HEALTHCARE, CLEANROOM & RESEARCH FACILITIES

USP <797> Program Support for Pharmacy Compounding

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.

The Trinity Consultants Life Sciences team brings deep, diverse expertise to help organizations that manufacture or compound medications deliver life-saving treatments. We provide timely, targeted support to ensure compliance and operational excellence.

We help our clients balance operational challenges with regulatory requirements. Our team brings expertise in pharmacy operations, engineering and design, commissioning, toxicology, and industrial hygiene as well as extensive health-system industry experience and with demonstrated success across multiple facilities.

Working directly with the client and in collaboration with the architect and engineering teams, we support pharmacies and healthcare facilities in achieving compliance with all pertinent USP compounding standards including: USP <795>, <797>, <800>, <823>, <825> and with FDA 503A & 503B pharmacies, for sterile compounding, non-sterile compounding, hazardous drug (HD) compounding, and radiopharmaceuticals.

About Trinity's Life Science Expertise

Trinity Consultants has acquired a variety of life science-focused companies that bring special areas of expertise to our clients in this sector: WorkingBuildings (design, commissioning, and operations of clinical and other complex facilities), Advent Engineering (process design, automation, and Commissioning, Qualification, and Validation (CQV) for pharma/biopharma), and SafeBridge Consultants (hazardous drug and potent compound toxicology, industrial hygiene, and regulatory support).

Pharmacy Compounding Program Support Services		
Challenge	Services Provided	Benefits to You / Your Team
Commissioning and construction quality control support	• Engineering commissioning of all HVAC mechanical systems to ensure compliance and operational efficiency of cleanroom spaces. • On-site construction quality oversight to ensure proper material installation • Coordinate simulated downtime to assess the overall environmental state of control at the facility prior to beginning operations.	• Ensure successful construction to ensure on-time project completion, appropriate installation of cleanroom materials

Cleanroom facility design engineering and administrative controls	• Facility design and design review (including throughput analysis and compliance alignment):
	  • HD containment and non-HD buffer rooms, isolators, HD storage areas and non-sterile containment, ventilated enclosures
	  • Anteroom design
	  • Differential pressure control design, including surveillance and historian systems
	• Primary Engineering Control selection and placement
	• Detailed architectural and mechanical design review to identify and eliminate design flaws
	• Primary engineering control
		• Compliance with regulatory requirements
		• Early detection of excursions
		• Minimize out of range results
		• Proper employee protection/safety measures

Pharmacy Compounding Program Support Services		
Challenge	Services Provided	Benefits to You / Your Team
Standard operating procedures (SOPs)	• Evaluation of existing cleanroom workflows • Development of Pharmacy Compounding SOPs • Development and training of Facility Department engineering and preventative maintenance SOPs • Staff training to ensure understanding and vigilance regarding critical procedures	• Objective and comprehensive documentation of current procedures • Expert assessment of compliance with USP <797>, <800>, and <823>, FDA Sections 503A and 503B, and State Boards of Pharmacy Compounding and manufacturing standards • Ensure pharmacy, maintenance, and environmental services staff are compliant with the revised SOPs
Operational workflow	• Analysis of facility design, SOPs, staff garbing, medication storage, and workflow	• Ensure appropriate facility, personnel, and procedures are in place for regulatory compliance and environmental monitoring program success
Environmental monitoring (EM) program development and committee involvement	• Assessment of facility design, SOPs, cleaning practices, and EM sampling program • Provide ongoing expertise for facility EM committees, review of microbiological sampling results • Evaluation of procedures related to receiving, compounding, labeling, transporting, administration, storage, and disposal of hazardous drugs • Development of safety data sheets (SDS) • Assessment/creation of wipe sampling program to assess HD environmental exposure • Development of medical surveillance program	• Ensure sterile compounding facilities operate in a state of control and aseptic processing/technique are maintained • Minimize and prevent microbiological contamination in ISO-classified rooms. • Manage risk associated with unintended exposure • Ensure staff are fully informed regarding hazardous substance handling • Monitoring and annual training programs enhance worker competencies and reduce risk
Regulatory and accrediting organization inquiry and response	• Assist program leadership in drafting regulatory responses to state boards of pharmacy, FDA, and accrediting bodies • Prepare for upcoming regulatory inspections and conduct mock inspections • FDA Type C Meeting Preparation	• Regulatory organization expertise and knowledge of regulatory and accrediting program requirements

We Can Help

Robust regulatory requirements and staff/patient safety concerns make sterile drug compounding and manufacturing and handling a critical process that requires careful attention. Trinity's specialized team are the right experts to provide the guidance needed to ensure regulatory compliance and a safe environment.

Team Leadership

KURT LAST

GMP/GTP
Pharmacy Design and
Regulatory Support

ELAINE STRAUSS, PHARMD, MS, BCSCP

Cleanrooms and
Sterile Compounding

PHILLIP STANFORD

Mechanical
Engineering

CONTACT OUR TEAM!

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

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