




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 |  northern new england nnecp compounding pharmacy | OTHER COMPOUNDING PHARMACY |
|---|---|----------------------------------|
| Are you <i>nationally accredited</i> for sterile compounding with the Pharmacy Compounding Accreditation Board (PCAB)? | X | |
| Are you committed to compliance with the USP <797> guidelines for 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 your clean room temperature and humidity? | X | |
| Is your staff required to complete specialized training and exhibit proficiency in aseptic 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 bar-code 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 | |
| Are you active members of the International Academy of Compounding Pharmacists, Profes- | X | |