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?
- Pharmacist/pharmacy manager
- Contractor
- Clean room designer
- 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

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

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

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:

Sample issues

- What is wrong with this picture?

Sample issues

- 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?
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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?
- Comfortable, ready to go
- Need some additional help
- Ready to call a contractor
- 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