



USP <797> CSPs

Pharmacies preparing individualized dosages of sterile drugs for patients must meet stringent requirements and standards for patient safety. USP <797> is designed for healthcare institutions, pharmacies, and related facilities to ensure the sterilization of drugs that are used in compounding sterile preparations. It applies to all those involved in sterile compounding; physicians, pharmacists, pharmacy technicians, and nurses.

Environmental monitoring and microbial evaluation of your staff's sterile techniques are critical components to patient care. Our <797> solution delivers qualified, trained and gowned Engineering Control Specialists to collect your samples with calibrated equipment and quality controlled media. Samples will be incubated within our validated chambers and analyzed by our trained Microbiology Analysts.

Service Offerings

Environmental sampling of CSPs
Surface monitoring (Contact Plate or Swab Methods)
Non-viable particulate monitoring

Analysis of personnel for aseptic qualification
Media fill incubation
Gloved fingertip/garb incubation

Microbial Identification
Characterization & morphology (visual description & gram stain)
Identification to Genus level
Identification to Species level

Training and Consultation Services

Cleanroom Basic Training: Our consultants will observe and test your staff on hand hygiene, aseptic technique, personnel garbing, and sterile gowning efficiency to document proficiency with USP <797> and cGMP protocols.

Investigation Support: We offer risk assessment, remediation consultation for any investigation.



CONTACT US FOR A FREE CONSULTATION

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