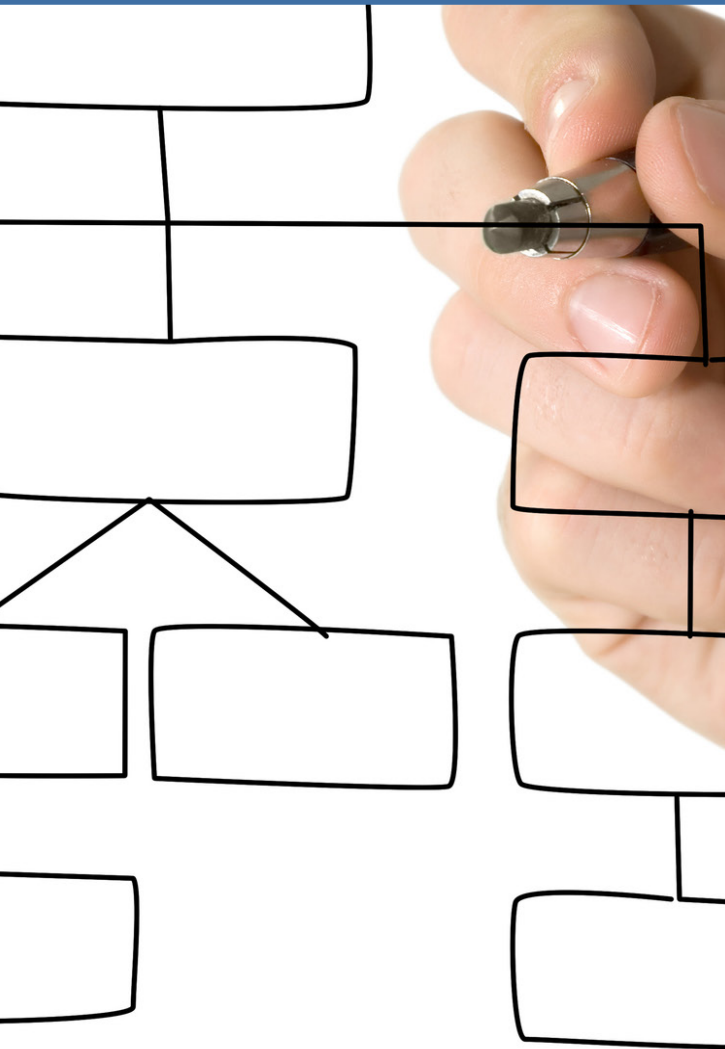


USP <797>/<800> Sterile Compounding

Common Design Pitfalls in USP <797>/<800>

We are building/renovating our pharmacy, now what?



Assemble the Team:

- Architects
- Compliance
- Engineering
- Infection Control
- Nursing
- Pharmacy Management
- Pharmacy Technicians
- 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

Common Mistakes - Design



Airflows and Ventilation of Hazardous Drug (HD) Receipt, Storage and Mixing Rooms

Cleanrooms not sized for growth and redundancy

Inappropriate finishes including cabinetry, 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

Temporary arrangements for compounding during construction not established

Common Mistakes - Construction



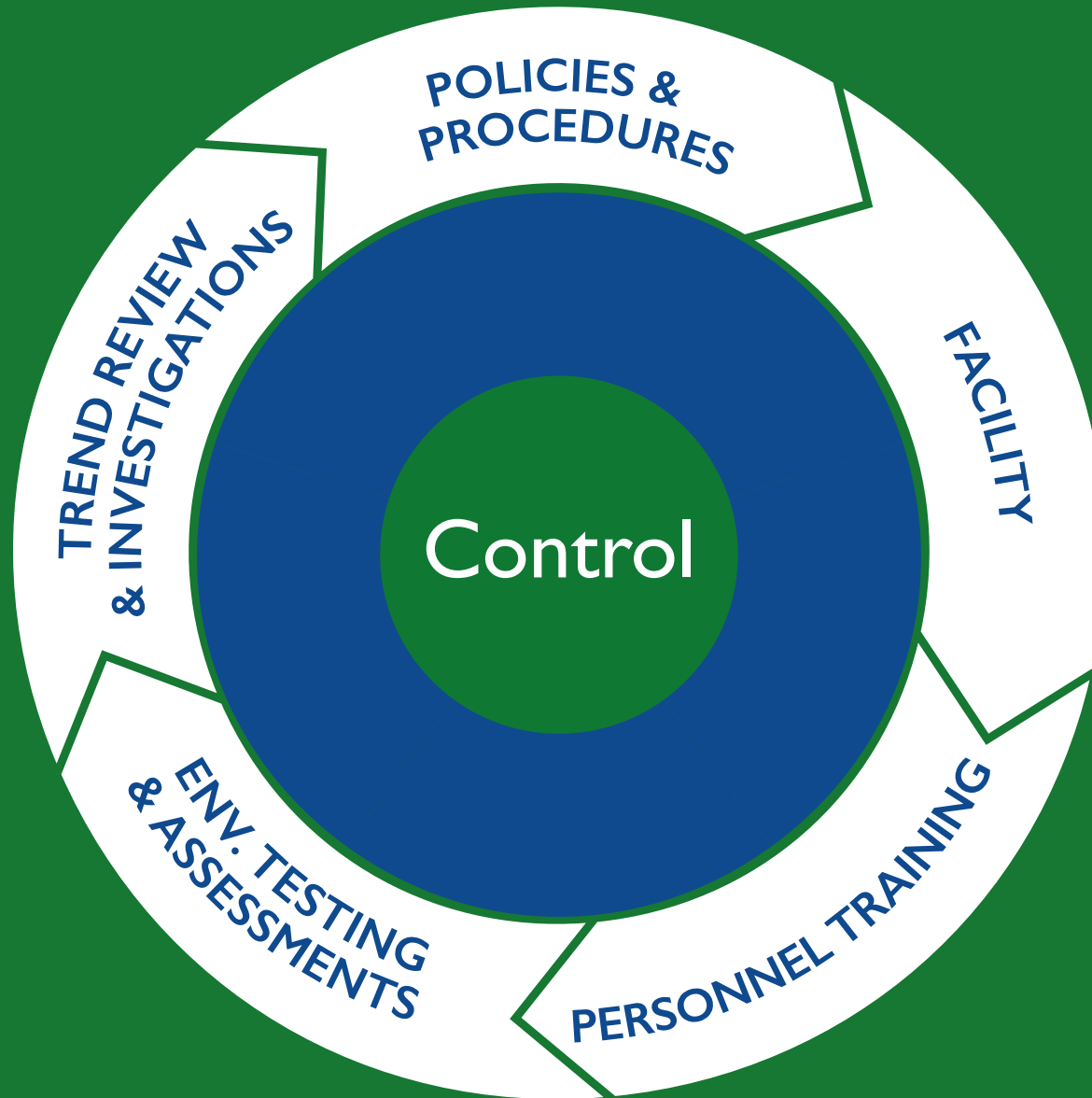
CONSTRUCTION

- 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 QS Can Help



Certification & Environmental Testing



Environmental Monitoring (EM) Kits



Facility Design and Assessment



Personnel Training & Assessment Support



Quality System and Compliance Consulting

EM Kits



QS can provide Kits and Reports to self perform routine environmental sampling

QS can support your testing with incubation and enumeration of test samples

Ensuring a Return on the Cost of Quality

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