USP <797>/<800> Sterile Compounding

Identifying Resources to Support Your Compliance Efforts

Quality Solutions, LLC

Identifying and Prioritizing Needs USP <797>

Review the existing Quality Program for gaps

Revise the program with critical requirements from <797>

- Cleaning

- Environmental Quality and Control

- Facilities and Engineering Controls

- Handling, Labeling, Mixing, Release and BUD of Non-HDz CSPs

- Personnel and Material Workflows

- Personnel Training and Assessment

- Policies, Procedures, Documentation and Records

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Identifying and Prioritizing Needs USP <800>

In addition to <797> requirements, revise program with critical requirements from <800>

- Chemo wipe sampling

- Facilities and Engineering- Containment and Ventilation

- HD List and Risk Assessment

- Hazard Communication Program and Medical Surveillance

- Storage, Handling, Labeling, Mixing, Release and BUD of HD CSPs

QA Program is in Place, Now What?

Identify compliance priorities and resources available

Key tasks commonly outsourced:

- Chemo wipe sampling

- Monthly environmental testing execution and support

- Personnel training and assessments-fingertip and media fill

- Policy and Procedure review and revision

- Review and approval of trend data and supporting documentation

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Keys to Choosing a Vendor

Assess their comprehension of the guidelines

Check references

Ensure vendor management is qualified

Evaluate vendor staff and resumes

Identify how out of specification data is reported

Review sample documentation

Understand scheduling process and timelines for reports

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Key Questions When Evaluating In-House vs. Outsourced

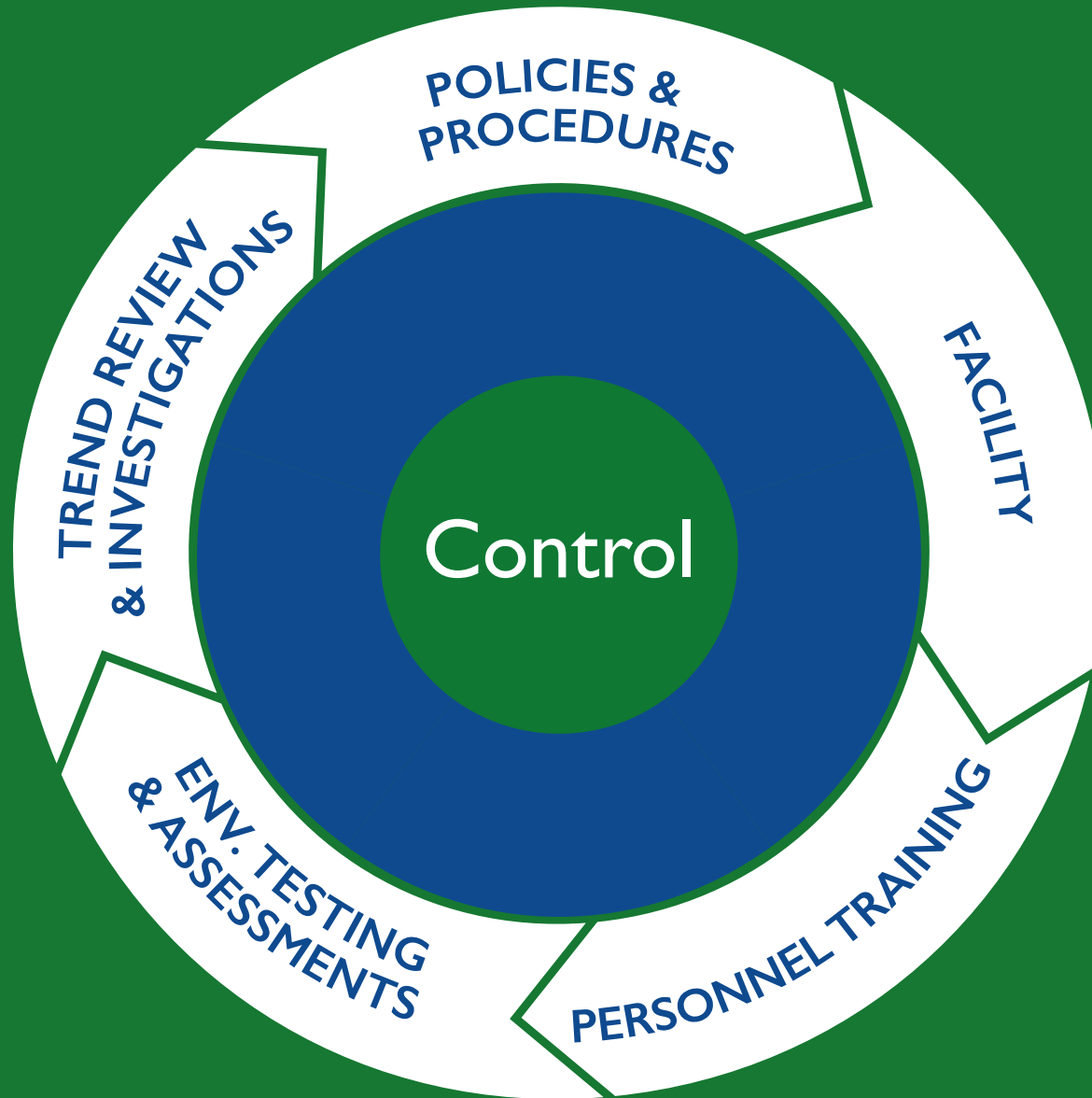Can we implement changes per revised <797> and <800>?

Can we maintain/calibrate necessary equipment- Incubators, Air Samplers, etc?

Do we have dedicated and trained staff to develop, execute and manage our compliance efforts?

Will our Quality Program and Documentation stand up to Board and JCAHO inspections?

What is the risk and cost involved with In-House Staff performing key Quality tasks?

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Quality Assurance Program

POLICIES & PROCEDURES

FACILITY

PERSONNEL TRAINING

ENV. TESTING & ASSESSMENTS

TREND REVIEW & INVESTIGATIONS

Control

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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

Quality Solutions,LLC

Ensuring a Return on the Cost of Quality

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