HEALTHCARE, CLEANROOM & RESEARCH FACILITIES

USP <800> Compliance Program Support

Trinity Consultants | LIFE SCIENCES

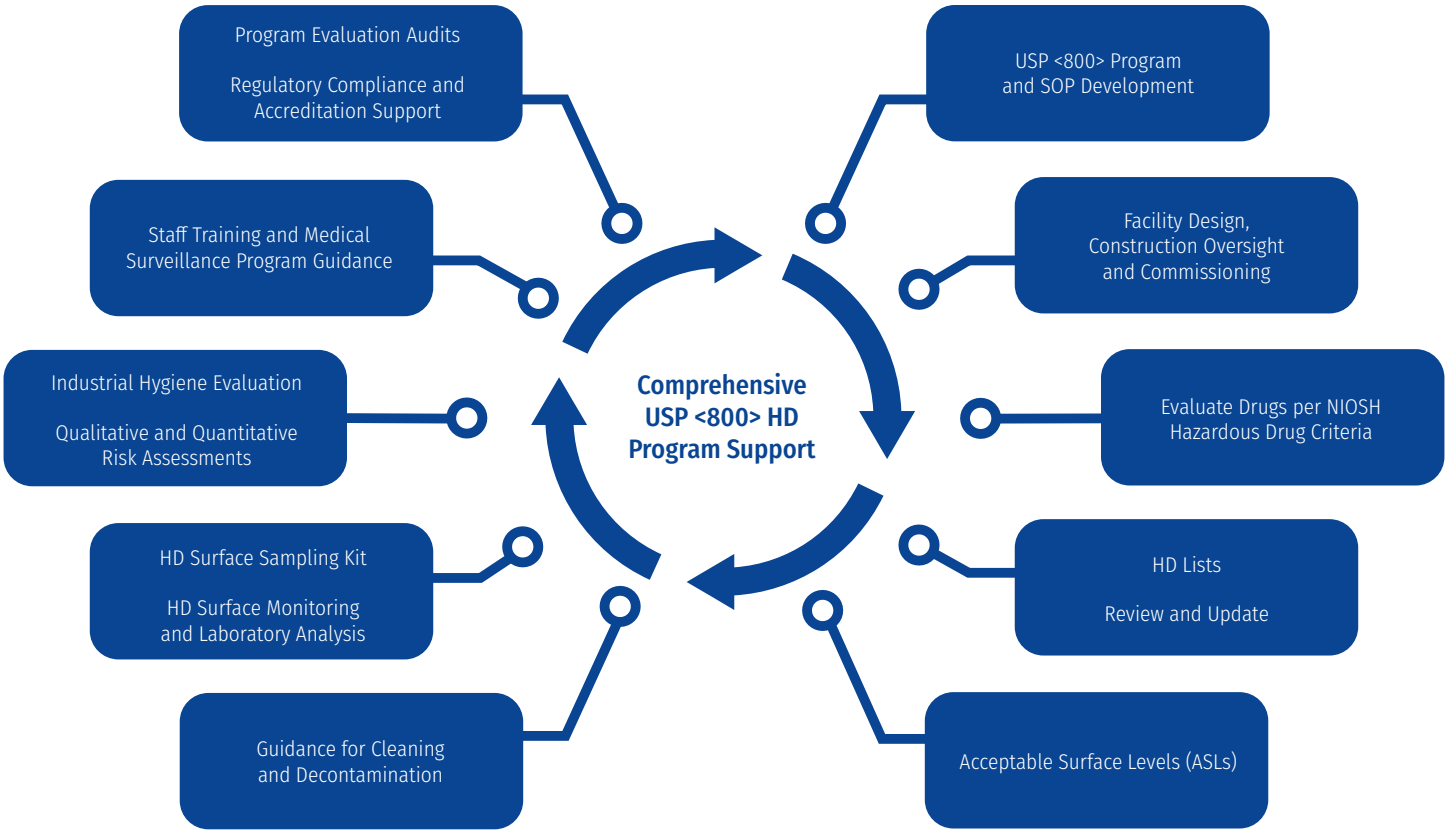
SAFEBRIDGE® | WORKINGBUILDINGS

Trinity Consultants is a leading global environmental consulting firm that brings 50 years of experience providing services and solutions in the EHS Regulatory Compliance, Built Environment, Life Sciences, and Water & Ecology markets. Trinity has the technical expertise and acute industry knowledge to provide optimal solutions to highly complex pharmaceutical development, process, safety, and facility design challenges.

