Inspection Details

Name	Test Pharmacy	**Case #**		**Permit**	14549
Address	123 Apple St Chapel Hill, NC 27516	**Person Providing Info**		**Inspection Date**	07/08/2024
		Person In Charge	Jack William Campbell, IV	**Inspection User**	Brashears, Krystal
				Inspection District	DISTRICT3
# RPhs	2	**Rx Volume/Date Hours**			
# Techs	2				
Follow-Up CAP	No	**Office**	No		
CAP Requested	No	**Commercial Use**	No		
CAP Documentation Received	No	**Ship to Other States**	No		
Additional Documents	Yes	**States Shipped To**			
Office Use		**Commercial Use**	No		
Office Use Comments		**Documented Clinical Indication**			

Non-Sterile Compounding

Non-Sterile	Yes
Does the pharmacy engage in Occasional Basic Non-Sterile Compounding?	Yes
Does facility engage in moderate or complex sterile compounding?	Yes
Does facility engage in Hazardous Drug Compounding?	Yes
Is there documented clinical indication for the approved medication?	

Sterile Compounding

Sterile Compounding	Yes
Does facility compound Immediate Use CSP?	Yes
Does facility compound Category 1 Sterile Compounding?	Yes
Does facility compound Category 2 Sterile Compounding?	Yes
Does facility compound Category 3 Sterile Compounding?	Yes
Does facility compound hazardous medications?	Yes
Does facility compound Allergenic Extracts?	Yes

Comments

None

General

	Answer	Question
1)	Unanswered	90-85.23- PM license, permit and current renewal shall be posted. Licenses and renewals of each RPh. are readily available for inspection.
2)	Unanswered	90-85.25 (b)- PM shall report within 10 days any disaster, accident, theft.
3)	Unanswered	90-85.15A (a) - tech must register with the Board within 30 days after the date of completing the training program.
4)	Unanswered	90-85.15A (c) - 2:1 ratio, if the ratio above provide waiver documentation. Any technician above the 2:1 ratio must be certified (document approval date).
5)	Unanswered	.1410 (a) - Pharmacy must be directed by a legally qualified pharmacist referred to as Pharmacy Manager (PM).
6)	Unanswered	(b) - Sufficient number of pharmacists and supportive personnel to operate pharmacy competently.
7)	Unanswered	(c) - PM must develop and implement written policies and procedures to specify the duties to be performed by pharmacists.
8)	Unanswered	(d) - Qualified, trained, adequately supervised supportive personnel to provide technical services. Supervising pharmacist must be fully aware of and responsible for all activities involved in the preparation and dispensing of medication.
9)	Unanswered	.1411 (a) - The PM shall establish written procedures for the safe and effective distribution of pharmaceutical

General		
	Answer	**Question**
		products. Procedures periodically reviewed. Copy should be readily available in pharmacy.
10)	Unanswered	(b)(3) - PM is responsible for participation in development and maintenance of a drug formulary when required by the health care facility.
11)	Unanswered	(b)(6) - drugs disp. only by RPh. or others allowed by law & supportive personnel are directed & supervised.
12)	Unanswered	(b)(7) - Policy & Procedure that d/c drugs, outdated drugs, recalled drugs, containers w/ worn, illegible or missing labels are rtnd. to pharmacy for disposition.
13)	Unanswered	(b)(8) - PM must maintain records and reports to ensure patient health, safety & welfare.
14)	Unanswered	.1411 (b)(9) - Reports of controlled substance discrepancies including report of action, steps taken to prevent recurrence, recurring losses or mishandling of significant quantities must be reported to the DEA.
15)	Unanswered	(b)(10) - aux med inventories are inspected.
16)	Unanswered	(b)(12) - Maintain policy and procedure regarding drug samples and patient's personal medications.
17)	Unanswered	.1412 - Sufficient floor space to ensure that drugs are prepared in sanitary, well lighted, and enclosed places.
18)	Unanswered	(1-2) - Compounding and dispensing areas; physically separate parenteral solution additive area when parenteral solutions are compounded.
19)	Unanswered	(3) - Area for receiving and storage.
20)	Unanswered	(4) - Packaging and repackaging area.
21)	Unanswered	(5) - Office space sufficient to allow for administrative function without interference with the safe compounding and dispensing of medication and security of pharmacy.
22)	Unanswered	(6) - All drugs shall be stored in designated areas within the pharmacy or decentralized pharmacy sufficient to provide sanitation to prevent contamination. Controlled Substances shall be stored in compliance with Federal and State laws and regulations.
23)	Unanswered	(7) - Security: All areas in the pharmacy, including auxiliary drug supplies and unit dose carts, shall remain secure at all times.
24)	Unanswered	.1413 (a)(2) - Authorized personnel allowed in the pharmacy after -hours.
25)	Unanswered	.1414 (a)(1) - Policy and procedure to establish a time frame in which oral medication order shall be put into writing and signed.
26)	Unanswered	(a)(2) - Medication orders must contain: patient name, location, medication name, strength, dosage form, route of and directions for administration, date of order written, and prescriber signature.
27)	Unanswered	(a)(3) - Policy and Procedure established for continuing therapy. Information required for patient profile includes patient's name, location, clinical information (height, weight, sex, age, and allergies), medication, strength, dosage form, route of and directions, medication start date, medication discontinue date, and identification of pharmacist responsible.
28)	Unanswered	(a)(4) - Abbreviations used in medication orders shall be agreed to, jointly adopted, and published by the medical, nursing, pharmacy, and medical records staff of the health care facility.
29)	Unanswered	(a)(5) - Protect health care facility patients from indefinite, open-ended medications orders.
30)	Unanswered	(c)(1)- Drugs are labeled and can be identified up to point of administration.
31)	Unanswered	(d)(1-7) - Auxiliary Medication Inventories
32)	Unanswered	(j)(1) - PM shall develop system of daily accountability for medication compounding & dispensing that permits the identification of the responsible RPh. & pharmacy technicians. Readily retrievable records shall be maintained for thirty (30) days. The system shall identify all personnel who preform these activities & the RPh responsible for: (A-G) (j)(1)(A) - Interpretation & appropriateness of new med orders. (j)(1)(B) - Profile entry of new med orders. (j)(1)(C) - Disp. of new med orders including stat doses. (j)(1)(D) - Daily cart fills.
33)	Unanswered	(j)(1)(G) - Preparation & release of drugs for replenishment of aux. med inventories & Auto. Disp. Devices in locations outside the pharmacy.
34)	Unanswered	(j)(2) - Documentation of med errors.
35)	Unanswered	(j)(3) - In case of death of patient retain all documents, physical evidence and internal investigative reports related to event; all items made available to North Carolina Board of Pharmacy upon request.
36)	Unanswered	(j)(4) - Records of ordering, receiving, and dispensing or transferred of controlled substances.
37)	Unanswered	(j)(4)(E) - Perpetual inventory shall be maintained on all controlled substances awaiting destruction.

