USP <797>/<800> Sterile Compounding

Overview & Trends Prior to Revision Implementation

Quality Solutions, LLC

Why USP<797>?

Earlier efforts were unsuccessful since USP 1206 was voluntary and initial USP<797> was confusing and not comprehensive

Reduce or prevent harm to patients resulting from bioburden, endotoxins and other contamination of compounded sterile products

The guidance represents a process to gain a documented state of control over pharmacy operation and performance

Quality Solutions, LLC

Why USP<800>?

Implement a Quality System that creates a documented state of control over the pharmacy

Outline containment strategies for Hazardous Drugs HDs

- Facility and Engineering Controls
- Protective Equipment
- Work Practices

Promote worker and patient safety through protection from exposure to HDs

Provide a framework to assess the risk of HDs

Quality Solutions, LLC

USP <797>/<800> Revisions

Continued emphasis on Pharmacy Management Responsibility & Self Reporting

Current revision addresses deficiencies, contradictions and ambiguities

Invest in a Quality Assurance System now or pay the "penalty" later

Microbial and Chemo Wipe Testing/Trending to demonstrate control over the pharmacy cleaning, material flow and personnel flow

State Boards are mobilizing to understand and enforce

Quality Solutions, LLC

Management Strategies

Document your plan

Define the resources needed to implement your plan

Develop a process to investigate excursions and maintain the pharmacy in a documented state of control

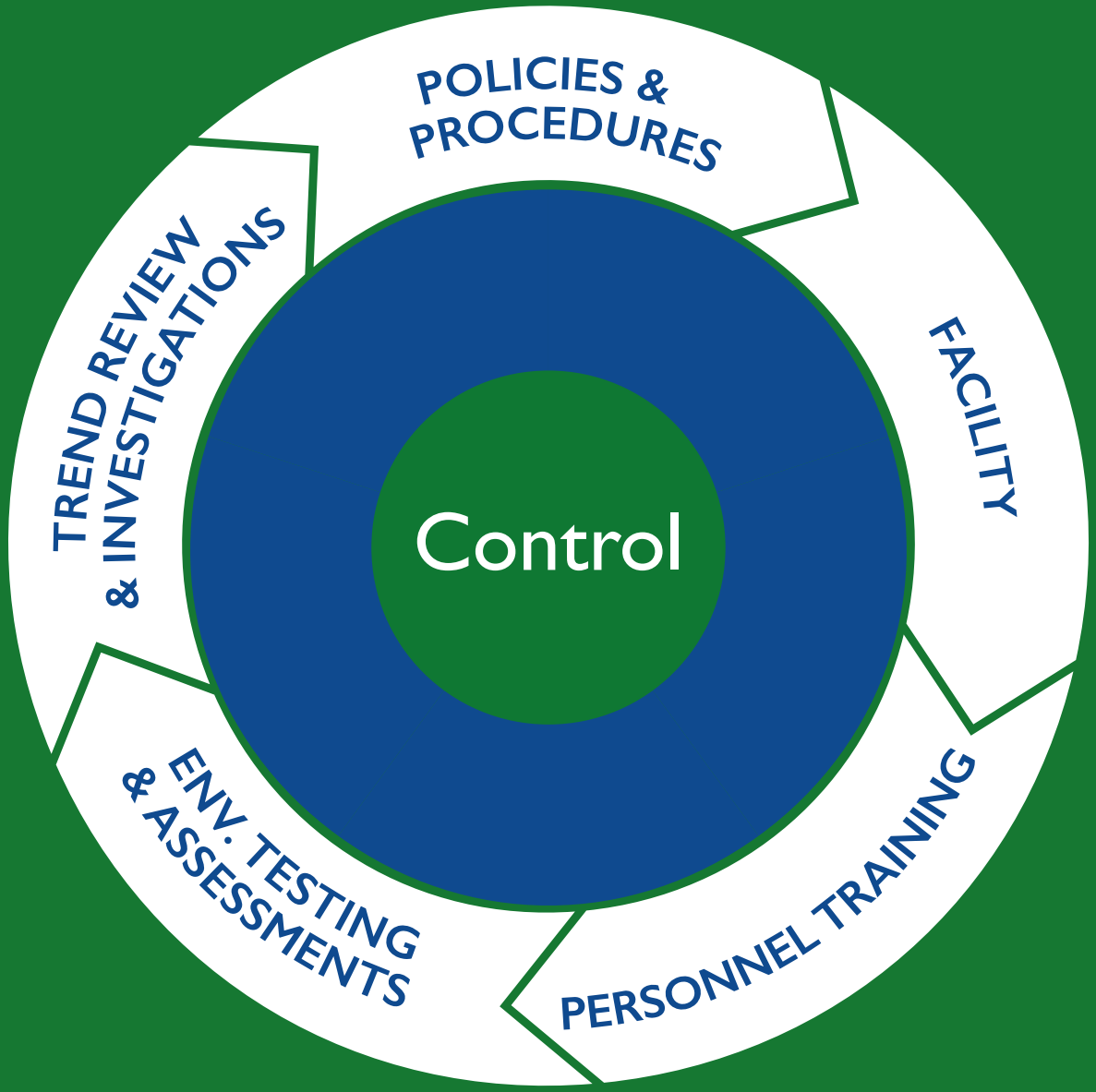
Focus on changing staff compounding culture

Full Commitment from Management and Personnel

Utilize specialized providers that can manage and report testing data as a tool

Quality Solutions, LLC

Quality Assurance Program



Quality Solutions, LLC

How QS Can Help

Certification & Environmental Testing

Environmental Monitoring (EM) Kits

Facility Design and Assessment

Personnel Training & Assessment Support

Quality System and Compliance Consulting

Quality Solutions, LLC

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

www.qualsolve.net

800-935-1146

9 Schilling Road

Suite 204

Hunt Valley, MD 21031

Quality Solutions, LLC