Tips for Designing a New Cleanroom

Many pharmacy practitioners have refocused their attention upon in-house sterile compounding as a critical segment of their medication management operations due to the challenges posed by multiple drug shortages, a growing demand for operational efficiencies, cost avoidance strategies, and an increased emphasis on risk mitigation strategies in the wake of the outsourced compounding tragedies that struck late last year. As part of this renewed focus, organizations are considering a capital investment in upgrading, expanding, or modernizing existing compounding capabilities or the construction of entirely new cleanrooms.

The design and construction of a modern, regulatory-compliant, and efficient cleanroom requires the thorough consideration of numerous elements, including budget, administration support, design and construction options, the use of consultants and vendors, as well as regulatory requirements.

Develop a Sound Proposal
Before undertaking a cleanroom design project of any size, there are several key elements that should be thoroughly explored, and thoughtfully vetted, so that a well-developed project plan may be put forth:

- Develop an accurate and realistic budget
- Address all applicable regulatory requirements and suggestions [see TABLE 1]
- Determine what organizational resources are available to the pharmacy to assist in a construction project of this type
- Determine the organization’s primary goals and priorities for the project
- Other than budget, anticipate and plan for possible project limitations

In addition, a proper project plan most likely will require the development of a white paper or other authoritative guide that details the rationale for the physical plant changes or upgrades to your facility. Historically, and for the large part inaccurately, hospital pharmacy departments are viewed as cost centers rather than as revenue generators, thus it is important to carefully consider the method and tone of any budgetary requests. Be sure to include special emphasis on a realistic ROI, as well as projected benefits to patient safety and workflow efficiency. Since the usable life cycle of most properly planned for and constructed cleanrooms may be measured in decades, the administration approving this project will likely need to parallel the pharmacy’s specific needs could ease the approval process significantly.

When initially compiling a wish list for an ideal cleanroom be sure to realistically prioritize any firm elements deemed essential. Examples of such elements include spatial footprint constraints, distances to shipping and receiving facilities, and other site-specific anomalies or constraints that must be addressed to ensure the overall success and compliance of the project.

Making Technical Decisions
Once a broad project plan has been developed (and an associated, supportive whitepaper has been written) the next steps must address the technical components of the cleanroom. As most pharmacists have little or no experience with cleanroom design and construction, assembling a broad-based, qualified design team to assist in the creation of a site-specific cleanroom design criteria is highly recommended. First look within your facility or organization for appropriate content experts including facility engineers/architects, HVAC technicians, environmental services staff, risk managers, IT staff, etc. If there are gaps in expertise or your facility does not have such staff members, the team may consider bringing in outside consultants with the necessary experience and technical knowledge in cleanroom design and construction.

The resulting design criteria document should provide guidance for both the physical and environmental design of the cleanroom intended for the production of compounded sterile preparations (CSPs) for your facility. Technical roadmaps for new or updated cleanrooms may be measured in terms of the years, the administration approving this project may not have any historical frame of reference to grant approval, furthering the role of a comprehensive project plan.

Presenting the Case to Administration
A key portion of the project presentation must come from a well-researched regulatory review of your state’s pharmacy practice act. Most state practice acts have clear spatial minimums as well as other important design cues that must be incorporated into the project plan to ensure the successful approval by the state board of pharmacy.

The long-range strategic plan of the organization also should be investigated for any initiatives that would increase the volume or type of compounding, or introduce other requirements not being met by your current cleanroom. An open dialogue with organizational leadership regarding any expansion or new strategic partnerships or practice acquisitions could avoid an embarrassing underestimation of your proposed project. Likewise, alignment with global organizational strategies that parallel the pharmacy’s specific needs could ease the approval process significantly.

Regulatory Influence and Guidance
There are several overlapping regulatory bodies whose mandates will influence the design of a new or updated cleanroom. It is important to review these organizations’ regulations when beginning a project of this scale.

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<tr>
<th>Organization</th>
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<tr>
<td>USP &lt;797&gt;</td>
<td><a href="http://www.usp.org">www.usp.org</a></td>
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<td>Occupational Safety and Health Administration (OSHA)</td>
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<tr>
<td>The National Institute for Occupational Safety and Health (NIOSH)</td>
<td><a href="http://www.cdc.gov/niosh">www.cdc.gov/niosh</a></td>
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<tr>
<td>Controlled Environmental Testing Association (CETA)</td>
<td><a href="http://www.CETAinternational.org">www.CETAinternational.org</a> [Review CAG-002—2006]</td>
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<tr>
<td>Your State’s Pharmacy Practice Act</td>
<td>Check your state government’s website for more information</td>
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<tr>
<td>Americans with Disabilities Act (ADA)</td>
<td><a href="http://www.ada.gov">www.ada.gov</a></td>
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TABLE 1

Regulatory Influence and Guidance

Related Articles & Resources

By Lou Diorio, RPh, and David L. Thomas, RPh, MBA

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should be integral to the acceptance criteria for any vendor bids and subsequent contracted work. 2

Assembling a Cleanroom Design Team

Recruiting a highly effective and qualified team of professionals to assist in a new cleanroom project can be challenging, as every project presents its own complexities and each organization or facility contains varying in-house resources. A solid starting point is to seek out the administration’s capital or development committee. Guidance from the capital committee or similar groups within the organization’s leadership structure will put the pharmacy in tune with all possible resources available within the organization. The committee may wish to directly or indirectly participate in the project’s initial development and may even have development funds already approved to begin the discovery process. Furthermore, moving beyond cursory fact-finding must be done carefully. Individual contractors, architects, and other service vendors should be carefully vetted in a formalized process that must include both a structured request for proposal (RFP) document and your cleanroom design criteria document. Previous experience and solid past customer references must be weighed in order to identify competent providers.