General		
	Answer	**Question**
38)	Unanswered	.1414 (j)(6) - Records must be maintained for three (3) years.
39)	Unanswered	.1415 (b)(1) - Drugs will only be dispensed to registered patients of the emergency department
40)	Unanswered	(b)(2) - The PM develop and supervise a system of control and accountability of all drugs administered in or dispensed from the Emergency Dept.
41)	Unanswered	(b)(3) - The pharmacy manager in conjunction with the appropriate committee responsible in the emergency department shall develop an emergency department formulary which may be dispensed to patients receiving care from the emergency department. Medications must be limited to no more than a twentyfour (24) hour supply or the smallest commercially available quantity.
42)	Unanswered	(b)(4) - Drugs shall be prepackaged in safety closure containers and pre-labeled by the pharmacist. Prior to dispensing, the following information must be on the label of the medication: name, address, telephone number of the health care facility pharmacy, dispensing date, full name of patient, generic or trade name, directions for use, the name of physician prescribing and dispensing, and cautionary information for the safety of the patient.
43)	Unanswered	.1418(b) - PM shall develop written policies and procedures that: (1) - permit a validating technician to validate only the following functions: (A)- stocking of patient care unit medication inventories; (B)- stocking of ancillary drug cabinet inventories (C)- stocking of automated dispensing or drug supply devices; (D)- stocking of emergency kits (E)- prepackaging of prescription drugs within the Hospital pharmacy; (2) - parameters for RPh. supervision of pharmacy technician validation functions; ((3) - facility specific training for technician validation functions; (4) - evaluation and assessment program to ensure functions are performed safely and accurately (5) - recordkeeping system that shall permit the identification of the validating technician. Records are readily retrievable and kept for 3 years.
44)	Unanswered	.1601(a)(3) - Obtaining and maintaining equipment in the pharmacy adequate to meet the pharmaceutical needs of patients. Pharmacy reference library should include medical dictionary, drug interaction reference books, if IV services are provided a reference book on Parenteral Incompatibilities.
45)	Unanswered	(a)(4) - Pharmacy is equipped with sanitary appliances including lavatory with hot and cold running water, well lighted, kept in a clean, and sanitary condition.
46)	Unanswered	(e) - Pharmacy permit is countersigned by rph-mgr. as represented in the application
47)	Unanswered	.2502 (b) - Present in the pharmacy for half the hours open or thirty- two (32) hours a week, whichever is less. Temporary pharmacist in charge should not exceed ninety (90) days, must be present twenty (20) hours a week in the pharmacy.
48)	Unanswered	(d) - Develop and implement system of inventory record keeping and control to enable detection of shortage or discrepancies of controlled substance medication at earliest time.
49)	Unanswered	(e) - Maintain authority and control over all keys to pharmacy and responsible for security of pharmacy. Pharmacy secured to prohibit entry if no pharmacist in pharmacy for ninety (90) minutes or more.
50)	Unanswered	(j) - Prepare disaster plan.
51)	Unanswered	(k) - Separate drug products more than six (6) months out of date.
52)	Unanswered	(l) - Reporting death of a patient or customer to North Carolina Board of Pharmacy within fourteen (14) days of becoming aware of incident.
53)	Unanswered	CFR 1301.75 (b) - controlled substances listed in II, III, IV, and V shall be stored in a substantially constructed cabinet, or disbursed throughout the non-controlled substances.
54)	Unanswered	CFR 1304.04 (2)(h)(1) - inventories and records of Sch. I & II substances maintained separate from all other records. (2)(h)(2)- paper prescriptions for Sch. II substances maintained in separate file.
55)	Unanswered	CFR 1304.11 (a) - complete/accurate inventory of all cs meds and maintained at the registered location. (c) - Biennial inventory.
56)	Unanswered	CFR 1305.05 (a) - power of attorney on file at registered location.
57)	Unanswered	CFR 1305.12 (b) - purchaser shall record 1 item on each numbered line. (c) - name/address of supplier on form. Only 1 supplier on any form. (d)- DEA Form 222 properly signed and dated.
58)	Unanswered	CFR 1305.13 (e) - purchaser must record the number of commercial or bulk containers furnished on each item and dates on which the containers are received.
59)	Unanswered	CFR 1305.22 Procedure for filling electronic orders. (g) - purchaser receives shipment, purchaser must create a record of the quantity of each item received and date received. Record must be electronically linked to the original order and archived.
60)	Unanswered	CFR 1305.27 Preservation of electronic orders. (a) purchaser must, for each order filled, retain the original

