HEALTHCARE, CLEANROOM & RESEARCH FACILITIES

USP <797> Program Support for Pharmacy Compounding

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 team supporting the Life Sciences industry has the varied and deep expertise needed to provide timely and targeted support for organizations that manufacture or compound medications to deliver life-saving treatments.

We help our clients balance operational challenges with regulatory requirements. Our team brings expertise in pharmacy operations, engineering and design, toxicology, and industrial hygiene as well as extensive health-system industry experience and a proven track record in numerous 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 503 A & B pharmacy programs, for sterile compounding, non-sterile compounding, hazardous drug (HD) compounding, and radio-pharmaceuticals.

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 CQV for pharma/biopharma), and SafeBridge Consultants (toxicology, industrial hygiene, and regulatory support).

Pharmacy Compounding Program Support Services		
Challenge	Services Provided	Benefits to You

Engineering and administrative controls	• Facility design (including throughput analysis and compliance alignment):
	  • HD containment and non-HD buffer rooms, isolators, HD storage areas and non-sterile containment, ventilated enclosures
	  • Ante room design
	  • Differential pressure control design, including surveillance and historian systems
	• PEC selection and placement
	• Workflow analysis
		• Compliance with regulatory requirements
		• Early detection of excursions
		• Minimize out of range results
		• Proper employee protection/safety measures

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, if needed • Expert assessment of adequacy for compliance with USP <797>, <800>, and <823>, FDA Sections 503A and B, and State Boards of Pharmacy Compounding and manufacturing standards • Ensure pharmacy, maintenance, and environmental services staff are compliant with the revised SOPs
Staff compounding 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

Pharmacy Compounding Program Support Services		
Challenge	Services Provided	Benefits to You
Patient and personnel safety	• Evaluation of exposures related to delivery of patient care and handling of contaminated materials	• Enhance understanding of risks associated with drug handling procedures
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
Construction quality support and commissioning	• On-site construction quality oversight to ensure proper material installation • Construction commissioning and qualification support	• Ensure successful construction to ensure on-time project completion, appropriate installation of cleanroom materials

For each of these aspects, we conduct a gap assessment to compare your current practices against relevant regulations and standards required for compliance, make recommendations on how to efficiently implement needed changes, and if desired, lead the efforts needed to ensure regulatory compliance and patient and staff safety.

We Can Help

Robust regulatory requirements as well as staff and 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

Cleanrooms and Sterile Compounding

TONY MARTIN, PE

Mechanical Engineering

CONTACT OUR TEAM!

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

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