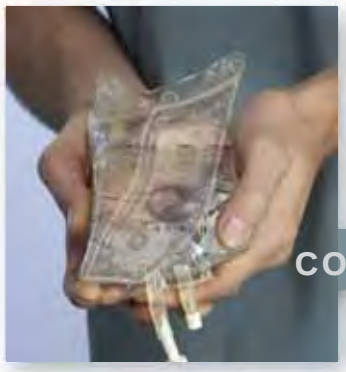

Effective Strategies for

MANY HOSPITAL AND ALTERNATE SITE PHARMACIES ARE MAKING SWEEPING changes to comply with the requirements of USP Chapter <797>. Even without a physical plant that meets the requirements of USP <797>, many worthwhile processes can be changed or put in place to reduce the risk of contamination to compounded sterile preparations (CSPs), thereby improving patient safety. Some of these practices include personnel hand-washing and garbing guidelines, cleaning and sanitization procedures, and an environmental monitoring program. There is no valid rationale for waiting, and it may be more important to implement these elements immediately, especially in inferior physical plants. In pharmacy compounding complexes that are not engineered to reduce particles through appropriate secondary engineering controls, proper materials handling, personnel garbing, routine cleaning, and environmental monitoring are the only mechanisms that the pharmacy can implement immediately to reduce the risk of contamination.

Eventually, however, for many organizations, physical plant improvements are required and must be made. Once the pharmacy determines the best course of action, successfully communicating this complicated and high-dollar request to individuals with approval authority may be difficult and time-consuming. This article will briefly review the factors influencing pharmacy design and detail suggested elements of a white paper, based on one that has been used to successfully obtain approval for major expenditures, such as pharmacy compounding complexes.

Insurers may **increase** premiums or **decline** future coverage to pharmacies that cannot demonstrate compliance with <797>.

Getting Started

Ideally, a gap analysis has been performed and you understand clearly how your pharmacy's practices and physical plant do not conform to <797>'s minimum requirements. Based on the outcome of the gap analysis, an action plan can be developed identifying policies, procedures, forms, training, and physical plant changes you wish to implement. I recommend developing a CSP risk-level matrix as part of a gap analysis. A historical review of the CSPs made at your pharmacy and a forward-looking assessment of probable future needs (based on new hospital programs or patient populations that will be serviced) is essential to creating a valid and meaningful risk-level matrix. With that it in hand, it is possible to make changes in that matrix by evaluating the use of alternative components, compounding methodologies, workload shifts (from unit to pharmacy or pharmacy to satellite), and opportunities to outsource high-risk or high-volume CSPs. Other factors that may influence the design of your compounding physical plant include:

- Total volume of CSPs prepared daily and weekly
- Types of CSPs prepared
- Staffing patterns
- Dose-recycling programs
- Current physical plant
- Other planned remodeling at your facility
- Upcoming pharmacy initiatives like pharmaceutical care clinical programs, robotic distribution, and/or bar coding implementation

Photo courtesy of Lasco Services

- Existence of satellite pharmacies on patient care units or specialty practices
- Current organizational practices
- Materials-management issues, such as preferred vendors and products
- Clinical issues in medication management
- Business environment issues, such as potential mergers or acquisitions

Once the final risk-level matrix is completed, a facility design criteria document (see example in Figure 1) can be developed. This document details your specific requirements and should be provided to all potential cleanroom vendors. Vendors should be asked to acknowledge in writing that their proposal will result in the achievement of the stated functional criteria. The document should also be used to drive initial discussions, as well as final design and engineering meetings.

Using a White Paper to Drive Budget Approvals

Assuming you have completed the steps above and have identified the final vendor or vendors, the challenge is to communicate this information effectively up the ranks to those who grant approval for such expenditures at your organization. You know what you need, and now it is time to put on your business/finance hat to communicate this information in a manner that is most likely to be well received. Writing a white paper can help you achieve that objective.

During the planning phase and while writing the white paper, it is helpful to think carefully about all of the possible internal stakeholders. Who is in a position to directly approve (or not approve) the expenditure? Who is in a position to influence the decision-makers? Have you included those who are in a position to exert influence in the process? If not, how can you market the value of the proposed cleanroom? It is important to identify all possible detractors, as well as those who – if given the right information – might be inclined to support the cleanroom build and positively influence decision-makers.

