Controlled Environments for Sterile and Nonsterile Compounding

The discussion of the regulatory requirements of facilities for both sterile and nonsterile compounding combined with the facility requirements of hazardous and nonhazardous compounding will further the understanding of the appropriate choices. When tied in with each facility's choice of personal protective equipment, the effects of these choices can lead to decisions which will protect both employee and patient from cross contamination, exposure to hazardous drugs, and the prevention of microbial incursions into these preparations. Leading participants towards scientific data upon which to make these decisions will only further the goal of compliance with science based regulatory requirements.

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ProPharma Cleanrooms

A pharmacist for more than 30 years, Mr. Latta is a nationally recognized expert in compounding pharmacy management and development, clean room design and building, pain management. He has written and taught extensively on these topics. Upon graduating from UNC – Chapel Hill School of Pharmacy in may 1978, Ken spent his career at Duke University Medical Center in many positions from the Lead Pharmacist on the Acute Pain Service for 12 years where he had to develop processes for compounding PCA syringes and Epidurals which transitioned to managing the Duke Compounding Facility for about 13 years until his retirement in 2013. In 2006, Ken became the ASHP representative to the Pharmacy Compounding Board Standards Committee and served as a surveyor for about 10 years.

Mr. Latta's specialty is matching pharmacy processes - current and potential - to Cleanroom facility design ensuring compliance with current and future standards. His design experience for Cleanrooms ranges from small clinics to large central fill facilities (150 sq. ft. to 7,000 sq. ft.) that may or may not include nonsterile compounding facilities compliant with USP <800> including receiving, packaging, storage, and compounding regulations. Mr Latta also owns HSCG which currently provides monthly and remedial cleaning and sanitizing services for health system pharmacies compliant with current and future USP 797 & 800 guidelines.

Mr Latta is Vice President of Design and Regulatory Compliance with ProPharma Cleanrooms, LLC, a Senior Associate with Gates Healthcare Associates, a Senior Associate with Visante, a course facilitator and technical services consultant for LP3, Inc and Medisca Australia.