STAYING CURRENT AND COMPLIANT WITH REGULATIONS & STANDARDS IN YOUR COMPOUNDING PRACTICE

ACTIVITY SCHEDULE	
1 hour 45 minutes	**What is Going on at the Federal Level?** • Review of actual and draft changes at the federal level including bulk substance requirements, hCG, veterinary compounding guidance, office-use medications and compounding for drug shortages, as well as FDA guidance on insanitary conditions.
30 minutes	**What is Going on with the USP Standards?** • Review of the status of USP <795> and <797> and how to prepare for the future. Review of the status of USP <800>, who it will apply to in the future, and who it applies to now.
15 minutes	Break
15 minutes	**QA, QC, QI and Standard Operating Procedures (SOPs)** • The differences between Quality Assurance, Quality Control and Quality Improvement, and why it is important to understand them. Tips for writing effective SOPs will also be discussed.
15 minutes	**Regulatory Compliance – Personnel Training, Competency and Documentation** • The differences between training and competency and why you must have evidence of both. How to properly document training and competency and document it for regulatory inspections.
30 minutes	**Personal Protective Equipment** • What is required under USP Standards? What are some guidelines under the current conditions?
15 minutes	**Equipment Requirements** • The equipment lifecycle, verification of equipment, and how to create a proper log.
15 minutes	**Monitoring Controlled Areas** • How to handle certifications and read reports.
1 hour	Lunch
1 hour 15 minutes	**Cleaning and Disinfecting, Deactivation and Decontamination** • The difference between cleaning and disinfecting. Best practices in non-sterile and sterile compounding facilities. Maintaining a state of control in sterile environments. Deactivation and decontamination.
30 minutes	**Master Formulation and Compounding Records** • Common regulatory problems with MFRs and CRs and how to avoid them.
15 minutes	Break
15 minutes	**Finished Preparations and BUDs** • Comparison of current standards and revised standards. Establishing and Documenting BUDs.
15 minutes	**Quality Control of Finished Preparations, Labeling of Preparations & Patient Counseling** • What is required, and regulatory pitfalls to avoid.
15 minutes	**Emergency Equipment** • Eye washes and other supplies.
1 hour 15 minutes	**Managing Inspections** • How to self inspect, pre-inspection preparations and documents, managing the inspector, post inspection activities, closing out the inspection.

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