The development of a structured white paper serves to:

- Convince the readers to care about the proposal by educating them about the factors driving the request.
- Help the readers understand the request by communicating the details.
- Cut detractors off "at the pass" by illustrating a comprehensive approach to

Cleanroom Budget Approval

By Kate Douglass

the evaluation of need and identifying all alternatives considered. Carefully assess alternatives and communicate them in the proposal; don't wait to be second-guessed.

- Demonstrate the business acumen of the pharmacy department. (Be smart; know what the finance and executive departments want to know and communicate it in terms they are familiar with.)

> A comprehensive white paper will substntially **improve your odds** for — and reduce your time to — approval.

Tips for Writing Your White Paper

The white paper template available at **www.pppmag.com/articles.php** can serve as a guide to cover all of the essential topics and facts needed to properly evaluate any request for funds. A comprehensive white paper will substantially improve your odds for – and reduce your time to – approval. It is important to consider your audience. Identify everyone who will be reading the white paper and write it in terms they can understand. Using the language of your reader – in this case, finance – is key to increasing the reader's receptivity to the document. Do not assume that readers inherently understand pharmacy regulatory and practice considerations. Explain these issues in clear terms. Keep in mind a white paper should not be longer than five to 10 pages, and preferably less. Using bullets and tables is helpful; avoid large expanses of narrative that frequently will not be read.

The white paper must include the forces driving the rationale for change. This background information should explain both general relevant drivers, as well as those specific to your institution. Rationale should include the following:

- Relevant regulatory requirements
- Applicable accreditation standards
- Patient safety issues
- Risk management benefits
- Strategic and tactical considerations that will quantify other potential benefits to your organization

The USP <797> Guidebook to the Proposed Revisions to Pharmaceutical Compounding – Sterile Preparations provides an excellent discussion about the enforceability and recognition of <797> and specifically addresses the FDA, JCAHO, NABP (National Association of Boards of Pharmacy), PCAB (Pharmacy Compounding Accreditation Board), and state laws, as well as a discussion of non-pharmacy organizations referencing <797> in their practice standards. This document can help you to prepare your bullet points referencing regulatory and accreditation rationale.

Patient-safety and risk-management issues must relate to your organization. Liability insurance is a large expense in most hospitals and pharmacy operations. Insurance underwriters have commonly expressed concern over pharmacy compounding, especially sterile compounding, and premiums are increasing. Insurers may increase premiums or decline future coverage to pharmacies that cannot demonstrate compliance with <797>. There is little question that non-compliance and failure to meet the acknowledged standards of practice puts hospitals at risk, based on their diminished ability to successfully defend themselves in the event of litigation.

Discuss how the proposed physical plant will impact both your business and operational requirements. Any negative impact must be outweighed by a positive impact, but be sure to mention both. List the operational benefits of the new cleanroom. For example, will the cleanroom improve efficiency and allow for greater throughput or capacity at your hospital? If so, might that be valuable? Are there any strategic or tactical considerations specific to your hospital or organization? If your pharmacy is in a fiercely competitive marketplace, might a cleanroom that complies with <797> offer a strategic marketing opportunity or competitive advantage? Is your hospital expanding or opening new programs to specific patient or disease

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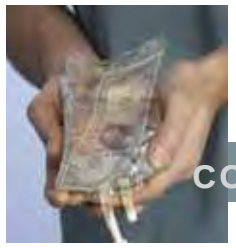
populations? Will this improve the pharmacy's image with key internal stakeholders such as physicians, nurses, or dietitians? Do any of those groups or others within your organization, such as marketing or product development, have focused initiatives with which a <797>-compliant pharmacy might dovetail?