General

	Answer	Question
		signed order and all linked records for that order for 2 years. Purchaser must also retain all copies of each unaccepted or defective order and each linked statement. (b) supplier must retain each original order filled and the linked records for 2 years. (c) If electronic order records are maintained on a central server, records must be readily retrievable at the registered location. Note: Federal law requires 2 years NC Law requires 3 years
61)	Unanswered	CFR 1306.05 (a) - all cs prescriptions shall bear full name and address of the patient along with date, drug, strength, dosage form, quantity, dirs. for use, and name, address and registration number of practitioner. (d) - computer generated prescription that is printed or faxed must be manually signed
62)	Unanswered	CFR 1306.08 (3)(b) - pharmacy may fill electronically transmitted prescription for a cs med provided the pharmacy complies with all requirements.
63)	Unanswered	CFR 1306.11 (a) - a Sch. II order signed by the practitioner.
64)	Unanswered	CFR 1306.14 (a) - prescription vials labeled for Sch. II display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.
65)	Unanswered	CFR 1306.21 (a) - order for Sch. III, IV, or V that is a facsimile is signed by practitioner.
66)	Unanswered	CFR 1306.22 (b) - cs refills entered on a medication record or electronic record must be uniformly maintained and readily retrievable.
67)	Unanswered	CFR 1306.24 (a) - prescription vials labeled for Sch. III, IV, or V display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.
68)	Unanswered	CFR 1311.10 Eligibility to obtain a CSOS digital certificate. (a) - person who signed the most recent DEA registration application or renewal application and a person authorized to sign a registration application. (b) - person granted power of attorney by a DEA registrant to sign orders for one or more schedules of controlled substances.
69)	Unanswered	CFR 1311.30 Requirements for storing and using a private key for digitally signing orders. (a) - Only the certificate holder may access or use his or her digital certificate and private key. (b) - The certificate holder must provide FIPSapproved secure storage for the private key, as discussed by FIPS 140-2, 180-2, 186-2, and accompanying change notices and annexes, as incorporated by reference in §1311.08. (c) - A certificate holder must ensure that no one else uses the private key. While the private key is activated, the certificate holder must prevent unauthorized use of that private key.
70)	Unanswered	CFR 1311.35 Number of CSOS digital certificates needed. A purchaser of Schedule I and II controlled substances must obtain a separate CSOS certificate for each registered location for which the purchaser will order these controlled substances.

Section A: OCCASIONAL BASIC NON-STERILE COMPOUNDING:

	Answer	Question
3)	Unanswered	Occasional Basic Non-Sterile Compounding means combining one or more conventionally manufactured products pursuant to an individual prescription on an occasional basis. This includes but is not limited to: Magic Mouthwash, GI Cocktail, creams or ointments using only conventionally manufactured products. Documentation includes the following:
4)	Unanswered	a) Official name, strength, and dosage of preparation.
5)	Unanswered	b) Name and quantities of all components.
6)	Unanswered	c) Sources, lot numbers, and expiration dates of components.
7)	Unanswered	d) Name of the person who compounded and the person who verified the preparation.
8)	Unanswered	e) Date preparation.
9)	Unanswered	f) Assigned BUD.
10)	Unanswered	g) Description of final preparation.
11)	Unanswered	h) Description of Compounding Steps

Section B: PERSONNEL TRAINING AND EVALUATION:

	Answer	Question
1)	Unanswered	Facility has a written SOP for knowledge and competency of core skills.
2)	Unanswered	Personnel are able to demonstrate knowledge of principles and competency of skills for performing non-sterile manipulations that include:

