



USP <797> <800> STERILE COMPOUNDING

Identifying Resources to Support Your Compliance Efforts

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-HD CSPs
 - Personnel and Material Work flows
 - Personnel Training and Assessment
 - Quality Assurance: Policies, Procedures, Documentation and Records

USP <800>

- In addition to <797> requirements, revise the 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



WHAT TO DO ONCE A QA PROGRAM IS IN PLACE

1. Identify compliance priorities and resources available
2. Determine which tasks should be outsourced
 - a. Chemo wipe sampling
 - b. Monthly environmental testing execution and support
 - c. Personnel training and assessments: fingertip and media fill
 - d. Policy and Procedure review and revision
 - e. Review and approval of trend data and supporting documentation



KEYS TO CHOOSING A VENDOR

- Assess their comprehension of the guidelines
- Check references
- Ensure vendor management is qualified
- Evaluate vendor staff and resumés
- Identify how out of specification data is reporting
- Review sample documentation
- Understand scheduling process and timelines for reports



KEY QUESTIONS TO EVALUATING IN-HOUSE VS. OUTSOURCED

1. Can we implement changes per current <797> and <800>?
2. Can we maintain/calibrate necessary equipment- Incubators, Air Samplers, etc?
3. Do we have dedicated and trained staff to develop, execute and manage our compliance efforts?
4. Will our Quality Program and Documentation stand up to Board and JCAHO inspections?
5. What is the risk and cost involved with InHouse Staff performing key Quality, testing and lab tasks?



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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