

Hospital Pharmacy Automation: Drug Storage and Retrieval

The technical information regarding USP Chapter (797) and the performance of the Swisslog device contained in this document has been reviewed by Eric Kastango and Jim Wagner based on their expertise and professional field observations.

**Eric Kastango, MBA, RPh,
FASHP**

President and CEO
Clinical IQ, LLC

James Wagner

President
Controlled Environment
Consulting

August 2011



Introduction

In recent years, health-system pharmacies have been developing strategies to comply with U.S. Pharmacopeia (USP) Chapter (797), a set of standards for sterile pharmacy compounding which became official on January 1, 2004 (and was revised in June 2008). This chapter is considered to be the United States' standard of practice for sterile compounding by the Centers for Medicare and Medicaid Services, state departments of health, and many state boards of pharmacy.

The intent of the chapter is to prevent patient harm and fatality from microbial and endotoxin contamination, medication errors in the strength of correct ingredients, and incorrect ingredients in compounded sterile preparations (CSPs). It also is harmonized with the NIOSH Alert to prevent occupational exposure to hazardous drugs.

The challenge of compliance is felt across many health-system organizations as the teams assigned to implement the chapter's requirements must address not only the many operational, organizational and procedural requirements, but also architectural, environmental and facility standards. Detailed information on the specific requirements of USP Chapter (797) can be found at www.usp.org.

The intelligent use of automation can assist pharmacy staff in meeting the requirements of USP Chapter (797), optimize workflow and material handling, and improve staff safety and efficiency. This paper will focus on the physical requirements within the hospital pharmacy, paying particular attention to the use of automation in the clean room design. Integration of automation into a pharmacy clean room design achieves greater efficiency, security and safety in the handling and storage of medications and products used for sterile compounding.



Facility Design Requirements for USP (797) Compliance

USP (797) requires that a vast majority of sterile compounding activities be performed in a controlled environment that is separated from other activities of the pharmacy. The facility requirements for these controlled environments are dictated by the inherent risk of contamination (low, medium, or high as defined by the chapter) of the CSP and correspond to ISO (International Organization for Standards) clean room classifications. ISO classified spaces commonly used for compounding range from ISO Class 5 through ISO Class 8.

The following should be considered when creating an environment to comply with the USP design requirements: workflow processes in the pharmacy environment (e.g. aseptic technique and movement in the clean room), engineering controls required when compounding hazardous and non-hazardous drugs, primary and secondary engineering controls selection and installation, and certification procedures required to verify the design.



Automation: Overcoming Challenges to Efficiency, Safety and Security

In addition to facility requirements necessary to reduce the risk of CSP contamination, hospital-based pharmacies must include provisions for staff workflow, material control, and security. Towards this end, it is common for facility planners to encompass specialized equipment (medical and non-medical) into the floor plan and lay-out of various technical work areas.

Hospitals that incorporate ISO Class 5 primary engineering controls (e.g., laminar airflow work stations) for compounding sterile preparations within ISO Class 7 buffer areas typically have storage shelves with casters for easy removal for cleaning. As such, these storage shelves must be constantly re-stocked from the pharmacy's central inventory supply. Having supplies and medications readily available and accessible for use (without having to de-garb and re-garb to retrieve additional supplies) improves operational efficiencies and improves ongoing employee compliance with required garbing practices.