The Inclusion of Purchasing Details

The second section of the white paper should communicate pertinent purchasing details. This information is best presented in a table format, that is easy to read and understand. It must include information on all vendors considered, with more detailed information on which vendor has been selected and why. It is particularly

Visit www.pppmag.com/articles.php to download the following resources:

- A white paper template
- A complete facility design criteria document
- Kate Douglass' article, "Design your Cleanroom for Easier Use, Cleaning & Maintenance":
  - Part 1 in Vol. 3 No.2
  - Part 2 in Vol. 3 No. 3



pertinent to discuss all reasonable alternatives considered and proactively discuss why each alternative was ruled out. For instance, you may have considered using barrier isolators in place of building a cleanroom, but ruled them out due to the inherent challenges and potential increased risk of contamination to CSPs when using barrier isolators in a non-ISO class space. Be sure to explain your choices clearly and in terms laypeople can understand.

A discussion of negotiated discounts is important to include. The white paper should also include any cost-savings decisions or trade-offs you made during the development process. Keep track of the many decisions you will make throughout the planning process and their attendant cost, so they may be later included in the discussion. Present the proposed solution based on both the percentage of negotiated savings and actual dollar savings, from the initial discussion through the final discussion. Demonstrate pharmacy's sensitivity to organizational cash flow by negotiating a reasonable payment schedule. Payment schedules should properly compensate the vendor, while preserving the organization's control over the vendor, with payments made at logical and critical points in the build process. The final payment should never be due until the cleanroom has been successfully certified by a qualified, independent cleanroom certifier, and results must achieve the specifications detailed in your facility design criteria document.

Securing organizational support for a cleanroom project requires understanding and communication of engineering, finance, marketing, operations, risk management, and other aspects beyond pharmacy practice. By using a white-paper approach familiar to business executives and the finance community, the likelihood of project approval is increased. This approach also tends to decrease the delays that often accompany proposal review, because all of the pertinent information required to evaluate the proposal's accuracy is included. Finally, cultivate relationships with your colleagues in the finance department and discuss your proposed approach with them before you submit the proposal. By following these recommendations, you can ensure that your path to <797> compliance is a relatively quick and expedient one. ■

Photo courtesy of Lasco Services

Kate Douglass is the president of Performance Strategies, LLC, a consulting company assisting the pharmacy, nursing, and health care markets. Kate served as a reviewer for ASHP's Sterile Product CD-ROM: A Multimedia Learning Tool, 1st and 2nd editions, *and has authored several articles on aseptic compounding quality and outsourcing. During her tenure as COO of SoluNet LLC, Douglass personally supervised the design, engineering, and builds of four pharmacy compounding complexes that meet or exceed USP <797> requirements.*

Figure 1: Facility Design Criteria Document CLEAN ROOM: *ISO CLASS 7*

Item Detail	Required Design Specifications
Ceilings	Cleanroom ceiling tile RTV to anodized aluminum T-Bar grid; perimeter of all ceiling tiles must be caulked with silicone caulk.
Floors	Seamless vinyl sheet with minimum 4" cove to the wall; flat molding on top sealed with silicone caulk; no floor drains permitted.
Walls	Fiberglass Reinforced Plastic or PVC Laminate Panel
Doors	Gasketed Anodized Aluminum door and frame; full-length windows preferred
Light Fixtures	Standard construction recessed cleanroom fixture; Room-Temperature Vulcanizing (RTV) silicone sealed to anodized aluminum T-bar ceiling grid; acrylic lens with baked enamel finish; must change bulbs within cleanroom; discuss emergency lighting.
Windows	Tempered safety glass; free of sills; frames of stainless steel or anodized aluminum
Air Changes	60 air changes per hour if integrated clean room benches; 15 ACPH if using discrete primary engineering controls such as LAFHs which will make contribute to overall air exchanges attaining at least 30 ACPH.
Air Pressure	Cleanroom must be +0.02" Water Column to adjacent work spaces.
Air Filtration	99.99% HEPA filter Type C or J per IEST RP CC 001.4 that has been both efficiency and leak tested.
Particulate Control	ISO Class 7 at 0.5 Ìm particles under dynamic operating conditions per ISO 14644-1
Temperature	64°F +/- 4°F
Relative Humidity	35 - 60%*

*The relative humidity will be controlled within the limits of the humidification equipment/controls of the HVAC System. Cooling of the make-up air will act as the primary means of dehumidification, however an integrated dehumidification unit must be considered to assure RH < 61% during times of maximum humidity.