Section B: PERSONNEL TRAINING AND EVALUATION:

	Answer	Question
3)	Unanswered	a) Hand hygiene
4)	Unanswered	b) Garbing
5)	Unanswered	c) Cleaning and sanitizing
6)	Unanswered	d) Handling and transporting components and CNSPs
7)	Unanswered	e) Measuring and mixing
8)	Unanswered	f) Proper use of equipment and devices used to compound CNSPs
9)	Unanswered	g) Documentation of the compounding process (e.g., master formulation and compounding records)
10)	Unanswered	Steps in the training procedure must include:
11)	Unanswered	a) Read and understand USP<795>, all referenced standards, and other relevant literature.
12)	Unanswered	b) Understand and interpret Safety Data Sheets (SDSs) and Certificates of Analysis (COAs).
13)	Unanswered	c) Read and understand facility compounding procedures related to staff duties.
14)	Unanswered	All personnel who conduct compounding activities or have direct oversight must be trained in the facility's SOPs.
15)	Unanswered	Initial and annual training documentation present for compounding personnel observed and verified by Designated Person(s) or Assigned Trainer(s).
16)	Unanswered	Proficiency and competency demonstrated every twelve (12) months. Any deficiencies identified must be addressed, corrective actions applied, and documented.

Section B HD: USP <800> TRAINING PROGRAM

	Answer	Question
1)	Unanswered	USP<800>: Facility has a written HD Training Program which includes:
2)	Unanswered	a) Review of facility's HD list and their assessment of risks.
3)	Unanswered	b) Review of facility's SOPs related to HDs. SOPs must be reviewed every twelve (12) months and must be documented in accordance with this chapter, OSHA standard (1910.120) and other applicable laws and regulations.
4)	Unanswered	c) Proper receiving, handling, and storage of HDs.
5)	Unanswered	d) Proper Use of PPE.
6)	Unanswered	e) Proper use of equipment and devices (e.g. engineering controls).
7)	Unanswered	f) Response to HD exposure – known or suspected.
8)	Unanswered	g) Spill Management.
9)	Unanswered	h) Proper disposal of HDs and trace-contaminated materials.
10)	Unanswered	Initial and annual training documentation present for all personnel who handle HDs observed and verified by Designated Person or Assigned Trainer.
11)	Unanswered	Proficiency and competency demonstrated every twelve (12) months.
12)	Unanswered	Personnel of reproductive capability must confirm in writing that they understand the risk of handling HDs.
13)	Unanswered	Qualified Personnel must be available for spill management at all times while HDs are handled.

Section C: PERSONAL HYGIENE AND GARBING:

	Answer	Question
1)	Unanswered	Prior to entering a compounding area, staff:
2)	Unanswered	a) Removes personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests).
3)	Unanswered	b) Removes all hand, wrist, and other exposed jewelry including piercings.
4)	Unanswered	c) Not wear earbuds or headphones.
5)	Unanswered	Garbing requirements and order of donning and doffing must be documented in facility SOPs.
6)	Unanswered	Hand Hygiene: wash hands and forearms up to the elbows, for at least 30 seconds, using soap and water.

Section C: PERSONAL HYGIENE AND GARBING:

	Answer	Question
7)	Unanswered	Reusable garb (e.g. goggles) should be cleaned and sanitized with 70% IPA before each use.

Section C HD: USP <800>: Personal Protective Equipment:

	Answer	Question
1)	Unanswered	Facility has written SOPs for PPE use based on risk of exposure and activities performed that include:
2)	Unanswered	a) Receipt
3)	Unanswered	b) Storage
4)	Unanswered	c) Transport
5)	Unanswered	d) Compounding (sterile and nonsterile)
6)	Unanswered	e) Deactivation/decontamination, cleaning, and disinfecting
7)	Unanswered	f) Spill control
8)	Unanswered	g) Waste disposal
9)	Unanswered	h) Contaminated clothing must not go home under any circumstances
10)	Unanswered	Two pairs of powder free chemotherapy gloves (ASTM D6978 or successor) must be used when compounding.
11)	Unanswered	Changed every thirty (30) minutes, according to manufacturer recommendation, torn, punctured, or suspected contamination.
12)	Unanswered	Hands must be washed with soap and water after doffing gloves.
13)	Unanswered	Coated disposable gowns that are impermeable to liquids.
14)	Unanswered	a) Open in back.
15)	Unanswered	b) Long sleeved with cuffs.
16)	Unanswered	c) Changed per manufacturer’s information or every two (2) to three (3) hours.
17)	Unanswered	Head, hair and shoe covers that:
18)	Unanswered	a) Protect against HDs.
19)	Unanswered	b) Second pair of shoe covers donned before entering C-SEC and doffed before exiting C-SEC.
20)	Unanswered	Goggles:
21)	Unanswered	a) Worn when risk for spill or splashes outside of a C-PEC.
22)	Unanswered	b) Best practice – goggles with face shield.
23)	Unanswered	Respiratory protection:
24)	Unanswered	a) Fit-tested NIOSH certified N-95 respirator – sufficient but offers not protection from gases and vapors or direct splash.
25)	Unanswered	b) Evidence of fit testing for workers of N95 mask or other respirator by an occupational health practitioner.
26)	Unanswered	c) Full face-piece chemical cartridge respirator or Powered Air-Purifying Respirator (PAPR) should be worn when there is a risk of respiratory exposure to HD.
27)	Unanswered	Gloves and sleeve covers in C-PEC – removed and discarded in container or sealed bag before exiting C-PEC.
28)	Unanswered	All waste disposed of accordance with local, state and federal regulation.

