


Due-Diligence Checklist

(FOR COMPOUNDING PHARMACY QUALITY AND STERILITY)

Because of the strict USP guidelines for compounding, it's more important than ever for physicians to choose a compounding pharmacy they can trust. When choosing a compounding pharmacy for sterile preparations be sure to ask questions like the ones listed below.

QUESTION	 EASTERN STATES COMPOUNDING PHARMACY	Other Compounding Pharmacy
Are you committed to compliance with the USP <797> and USP <795> guidelines for sterile and non-sterile compounding?	X	
If you are compounding sterile preparations, do you conduct weekly lab test of air and surface samples in your clean room and other controlled environments?	X	
Do you obtain independent, routine certifications of your clean rooms and laminar flow hoods?	X	
Do you perform daily monitoring and documentation of temperature and humidity of all compounding areas?	X	
Is your staff required to complete specialized training and exhibit proficiency in compounding manipulation skills, gowning technique, and clean room use?	X	
Do you filter (0.2 micron) in a Class 100 (ISO 5) laminar airflow hood contained in an ISO 7 clean room, or autoclave or dry heat sterilize where appropriate to achieve sterility?	X	
Do you perform process validation for each type sterile preparation compounded?	X	
Do you perform sterility testing according to USP <71> Sterility Tests and USP <85> Bacterial Endotoxin Test?	X	
Do you perform post-filtration filter-integrity testing?	X	
Do you have systems in place for handling complaints and conducting recalls?	X	
Do you employ barcode technology to reduce errors and improve quality control?	X	
Do you purchase pharmaceutical-grade chemicals (USP, NF equivalent) from FDA-registered suppliers?	X	
Do you obtain Certificates of Analysis for all formula ingredients?	X	
Do you maintain both master formulas and lot-specific worksheets for all compounds?	X	
Can you immediately trace a prescription back to the original formula log sheet and the source of all ingredients?	X	
Do you conduct quality assessment, including pH, on each finished compounded medication?	X	
Do you perform HPLC verification on selected formulations?	X	
Is your facility open for inspection and review by physicians?	X	
Does the pharmacy have adequate liability insurance?	X	
Do you accept most private insurance plans?	X	