perform all their own compounding must ensure they have enough compounding personnel to fulfill the demands.

The personnel must be well trained and show competence in compounding or patients will be placed at risk. These compounds are given beyond use dates which differ from expiration dates. An expiration date is given by a manufacturer. A beyond-use date is given by a compounder and takes into consideration the sterility once the medication has been compounded and the physical/chemical stability. The United States Pharmacopeia (USP) Chapter <797> places limits on beyond-use dates. If extended beyond use dates are wanted, there are more requirements that personnel will need to be competent in.

The facility must also ensure that they have enough space for the compounding to take place.

Many facilities have started looking into automation (or compounding robots) to assist in fulfilling their requirements. They may have a hard time filling compounding positions or have a high turnover rate which does not allow for expertise in compounding. Berkley Sykes, PharmD from Huntsville Hospital Health System, stated, "Our hospital made the decision to assume control over sterile compounding by bringing the process in-house through robotic automation for IV dose preparation. The primary motivations for this change are to establish control over the quality and quantity of products produced,

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improve operational efficiency, create cost savings and most importantly, ensure confidence in the safety of the products we provide to patients.”²

Hospitals need to evaluate the outsourcing facilities’ performance.

Visit [ASHP Guidelines](#) for assistance.

Now let’s address those who do outsource their sterile compounding. Those hospitals need to evaluate the outsourcing facilities performance to ensure the quality of products they receive for their patients. The American Society of Health-System Pharmacists ([ASHP Guidelines](#)³) offer recommendations on working with outsourcing facilities.

Many facilities go this route because they are concerned about the risk of compounding a medication they do not have experience compounding. They may not want to invest in the resources and/or create standard operating procedures for complex processes. The benefits of outsourcing may be that the outsourcer has expertise in compounding a medication your personnel does not have experience with. They also may have sterility/stability testing which enables for longer beyond use dates established which is not the case for most hospital pharmacies. This allows the outsourcer to extend beyond use dates and allows for storage outside of the refrigerator for some of these compounded medications, which is often helpful for hospitals with limited refrigerator space and assists with many hospital workflows, especially in the operating room.

A common misconception is that the outsourcer is more competent than the hospital to prepare medications which may or may not be the case. If you have not heard about the New England Compounding Center tragedies “google it” and you will understand the latter statement.

Costs are a driving factor that is taken into consideration. Facilities must determine if there are cost savings or not when utilizing an outsourcing facility versus compounding themselves. Sometimes it may be cheaper to utilize outsourcing facilities and sometimes it may not be. All the factors above must be taken into consideration.

We know compounding sterile preparations is not going away. According to the Global Market Insights, the increasing geriatric population across the globe coupled with rising prevalence of cardiovascular disease, diabetes, hypertension respiratory disorders will serve to be a high impact rendering factor for compounding pharmacies market.¹ The shortage of medications also has increased the demand for compounding. You can refer to our white paper “Lack of Continuity of Supply in the Injectables Market and It’s Impact on Hospitals” to learn more about shortages.

The Institute for Safe Medication Practices states in its Guidelines for Safe Preparation of Compounded Sterile Preparations, “To the maximum extent possible, commercially-prepared, premixed parenteral products and unit dose syringes are used versus manually compounded sterile products.”⁴ The increase in ready-

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to-use (RTU) products decreases the demand for compounding and ultimately facilities should be using these products whenever they are available. The main concern with these is the cost and supply. There cost may prohibit facilities from purchasing them. These may also go on backorder due to high demand which requires hospitals to have to carry a backup product and compounding procedures, which can be very frustrating to hospital pharmacies.

“Growing shortage of prescription drugs and rising prices of FDA approved drugs will escalate demand for compounded medication”¹

According to the Global Market Insights, the lack of skilled lab technicians and pharmacists, to prepare compounded medications in exact strength and dosage as per the patient’s requirement is a major industry restraint.¹ Moreover, the high cost of equipment required for compounding, maintenance of sterility and continuously changing regulatory guidelines will hamper the industry growth.¹ However, they also state the “U.S. dominated the global

market in 2017 (for compounding pharmacies market) and will witness robust growth over the forecast period.”¹ Several government initiatives to increase adoption of compounded medicine will fuel industry growth in U.S.¹ Growing shortage of prescription drugs and rising prices of FDA approved drugs will escalate demand for compounded medication.¹

If you decide to take on your own compounding, ensure your personnel has the proper resources, education and training to provide quality compounded preparations. If you are building new facilities for larger hospitals, consider space for future growth with robotics. If you decide to outsource ensure the facility preparing your sterile preparations is producing quality products. Utilize the ASHP Guidelines to help facilitate your process. Continue looking for more ready-to-use products and new dosage forms to provide quality medications to your patients.

1. Global Market Insights: Compounding Pharmacies Market to exceed USD 12.5 billion by 2024. <https://www.gminsights.com/pressrelease/compounding-pharmacies-market>
2. Maximize Production with IV Compounding Robots. Berkley Sykes, PharmD. May 2018 – Vol. 15 No. 5 – Page #26. <https://www.pppmag.com/article/2224>
3. ASHP Guidelines on Outsourcing Sterile Compounding Services. <https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/outsourcing-sterile-compounding-services.ashx?la=en&hash=9D2B4A0467990398AA70BFA0765A545FA7FE14B7>
4. Institute for Safe Medication Practices, ISMP Guidelines for Safe Preparation of Compounded Sterile Preparations, ISMP 2016. <https://www.ismp.org/sites/default/files/attachments/2017-11/Guidelines%20for%20Safe%20Preparation%20of%20Compounded%20Sterile%20Preperations%20revised%202016.pdf>