Section D: BUILDING AND FACILITIES:

	Answer	Question
1)	Unanswered	Area is specifically designated for non-sterile compounding & method of designation is identified in facility SOP.
2)	Unanswered	Compounding space is well lighted.
3)	Unanswered	Clean, orderly, sanitary, in good repair. It allows for orderly placement of equipment and minimizes cross-contamination.
4)	Unanswered	Temperatures monitored daily and documented on temperature log. Documentation from electronic recording device must be retrievable.
5)	Unanswered	Temperature monitoring equipment is calibrated or verified per manufacturer recommendation (or every 12 months

Section D: BUILDING AND FACILITIES:

	Answer	Question
		if not specified).
6)	Unanswered	Compounding components, equipment, and containers are stored off the floor to prevent contamination and promote cleaning.
7)	Unanswered	Sink with hot and cold water is easily accessible.
8)	Unanswered	Sink is emptied of all items not related to compounding & cleaned when visibly soiled.
9)	Unanswered	Plumbing system free of defects that could contribute to the contamination of any CNSP.

Section D HD: USP <800> FACILITIES & ENGINEERING CONTROLS:

	Answer	Question
10)	Unanswered	HD Handling areas located away from breakrooms, refreshment areas for personnel, patients, or visitors.
11)	Unanswered	Designated areas for: receipts & unpacking of HD in neutral or negative pressure relative to surrounding areas.
12)	Unanswered	All HD API's and HDs requiring manipulation other than counting/repackaging of final dosage forms or reconstitution according to the manufacturer's directions in the FDA approved labeled stored in externally vented, negative pressure with 12ACPH (Non-antineoplastic, reproductive risk only, may be stored with other inventory if facility policy & Assessment of Risk allows).
13)	Unanswered	HDs stored off the floor in a manner that prevents spillage or container breakage in negative pressure with 12 ACPH. (e.g low to the floor; use of resealable plastic bag if appropriate for small container, etc).
14)	Unanswered	C-SEC where compounding activities occur and storage area for HDs is externally vented, physically separated, has minimum 12 ACPH, and negative pressure 0.01-0.03 in water column relative to adjacent areas.
15)	Unanswered	Facility has signs and spill kits readily available to identify and contain spills.

Section E: CLEANING AND SANITIZING:

	Answer	Question
16)	Unanswered	Work surfaces and floors are cleaned and sanitized at the beginning of each shift on days compounding occurs, after spills, and when contamination is known or suspected.
17)	Unanswered	Walls are visible soiled, after spills, and when contamination known or suspected.
18)	Unanswered	Ceilings cleaned and sanitized when visibly soiled or contaminated.
19)	Unanswered	Storage areas cleaned and sanitized quarterly.
20)	Unanswered	Cleaning and sanitizing agents must be selected and used with consideration of compatibilities, effectiveness, and to minimize the potential to leave residues. If performed as separated steps, cleaning occurs prior to sanitizing.

Section E HD: USP <800> DEACTIVATING, DECONTAMINATING, CLEANING, DISINFECTING:

	Answer	Question
21)	Unanswered	Reusable equipment and areas are deactivated, decontaminated, and cleaned according to facility's written procedures.
22)	Unanswered	Procedures include agents used, dilutions (if applicable), frequency, and documentation requirements.
23)	Unanswered	Agents used are compatible with facility surfaces and appropriate for the documented task(s) (List Agents used).
24)	Unanswered	C-PEC Deactivation, decontamination, and cleaning occurs daily and is documented.
25)	Unanswered	Underside of C-PEC work tray is deactivated and decontaminated, cleaned at least monthly and is documented.

Section F: EQUIPMENT AND COMPONENTS:

	Answer	Question
Equipment:		
1)	Unanswered	Equipment and supplies are suitable for the specific compounding process. Must not be reactive, additive, sorptive, or alter quality of non-sterile preparations. Storage prevents risk of contamination
2)	Unanswered	Equipment and devices used in compounding or testing compounded preparations are inspected before use and verified for accuracy per manufacturer recommendation or every 12 months, whichever is more frequent

Section F: EQUIPMENT AND COMPONENTS:

