



PROJECT TALK

DESIGN INNOVATIONS AND MODULAR CASEWORK NEWS FROM R.C. SMITH COMPANY



USP-797: ARE YOU READY?

Is Your Pharmacy in Compliance with the New USP General Chapter <797> Pertaining to the Compounding of Sterile Preparations?

U.S. Pharmacopeia (USP), ASHP, the State Boards of Pharmacy, JCAHO and the FDA are all working together to forever change the standards by which your pharmacy compounds sterile preparations.

On January 1st of 2004, USP published the guide by which your pharmacies sterile compounding program will be evaluated and potentially regulated by...the USP General Chapter <797> Pharmaceutical Compounding-Sterile Preparations. **Continued Inside**

"It is vital that a proper physical layout of the sterile preparation area is achieved and that proper equipment is utilized, maintained and monitored."

PRODUCT SHOWCASE

Radiused Corners

Traditional 90 degree corners are less than ideal for space utilization and ergonomics. R.C. Smith has a solution for the poor performance of 90 degree corners...radius them!

Especially useful in picking stations and order review areas, radiused corners encourage better space utilization and they support healthier ergonomics with more user friendly access to the product being stored and functions being performed.



Unit Dose Picking



Order Entry/Review

Pass-Thru Solution Storage

The R.C. Smith solution storage pass thru module helps manage a sterile environment while enhancing workflow and efficiency.

The integrated air block shutter allows for easy and unhindered access to the loading side of the module (also available with doors). The design of the solution storage pass thru module naturally promotes a First In-First Out inventory system (FIFO) and the wire racking has gravity fed shelving that is adjustable in height, dividable and is easy to keep sterilized.

The module is also available as a pass thru cart, rather than the rack.



Loading Side



Ante-Area Side

USP-797 Continued from front page

In the April 2004 issue of JCAHO's Perspectives newsletter, JCAHO announced that they would begin monitoring for compliance with USP-797. R.C. Smith recently polled the various State Boards of Pharmacy and found that most are currently reviewing USP-797 and will announce their stance on their adop-

tion of it in the near future. Rumor on the street is that the FDA is seriously looking at regulating the compliance of USP-797. Although the final stance and magnitude of enforcement by all agencies mentioned is yet to be seen, one thing is certain: USP-797 is real and needs to be addressed and complied with!

The underlying objective of USP-797 is a very honorable one that reads "to prevent harm and fatality to patients that could result from microbial contamination (nonsterility), excessive bacterial endotoxins, large content errors in the strength of correct ingredients, and incorrect ingredients in compounded sterile products (CSP's)." The USP-797 document provides a foundation for procedures and practices required to best promote the safe preparation of CSP's in three risk levels, classified according to the potential for microbial, chemical and physical contamination.

To be in compliance with USP-797, it is vital that a proper physical layout of the sterile preparation area is achieved and that proper equipment is utilized, maintained and monitored. The physical layout must address such factors as the proper placement and adjacency of hoods, a buffer area, an ante area, location of stock, refrigerators/freezers, the gowning and personnel cleansing location, the transfer of products and other related functions. In addition, proper construction materials and techniques must be utilized along with an air flow layout that reduces particulates to the classification level required for the assigned risk level. An important goal should be to achieve compliance while at the same time improving on functionality, ergonomics and work flow.

The first step to developing a compliant and functional sterile preparation layout is to acquire a copy of the USP-797 document and perform a self evaluation to determine which risk level your facility will fall into (R.C. Smith has copies available for \$25 plus a \$5 postage and processing fee).

To assist pharmacies with the development of a proper physical layout, R.C. Smith Company has a design team that can provide layout options that comply with USP-797 while providing for optimal functionality, workflow and ergonomics.



Buffer Area with Barrier Isolation Technology



Ante Area with Pass-Thru Solution Storage

You may purchase a copy of USP-797 from R.C. Smith for \$25 plus a \$5 postage and processing fee. See the order form in this issue of Rx ProjectTalk.