



## 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](http://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](mailto:marcstranz@gmail.com)
- ❖ Comply797, Willis Triplett, PharmD, 20 Waterford Ct., Zionsville, IN 46077, 317.626.6973, [willis.triplett@comply797.com](mailto:willis.triplett@comply797.com)



### Resources

- ❖ CriticalPoint, LLC, 12154 Darnestown Rd, Suite 360, Gaithersburg, MD 20878, 734.344.2583, [www.criticalpoint.info](http://www.criticalpoint.info)
- ❖ [www.iqsdirectory.com](http://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](http://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