	Answer	Question
3)	Unanswered	Equipment is cleaned after each preparation to prevent cross-contamination
4)	Unanswered	Weighing, measuring, and manipulating components that could generate airborne particles is assessed to determine if the activity requires closed system processing device (e.g. CVE, BSC, or single-use containment glove bag). Must be documented.
5)	Unanswered	CVE or BSC is certified at least every 12 months
6)	Unanswered	CVE is cleaned and sanitized at the beginning and end of each shift, between compounds with different components, after spills, and when contamination is suspected.
7)	Unanswered	Equipment and devices are cleaned and sanitized before use, and between compounds using different components.
Components:		
8)	Unanswered	Compounding personnel follow SOP that addresses the selection, receipt, evaluation, handling, storage, and documentation of all CNSP components, including ingredients, containers, and closures.
9)	Unanswered	CNSP components meet the following criteria:
10)	Unanswered	a) An active ingredient in an FDA approved drug
11)	Unanswered	b) Comply with an applicable USP-NF monograph if one exists:
12)	Unanswered	c) Have a COA that includes specifications and testing results.
13)	Unanswered	d) Obtained from a registered FDA facility or selected from a acceptable reliable source.
14)	Unanswered	Certificates of Analysis (COA) are examined at the time of receipt of the API. Information from the COA is noted and used as appropriate in the compounding process to ensure quality compounds.
15)	Unanswered	The receipt date, quantity received, supplier name, lot number, expiration date, and any in-house or third-party testing performed must be documented for all components.
16)	Unanswered	Components are examined for deterioration and other aspects of unacceptable quality when received and re-inspected before use.
17)	Unanswered	Unacceptable components are clearly labeled and segregated for disposal.
18)	Unanswered	Date of receipt is marked or added on each API that lacks expiration date. An conservative expiration date that does not exceed 3 years is noted on API packaging.
19)	Unanswered	Components stored under appropriate conditions according to manufacture requirements.
20)	Unanswered	Facility maintains SDS and updates chemical hazard & disposal information every 12 months.
21)	Unanswered	Waste is disposed in accordance with applicable laws & regulations (e.g. USP 800, EPA, OSHA, etc).

Section F HD: USP <800> EQUIPMENT AND COMPONENTS

	Answer	Question
1)	Unanswered	USP <800>: C-PEC used for compounding HD CNSP is externally vented to the outside or has a redundant HEPA filter in series. The C-PEC is placed within the C-SEC under negative pressure.

Section G: MASTER FORMULATION AND COMPOUNDING RECORD:

	Answer	Question
Master Formulation Record:		
1)	Unanswered	Master Formulation Record created for each unique formulation CNSP.
2)	Unanswered	The Master formulation record includes name, strength, activity, and dosage form of CNSP.
3)	Unanswered	Identities and amounts of all components.
4)	Unanswered	Container Closure system
5)	Unanswered	Complete instructions for preparing the CNSP, including:
6)	Unanswered	Equipment
7)	Unanswered	Supplies
8)	Unanswered	Description of compounding steps

Section G: MASTER FORMULATION AND COMPOUNDING RECORD:

	Answer	Question
9)	Unanswered	Physical description for expected appearance of final CNSP.
10)	Unanswered	Assigned BUD and storage requirements with referenced sources.
11)	Unanswered	Calculation to determine and verify quantities and/or concentration of components.
12)	Unanswered	Labeling requirements
13)	Unanswered	QC procedures and expected results (pH testing, visual inspection)
14)	Unanswered	Other information needed to describe the compounding process (ie: adjusting pH and temperature, adjustment for assay, loss on drying of or waters of hydration of the API.)
15)	Unanswered	Source for stability-indicating study or USP monograph that allows extension of BUDs beyond <795> defaults. Make sure they are performing all required tests in the USP Compounded Preparation Monograph. (e.g. pH).
16)	Unanswered	Any changes or alterations to the MFR must be approved and documented according to facility's SOP.

Compounding Record:

17)	Unanswered	Compounding Record includes name, strength, activity, and dosage form of CNSP.
18)	Unanswered	Date and time of preparation of the CNSP.
19)	Unanswered	Assigned identification number (Rx number, Lot number, order number, etc).
20)	Unanswered	Identity of personnel involved in compounding and verifying the CNSP.
21)	Unanswered	Name, vendor or manufacturer, lot number, and expiration date of each component.
22)	Unanswered	Weigh or measurement of each component.
23)	Unanswered	Total quantity compounded.
24)	Unanswered	Assigned BUD and storage requirements.
25)	Unanswered	Physical description of appearance for final CNSP.
26)	Unanswered	QC results (pH testing and visual inspection).
27)	Unanswered	Master Formulation Reference.

Section H: RELEASE INSPECTION:

	Answer	Question
1)	Unanswered	1. CNSP visually inspected to determine physical appearance meet expectations.
2)	Unanswered	2. Checks, inspections, and test conducted in accordance to the Master Formulation Record.
3)	Unanswered	3. Checks, inspections, and test documented in Compounding Record.
4)	Unanswered	4. Pre-Release inspection includes visual inspection of container closure integrity (ie: check of leakage, cracks, or improper packaging).
5)	Unanswered	5. Inspection confirm the CSNP and its label match Compounding Record and prescription order.