BoxPicker—Ideal Storage/Retrieval Solution for Clean Room Applications

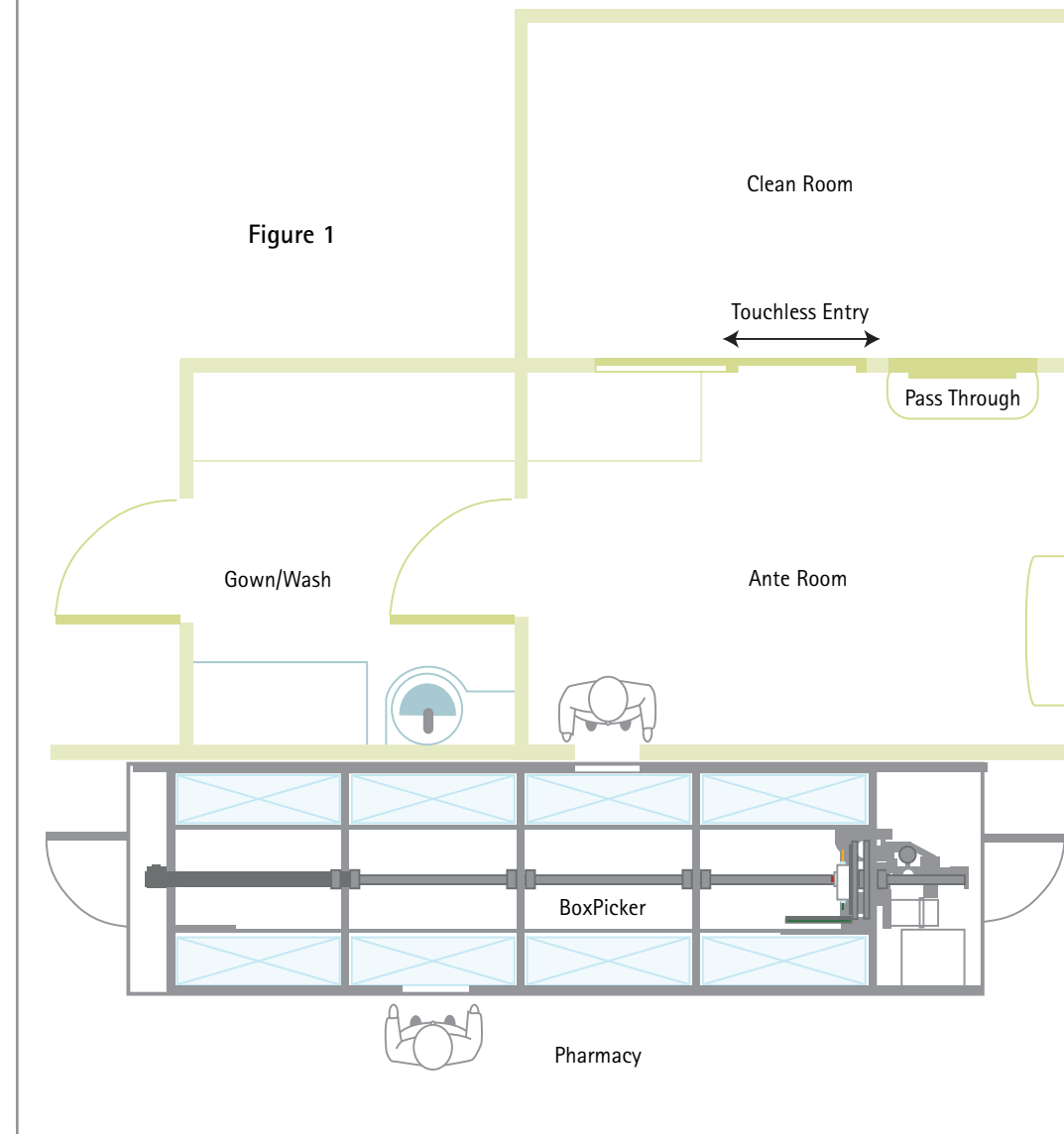
An ideal cleanroom storage solution is to incorporate an automated storage and retrieval system that serves the main pharmacy operation as its primary storage and bulk medication warehouse, while at the same time providing secure access to all supplies and medications needed within the sterile compounding suite. Such a solution is available through Swisslog, a global manufacturer and provider of advanced pharmacy automation systems.

The company manufactures an automated high-density storage and retrieval system for controlled and verified dispensing of medications and supplies. Swisslog's BoxPicker unit is recessed into the pharmacy's ante room (see figure 1), providing personnel working within the cleanroom access to medications and supplies through secure access drawers which automatically open when specific items are requested through the system. As such, the system is completely enclosed and flush with the ante room wall to ensure proper ISO compliance. The normal over-pressurization of the ante room relative to the surrounding support areas prevents transfer of particulate contamination into the cleanroom space.

When the operator fills a bin with medications or supplies, the BoxPicker automatically stores it on shelving inside a secure enclosure. All transactions begin and end through a locked drawer. Information on the contents of each bin is entered at a workstation using a keyboard or a barcode scanner. A drawer is unlocked presenting the user with a bin for the new item storage. When the drawer is closed, the bin is moved to a location for storage until the item is requested. Retrieval is the same process in reverse. The user accesses the computer workstation, enters the requested item via keyboard, and a drawer opens with the correct item inside for access.

The BoxPicker design has a major impact on cleanroom staff efficiency by enabling the retrieval of all types of supplies and medications without having to leave the ante room or having to de-gown. Workstations can be installed on the ante room side for access only by those inside the ante room while the other side is accessible to an open corridor or central pharmacy (see figure 1).

BoxPicker is available with a refrigeration option for the storage and retrieval of temperature-sensitive medications and supplies.



All transactions begin and end through a locked drawer.

The BoxPicker system is superior to conventional shelving because the product is identified and verified electronically, providing inventory tracking, access and replenishment. It also provides for greater safety and security because, not only is the product tracked electronically, it is released by the system one bin (or one type of item) at a time. Single-drawer dispensing is ideal for containment of controlled substances and other medications or supplies that require secure storage. Due to its secure-access feature, the system is also ideal for providing 24-hour on-demand retrieval.

The system performs the same functions as a vertical carousel but its picking speed is three times faster, greatly enhancing hourly throughput and production. Instead of providing users rotating rows of medication bins driven by a chain and wheel, typical of vertical carousels, the BoxPicker operates by an automated storage and retrieval robot with a mechanism that stores and retrieves individual bins in specific internal rack locations. Another improvement over a carousel equipment approach is the BoxPicker's expandability. The system's standard design consists of three storage

modules each capable of storing 240 bins. Just as hospital pharmacy layouts vary, this automated system can be expanded to meet the unique storage and retrieval demands of each specific hospital through customized configuration. Its high-density design enables 687 bins to be stored in less than 75 square feet.



One Solution for the Entire Pharmacy

In summary, the BoxPicker system addresses and solves many of the storage and retrieval challenges for hospitals working to achieve and maintain compliance with the operational and facility design requirements of USP (797). In a properly designed and certified sterile compounding facility, the BoxPicker has a positive impact on the environmental state of control while providing access to a wide variety of supplies and medications. Because of its single-loading/

unloading bins and electronic tracking capability, the system assures greater security, safety and efficiency. Its dual workstation design enables greater productivity for the central pharmacy as well. This type of solution is unique in the marketplace, but its versatility and its focus on patient safety make it worthy of review for any hospital addressing the facility design requirements of USP Chapter (797).

For more information, visit the Automated Drug Management Systems page at the Swisslog website, or call 1.800.764.0300.