



Anticipating Potential Challenges when Building a Clean Room

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Disclosures

The program chair and presenters for this continuing education activity have reported no relevant financial relationships.



Working with the contractor and designer

- ❖ Who is responsible for the management of the project?
- ❖ Is this completely new construction?
- ❖ Is this a new facility?
- ❖ Is this a renovation of a current facility?
- ❖ Have you decided on type of construction?
 - Modular
 - Hard wall
- ❖ Is there any additional construction included in the project?
 - Is the entire pharmacy being renovated?
 - Are other services or facilities being added?



Who is responsible for accurate clean room construction?

- A Pharmacist/pharmacy manager
- B Contractor
- C Clean room designer
- D All of the above



Working with the contractor and designer

- ❖ Contracts
- ❖ Permits
- ❖ Timetables
- ❖ Designers
- ❖ Consultants
- ❖ Use of a temporary facility
- ❖ Being on site vs managing from "afar"



Regulatory issues and design

- ❖ USP <797> current
- ❖ USP <797> proposed revision
- ❖ USP <800>
- ❖ Accreditation
- ❖ Licensure
 - Resident
 - Non-resident



Issues with equipment and certification

- ❖ HVAC requirements
 - What if you can't get your temperature in range?
- ❖ Hoods
- ❖ Carts
- ❖ Storage
- ❖ Sink



Issues with equipment and certification

- ❖ Floors
 - Correct finish
 - Ante room demarcation
- ❖ Walls
- ❖ Doors
 - What is non-porous?
 - How big do the doors need to be to get your equipment into the room?



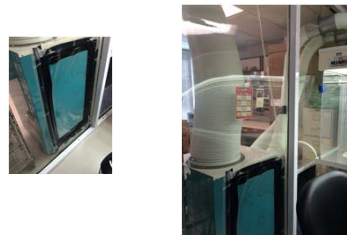
Sample issues

- ❖ Certifier is scheduled and construction is not done
- ❖ The city manager does not approve the plans and the permit has been delayed until the drawings are redone
- ❖ The HVAC installers do not show up to balance the air in the clean room complex
- ❖ The flooring you chose is now on backorder
- ❖ The special order ceiling tiles arrive and 90% of them are damaged
- ❖ The certifier is scheduled for tomorrow and while cleaning you discover that the walls are not smooth and your cleaning wipes are literally shredding while you wash the walls



Sample issues

- ❖ What is wrong with this picture?



Sample issues

- ❖ After a heavy rainfall you find water in your clean room complex
- ❖ Your hood arrives and it won't fit through the door
- ❖ Hunting season starts and the contractors take the week off and your HVAC crew can't get their equipment installed when scheduled and they move on to a new job
- ❖ Your examples:



Resources

- ❖ Starrco, 11700 Fairgrove Industrial Blvd, Maryland Heights, MO 63043, 800.325.4259
- ❖ Cleanroom Design LLC, www.cleanroomdesignllc.com
- ❖ Controlled Environment Structures, LLC, 137 High St., Mansfield, MA, 02048, 508.339.4237
- ❖ Marc Stranz, PharmD, Consultant, 1052 Victor Drive, East Greenville, PA 18041, 610.737.9250, marcstranz@gmail.com
- ❖ Comply797, Willis Triplett, PharmD, 20 Waterford Ct., Zionsville, IN 46077, 317.626.6973, willis.triplett@comply797.com



Resources

- ❖ CriticalPoint, LLC, 12154 Darnestown Rd, Suite 360, Gaithersburg, MD 20878, 734.344.2583, www.criticalpoint.info
- ❖ www.iqsdirectory.com
- ❖ American Cleanroom Systems, 29722 Avenida de las Banderas, Rancho Santa Margarita, CA 92688, 949.589.5656
- ❖ National Home Infusion Association, 100 Daingerfield Road, Alexandria, VA 22314, 703.549.3740
- ❖ ASHP, 7272 Wisconsin Ave, Bethesda, MD 20814, 866.279.0681
- ❖ www.USP.org



How comfortable are you?

- A Comfortable, ready to go
- B Need some additional help
- C Ready to call a contractor
- D Will delay the project for now



Advance planning eliminates all issues when building a clean room

- True
- False



Key Takeaways

- ❖ Key Takeaway #1
 - Example: Correct design will make the construction process work better
- ❖ Key Takeaway #2
 - Adhering to all USP <797> requirements (and anticipating the revisions) will reduce future costs of renovation
- ❖ Key Takeaway #3
 - Complete and accurate construction will ensure that the certification process is successful