For the past 25 years, Trinity has helped pharmaceutical manufacturing organizations and healthcare organizations implement programs to effectively manage potent compounds and hazardous drugs (HDs). Our SafeBridge and WorkingBuildings team possess the technical expertise regarding pharmacy cleanroom design and operations, regulatory compliance, industrial hygiene, hazard assessment, risk assessment and occupational health and safety, and toxicology to help hospital/health-system pharmacies make the changes needed for safe and compliant hazardous drug (HD) compounding. We are pleased to bring this extensive experience to the healthcare industry as it navigates compliance with USP <800> Hazardous Drug programs.

Regulatory Compliance Program for Controlling HD Exposure

Most facilities have centered their USP <800> compliance program within the pharmacy and patient administration areas due to exposures related to compounding and administration. However, once HDs leave the pharmacy, many staff are subject to unintended HD exposure. Our comprehensive services for USP <800> compliance enable you to implement an effective program for protecting all staff who handle HDs and HD-contaminated materials resulting from patient care activities and cleaning procedures.



USP <800> HD Program Support Services

HD Program Development and Regulatory Compliance Audits

- **USP <800> compliance checklist** – walk-through of facility to provide guidance based on compounding standards and regulatory authorities.
- **A tailored plan created in collaboration with your team** to target your facility's needs. Focused on the greatest areas of risk regarding USP <800> and HD contamination control.

Facility Design and Engineering Control Selection Commissioning

New Construction/ Renovations

- Review and engage on all elements of facility design, equipment, and engineering control selection, differential pressure control design, **construction quality control, commissioning**, and **certification testing oversight.**

Industrial Hygiene Program Evaluation/Audits and Risk Assessments

- **Qualitative evaluations & Risk Assessments**
  - Occupational health and industrial hygiene experts assess HD exposure risk, focusing on personnel handling practices, patient administration areas, and waste management.
  - A prioritized approach for high-risk tasks throughout the HD life cycle in the facility.
- **Quantitative evaluations & Risk Assessments**
  - Surface sampling for HD residue.
  - Air sampling for potential exposure (eg. aerosolized delivery systems)
- **Guidance for cleaning and decontamination.**

Toxicology Expert Opinion Acceptable Surface Levels (ASLs)

- **OEL and ASL development** for new and emerging HD products
- Determination of HD according to NIOSH definition.

In-House Analytical Laboratory HD Surface Monitoring Sampling Kits and Laboratory Analysis

- **Laboratory assessments of acceptable cleaning procedures to identify methods used to protect workers and to prevent product cross-contamination.**
- **Assess HDs and surrogate compounds** with a risk assessment approach, driving continuous improvement in your program.
- **Certified Industrial Hygienists (CIHs) can come on-site to collect surface samples**, analyze results, and assist your team in developing a surface sampling program.
- **Surface sampling kit allows your staff to collect the sample and ship it back to our laboratory for analysis.** Detailed analysis of results.
- SafeBridge Analytical Laboratory routinely develops methods and analyzes samples that contain biologically active pharmaceuticals such as steroid hormones, enzymes, peptide hormones, antibody drug conjugates (ADCs) and "cytotoxic" compounds. The laboratory employs HPLC, LC/MS, and ELISA technologies to detect low concentrations of highly potent drug on filters and swabs (picogram detection limits).

Periodic Program Review and Updates

- **HD list reviews and updates.**
- **Standard Operating Procedures (SOPs)** Develop or edit SOPs which cover receiving, compounding, labeling, transporting, administration, storage, cleaning, and disposal of hazardous or contaminated materials.

Staff Training

- **Provide effective training for management and healthcare workers** on HD SOPs, surface collection techniques, Hazard vs. Exposure Risk, and best practices when handling HDs.

Medical Surveillance

- Toxicologists and occupational medicine professionals can assist with guidance for an effective medical surveillance program to ensure worker safety.

CONTACT OUR TEAM!

For more information about how we can help your organization, please contact us.

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