



USP <797> <800> STERILE COMPOUNDING

Common Design Pitfalls in USP <797> <800>

WHAT TO DO WHEN BUILDING/RENOVATING YOUR PHARMACY

Assemble the Team:

1. Architects
2. Compliance
3. Engineering
4. Infection Control
5. Nursing
6. Pharmacy Management
7. Pharmacy Technicians
8. Project Management



COMMON MISTAKES

Resources

- Budget is not appropriate to deliver quality
- Corporate leadership does not understand risk (operational and financial) if not properly planned and constructed
- Pharmacy Management not supported with compliance expertise
- Project is lacking key stakeholders

Design

- Airflows and Ventilation of Hazardous Drug (HD) Receipt, Storage and Mixing rooms
- BSCs placed too close to ceiling HEPAs
- Cleanrooms not sized for growth and redundancy
- Inappropriate finishes including ceilings, floors, paint, walls, etc.
- Inappropriate HVAC design yielding ongoing airflow issues
- Lack of continuous monitoring devices for temperature, relative humidity and differential pressure
- Misplacement of line of demarcation and sink
- Not recognizing impact of process flows and storage in the design



COMMON MISTAKES

Construction

- Lack of owner presence during the process
- No operational and cleaning procedures in place
- No process to verify as-built conditions to the approved design
- Unprepared for construction delays

Post-Construction

- Incomplete commissioning, HVAC balancing and certification
- Lack of comprehensive cleaning and environmental sampling prior to inspection
- No staff training to ensure personnel and material workflows make the engineering controls effective



QUALITY ASSURANCE PROGRAM



HOW QUALITY SOLUTIONS CAN HELP



**Certification &
Environmental
Testing**



**Environmental
Monitoring (EM)
Kits**



**Facility Design
and Assessment**



**Personnel
Training &
Assessment
Support**

Quality System and Compliance Consulting



EM KITS

- Provide Kits and Reports to self perform routine environmental sampling
- Support your in-house testing with incubation and enumeration of test samples





ENSURING A RETURN ON THE COST OF QUALITY

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