Outsourced Sterile Compounding:

A Strategic Decision for Advancing Patient Safety, Operational Efficiency and Sustainable Growth

Patients seeking a high-quality, cost effective alternative to inpatient hospital care are migrating to Ambulatory Surgery Centers (ASCs) for surgical procedures. As patient volume grows and the type and complexity of services provided continues to expand, it is increasingly important for ASCs to find more efficient ways to deliver high quality care at a sustainable cost. Partnering with PharMEDium, an FDA Registered 503B Outsourcing Facility, can help ASCs meet strategic quality, compliance and cost initiatives to achieve meaningful operational gains for long-term business success.

In-house compounding: Are you taking unnecessary risks?

When commercially available medicine is not clinically appropriate, compounding plays a critical role in treating patients with unique or specific needs.

In-house ASC staff often handles the daily responsibility of preparing compounded preparations required for scheduled procedures—otherwise known as in-house compounding or "mixing." Only immediate-use compounding is allowed in a surgery center following specific guidelines and infection control standards. These guidelines govern everything from who can prepare compounded sterile preparations (CSPs) and in what manner, to labeling requirements, to how soon CSPs must be administered.[1]

Compounding in-house may pose challenges because:

- Most sterile admixtures compounded in-house have shorter shelf life, leading to medication waste;[2]
- Staff resources must be allocated to mix CSPs rather than to hands-on patient care activities;[2] and
- Investments in sufficient infrastructure and training resources to meet USP Chapter <797> Standards and monitor aseptic technique can be cost-prohibitive.[2]

ASCs with a strategic imperative to improve service and quality care know the importance of getting drug preparation and administration right, every time, for every patient. As an FDA Registered 503B Outsourcing Facility, PharMEDium voluntarily registers with the FDA and welcomes increased oversight—including inspections on a risk-based schedule.

> **Outsourcing the preparation of CSPs to an FDA Registered 503B Outsourcing Facility may augment safety and quality initiatives within the ASC.**

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Not all compounders are created equal

Contracting with PharMEDium, an FDA Registered 503B Outsourcing Facility, provides your ASC with a trusted partner committed to quality, transparency and accountability.

FDA Registered 503B Outsourcing Facilities are held to more stringent standards. A compounding pharmacy may be an easy partner to find, but they may not adhere to the same current Good Manufacturing Practice (cGMP) regulations as an FDA Registered 503B Outsourcing Facility whose processes, facilities, pharmacy personnel and preparations undergo rigorous routine monitoring necessary to help ensure patient safety.

By volunteering for this level of scrutiny, PharMEDium demonstrates its dedication to quality and patient safety, commitment to applicable cGMPs, ethical conduct and proven performance.

503B partner benefits

Using PharMEDium, an FDA Registered 503B Outsourcing Facility, may help bolster safe and efficient medication management practices.

Streamlines operating room workflows

Ready to use CSPs can improve efficiency. By reducing the steps associated with the perioperative medication preparation process, clinicians can focus more time on essential patient care activities.[3]

Mitigates compliance risk

503B compounded sterile preparations including prefilled syringes can lessen regulatory exposure by reducing the need to rely on staff compliance with applicable aseptic technique[4] and certain labeling requirements.[5]

Optimizes patient safety

Adopting pre-labeled, ready to use CSPs from an FDA Registered 503B Outsourcing Facility like PharMEDium supports patient safety by helping to reduce drug related errors (incorrect dilution, vial / ampule misidentification, syringe swap) associated with labeling and preparation.[6]

Reduces waste

Providing drugs in commonly used single dosage forms with extended dating in conjunction with tamper evidence can reduce overall drug waste by 61 percent.[7]

Improves the bottom line

By helping to improve efficiency, compliance and safety while reducing waste, ready to use medications can have a direct, positive impact on cost-reduction/containment initiatives.[7]

Discover the difference by partnering with PharMEDium, a leading FDA Registered 503B Outsourcing Facility.

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3. Chernin E. Medication safety in the operating room – what's different? Presentation presented at American Society of Health-System Pharmacists Summer Meeting and Exhibition. Seattle, WA; 2008 June.
4. Centers for Disease Control and Prevention: Safe injection practices to prevent transmission of infections to patients (April 2011). http://www.cdc.gov/injectionsafety/IP07_standardPrecaution.html (accessed 2016 May 25).
5. The Joint Commission. Standards FAQ Details. Punctured or Opened New Expiration Date. https://www.jointcommission.org/standards_information/jcfaqdetails.aspx?StandardsFaqId=1080&ProgramId=46 (accessed 2016 July 7).
6. Abeysekera A, Bergman IJ, Kluger MT, Short TG. Drug error in anaesthesia practice: a review of 896 reports from the Australian Incident Monitoring Study Database. *Anaesthesia*. 2005; 60:220-27.
7. Kellner A, Fortier CR, Weber J, Guidry OF. Outsourced pre-filled syringe system conversion: an assessment of OR IV waste reduction and anesthesia clinician satisfaction. Poster presented at American Society of Health-System Pharmacists Midyear Clinical Meeting. Anaheim, CA; 2010 December.

Get to know PharMEDium.

For more information on how PharMEDium services could benefit your ASC, visit **PharMEDium.com** or call **1.800.523.7749**.

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