Section I: LABELING:

	Answer	Question
1)	Unanswered	Labeling for each CNSP contains at minimum:
2)	Unanswered	a) Identification number (ie: prescription number, lot number, barcode).
3)	Unanswered	b) Active components, amounts, activities, or concentrations (no abbreviations).
4)	Unanswered	c) Dosage form.
5)	Unanswered	d) Amount or volume in each container.
6)	Unanswered	e) Storage condition if other than controlled room temperature.
7)	Unanswered	f) Beyond Use Date.
8)	Unanswered	g) Route of administration.
9)	Unanswered	h) Indication that the preparation is compounded.
10)	Unanswered	i) Any special handling instructions.

Section I: LABELING:

	Answer	Question
11)	Unanswered	j) Any warning statements if applicable.
12)	Unanswered	k) Name, address, and contact information of the compounding facility if the CNSP is to be sent outside of a healthcare facility.
13)	Unanswered	l) Compounded medications for Veterinary application labeled to indicate “Veterinary Use”.
14)	Unanswered	Labeling procedures followed as described in facility SOP to prevent mix-ups and errors.
15)	Unanswered	Label verified to ensure it conforms to prescription/medication order, MFR, and compounding record.

Section I HD: USP <800>

	Answer	Question
1)	Unanswered	HD handling precautions must be clearly labeled at all times during transport.
2)	Unanswered	Personnel ensure that the labeling process for compounded preparation do not introduce contamination into the non-HD areas.

Section J: ESTABLISHING BEYOND USE DATING:

	Answer	Question
Parameters for Establishing a BUD:		
1)	Unanswered	The chemical and physical stability properties of the API and any added substance in the preparation (e.g. if the API and added substance in the preparation are known to degrade over time and/or under certain storage conditions, which would reduce strength and/or produce harmful impurities).
2)	Unanswered	The compatibility of the container closure system with the finished preparation (e.g. leachables, interactions, adsorption, and storage conditions.
3)	Unanswered	Degradation of the container closure system, which can lead to reduction in integrity of the CNSP.
4)	Unanswered	The potential for microbial proliferation in the CNSP.
BUD limits in absence of a USP-NF Compound monograph or specific stability information or BUDs that are known to be shorter due to instability:		
5)	Unanswered	Non-preserved aqueous (water activity greater than 0.60) dosage form BUD is 14 days refrigerated.
6)	Unanswered	Preserved aqueous dosage form BUD is 35 days at controlled room temperature or refrigerated.
7)	Unanswered	Nonaqueous dosage form (water activity less than 0.6) BUD is 90 days at controlled room temperature or refrigerated.
8)	Unanswered	Solid dosage forms BUD is 180 days at controlled room temperature or refrigerated.
Shorter Beyond Use Dates:		
9)	Unanswered	If the API or any other components in the CNSP have an expiration date that is earlier than the BUD that could be assigned in the absence of a USP-NF compounded preparation monograph or CNSP- specific stability information., the expiration date supersedes the BUD and must be the assigned shortest date.
10)	Unanswered	If the CNSP includes components from conventionally manufactured products, the BUD of the CNSP must not exceed the shortest remaining expiration date of any of those products.
11)	Unanswered	If the CNSP includes components from other compounded preparations, the BUD of the final CNSP must not exceed the shortest remaining BUD of any of those compounded preparations.
12)	Unanswered	If the formulation is known to require a shorter BUD.
Extended Beyond Use Dates:		
13)	Unanswered	If there is a USP-NF compounded preparation monograph for the CNSP, the BUD must not exceed the BUD specified in the monograph.
14)	Unanswered	The BUD for aqueous dosage forms and nonaqueous dosage forms may be extended up to a maximum of 180 days if there is a stability study (Stability indicating assay USP <1163> Potency over time not acceptable).
15)	Unanswered	Aqueous formulations that are extended must be tested for antimicrobial effectiveness (USP<51>).
16)	Unanswered	When using peered reviewed source compounding process must follow all aspects documented in source to include exact ingredients and container closures and tests performed.

Section K: QUALITY ASSURANCE AND QUALITY CONTROL:

	Answer	Question
1)	Unanswered	Facility has written SOP Quality Assurance and Quality Control Program for non-sterile compounding procedures. The Program must be able to identity the following:
2)	Unanswered	a) That procedures were followed
3)	Unanswered	b) Prevention and Detection of Errors and other quality problems.
4)	Unanswered	c) Evaluation of Complaints and Adverse Events with documentation.
5)	Unanswered	d) Appropriate Investigations and Corrective Actions
6)	Unanswered	Facility has a designated person(s) responsible for QA and QC program for non-sterile compounding.
7)	Unanswered	Designated QA and QC person has documented training for non-sterile compounding.
8)	Unanswered	QA and QC program reviewed annually and documented.

Section L: CNSP PACKAGING AND TRANSPORTING

	Answer	Question
9)	Unanswered	SOP for packaging CNSPs.
10)	Unanswered	Materials used for packaging maintain physical and chemical integrity and stability of the CNSPs.
11)	Unanswered	Materials used for packaging protect the CNSPs from damage, leakage, contamination, and degradation.