When seeking to augment an internal design team, you may consider integrating a vendor of cleanroom components as a way to spread out some of the design costs or consulting fees deeper into the project. This approach must be carefully weighed, as it can limit the organization’s options. The alternate approach of adding a qualified cleanroom consultant to the team may offer your organization an independent resource in the design, build, and post-implementation phases of your project. The outside perspective and experience brought to the team by the right cleanroom consultant may prove invaluable in the bidding process (and analysis of bids) as the project rolls out. Some consultants offer capituated service plans so that their involvement can be integrated into the budget early and accurately.

Choosing Modular or Stick-built Construction

While developing design criteria that will serve as a technical roadmap, careful consideration should be given to basic design and construction questions:

- Is the physical plant, staff makeup, and projected workload best suited for prefabricated (modular) construction or is traditional drywall (epoxy coated gypsum) sufficient for your operation? What are the projected usable lives of each type of construction?
- Can any current mechanical systems (air handlers, HVAC systems, etc) within your facility be repurposed to help lower project costs?
- Should construction be done by your employees or should installation/construction be part of a bundled pricing proposal?

Answering the latter questions should lead to the answer of the first question—modular or gypsum board construction. In general, simply using the apparent cost of modular components versus the projected cost of stick-built (constructed on-site as opposed to a factory or other location) cleanroom may be deceiving, and may lead an organization down the path of more traditional gypsum board construction, without a thorough investigation of both configurations. A generally higher initial investment in modern, modular construction may reap financial benefit beyond the initial installation. Consider the benefits of a reduction in on-site construction times and installation costs, more efficient mechanical systems built into modular components (such as energy savings and possible tax breaks), as well as the ability to clean the area quickly and efficiently. The cleaning labor components are an ongoing expense for any organization.

Matching Design with Workflow Needs

Armed with basic design criteria, a solid idea of organizational direction and preliminary budgetary approval from administration, and a detailed review of the projected cleanroom’s size and floorplan layout, the next step is to analyze the workflow that those variables dictate. For example, the size of a cleanroom complex should be based in part on the personnel load (number of compounding staff) the room must accommodate on a daily basis. Overstaffing an inadequately sized room can quickly overwhelm the environmental controls and create a dangerous breeding ground for microbial contamination. This philosophy must be considered all the way through certification of the cleanroom complex to assure that the containing environment can be controlled under the most stressful (personnel-loaded) conditions.

Furthermore, when developing the cleanroom design several key items should be worked into the plan. First, entry points for staff compounders and the products they use should be segregated. The anteroom of a cleanroom complex should be used for personnel gowning and hand hygiene only. Drug products, diluents, and other compounding supplies should be transferred into the cleanroom using another strategically located access point such as a pass-through window or cabinet.

Secondly, it is important to avoid workflow patterns that retrace steps. Overlapping workflows in the compounding room create inefficiencies and increase the risk of mix-ups and cross-contamination. Careful consideration of the placement of compounding, checking, and labeling areas must be made to avoid these points of confusion when designing the cleanroom.

Finally, due to the high costs of construction and materials, it is not realistic nor desirable to make any changes once the construction is in progress. Therefore, a clear and approved concept of design is paramount before any construction begins. Within USP <797> there are basic design directions that can assist in the preliminary development of your design. It should be noted that the general chapter also highlights the guidance of the Controlled Environmental Testing Association (CETA) to assist in confirming the correct performance of your cleanroom.

Conclusion

Design and construction of a modern, regulatory compliant, and efficient cleanroom requires the careful consideration of myriad factors. While recruiting for and assembling a skilled and experienced project planning team to analyze these factors can seem more difficult than the construction of the cleanroom itself, nevertheless, it will greatly improve the long-term success of the project. Enlisting the help of available resources to aid you in this task is half the battle, and gaining an understanding of local, state, and federal regulations will save frustration and re-work down the line. Ultimately, the goal is to provide safe and effective CSPs for your patients within the confines of operational and fiscal policies, procedures, and mandates. Regardless of the type of cleanroom you choose to fit within those confines, creating a detailed action plan from the onset will provide the most direct path to that goal.

References


Lou Diorio, RPh, is a principal of LDT Health Solutions, Inc, a quality management consulting company. He is a graduate of Long Island University’s Schwartz College of Pharmacy and can be reached at LSDiorio@LDTRx.com.

David L. Thomas, RPh, MBA, is a principal of LDT Health Solutions, Inc. He is a graduate of St Louis College of Pharmacy and can be reached at DThomas@LDTRx.com.