



USP <797> Checklist

Item or area	What is required
Hand Washing Gowning	Procedure CTG recommendations Lab coat and optional gloves When handling drugs
Define Risk level of compounding area	Low / Medium / High
Quality Assurance Low	Media Fill-annually Viable air monitoring
Medium	Media Fill-annually Viable air monitoring
High	Semi annually Media Fill- & Viable air monitoring
Personnel Training	Audio video Professional publications Didactic review Written exam Media Fill
Hazardous Drugs Storage Compounding	CTG recommendations Negative pressure MIC Negative pressure room not required
IV admixtures	Positive pressure MIC ISO 7 cleanroom not required Follow CTG protocol for using non-sterile hydrogen peroxide
Non-Viable air monitoring	Per CTG protocols every six months
Viable air monitoring	Volumetric air sampler – six months Inside MIC & area near MIC CTG will provide protocols and service
Cleaning and disinfection	FREQUENCY SCHEDULE A. <u>Inside the MIC</u> at the beginning of each shift, before each batch and no longer than thirty-minute intervals during continuous compounding. If a spill occurs follow cleaning procedure and re-sanitize.



- B. Daily cleaning and sanitizing – counters, work surfaces and floors
- C. Monthly – walls, ceilings and shelving surfaces

Written procedures

Training for cleaning staff
Need cleaning logs

Changes concerning the MIC

Sterile gloves – we carry
Sterile wipes - we carry
Sterile Alcohol – we carry

Environmental monitoring

- (1) Viable airborne particulate sampling shall occur in the MIC-EDU using a volumetric collection method. See USP <1116>
- (2) Surfaces in the interior of the MIC are sampled monthly utilizing touch plates. Surfaces tested are gloves, sleeves, floor, window, side walls. The day of the week and time of day are rotated.
- (1) Gloved finger tip sampling shall occur as follows:
 - a. Before compounding an individual must successfully complete an initial competency test using a sterile agar plate and touching it three time with results showing zero cfu's.
 - b. The finger tip test is required annually for low & medium risk and semi-annually for high risk
 - c. This testing should be incorporated into the media-fill test procedure. Results should be recorded per hand per employee. The cfu action level will be based on the total cfu's on both hands.
- (4) Results of the sampling are documented in a log.

Temperature monitoring
Storage area

Required monitoring
daily logs
We have automatic data logger

IV room

Not required unless drugs are stored
in the area – If so daily logs
We have automatic data logger