Section L HD: USP <800>

	Answer	Question
12)	Unanswered	Packaging materials must protect the healthcare worker from exposure.
13)	Unanswered	Facility does not use pneumatic tubes to transport HDs.

Section M: COMPLAINT HANDLING AND ADVERSE EVENT REPORTING:

	Answer	Question
14)	Unanswered	Facility has an SOP for Complaint handling and adverse Event reporting.
15)	Unanswered	Facility has a designated person who is responsible for reviewing complaints to determine if the complaint indicates a potential quality problem with CNSP.
16)	Unanswered	Facility does an investigation into the complaint if a quality problem is identified.
17)	Unanswered	Facility has a readily retrievable record-keeping system of all complaints with CNSPs that include
18)	Unanswered	a) name of patient,
19)	Unanswered	b) prescription number,
20)	Unanswered	c) name and strength of CNSP,
21)	Unanswered	d) date of complaint,
22)	Unanswered	e) nature of complaint,
23)	Unanswered	f) results of the investigation and follow up.
24)	Unanswered	The compounding record permits traceability, and the facility can initiate recall.

Section A: IMMEDIATE USE CSP:

	Answer	Question
1)	Unanswered	The facility has an SOP that describes CSPs made for immediate use and includes information on how to avoid contamination and mix-ups.
2)	Unanswered	Aseptic Technique, processes, and procedures are followed.
3)	Unanswered	Prepared using evidence that proves the CSP is stable up to BUD or for 4 hours (e.g. package insert, Trissell's, stability studies) whichever is less.
4)	Unanswered	Prepared with no more than 3 different sterile products.
5)	Unanswered	Single-dose containers are not used on more than one patient . unused single-dose components are discarded after preparation.
6)	Unanswered	CSPs are administered within 4 hours of the start of preparation.

Section A: IMMEDIATE USE CSP:

	Answer	Question
7)	Unanswered	Unless directly administered by the person who prepared the immediate use CSP, the CSP is labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the exact 4-hour time period within which administration must begin.
8)	Unanswered	A compounding record for immediate use CSPs that are made for more than one patient.

Section A HD: USP <800>

	Answer	Question
1)	Unanswered	For Immediate Use HD CSPs USP <800> requirements are followed.

Section B: PERSONNEL TRAINING AND EVALUATION:

	Answer	Question
Demonstrate Knowledge and Competency of Core Skills		
1)	Unanswered	Facility has a written SOP for knowledge and competency of core skills. Personnel are able to demonstrate knowledge of principles and competency of skills for performing sterile manipulations that include:
2)	Unanswered	a) Hand hygiene
3)	Unanswered	b) Garbing
4)	Unanswered	c) Cleaning and disinfection
5)	Unanswered	d) Calculations, measuring, and mixing
6)	Unanswered	e) Aseptic technique
7)	Unanswered	f) Achieving and/or maintaining sterility and apyrogenicity
8)	Unanswered	g) Use of equipment
9)	Unanswered	h) Documentation of the compounding process (e.g., master formulation and compounding records)
10)	Unanswered	i) Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area
11)	Unanswered	j) Proper use of primary engineering controls (PECs)
12)	Unanswered	k) Principles of movement of materials and personnel within the compounding area
13)	Unanswered	Documentation present for initial training and competency assessment of skills for compounding personnel or personnel who have direct oversight.
14)	Unanswered	Documentation present for training and competency completed every 12 months.
15)	Unanswered	Documentation present for training and competency for any other personnel accessing the compounding area (e.g cleaning staff/companies).
Garbing and Hand Hygiene Competency		
16)	Unanswered	Facility has SOP for Garbing and Hand Hygiene Competency which includes procedures, documentation, incubation, and interpreting results.
17)	Unanswered	Garbing and Hand Hygiene Competency (Gloved Fingertip Testing) observed and documented for compounding personnel or personnel who have direct oversight initially in the classified area or Segregated Compounding Area (SCA).
18)	Unanswered	Hand Hygiene, Garbing, and Gloved Fingertip Testing is completed three (3) separate times in succession.
19)	Unanswered	All failures of Gloved Fingertip Testing documented along with corrective action taken that includes retesting the entire process.
20)	Unanswered	Documentation must include:
21)	Unanswered	a) Name of the person evaluated.
22)	Unanswered	b) Evaluation date/time.
23)	Unanswered	c) Manufacturer, lot, and expiration numbers of media and components used.
24)	Unanswered	d) Incubation temperature intervals (30-35 degrees C for first 48 hours 20-25 degrees C for no less than 5 days) .
25)	Unanswered	e) Dates of incubation.
26)	Unanswered	f) Results.

Section B: PERSONNEL TRAINING AND EVALUATION:

	Answer	Question
27)	Unanswered	g) Name of observer and the person who reads/documents the results.
28)	Unanswered	All failures of Gloved Fingertip Testing documented along with corrective action taken that includes retesting the entire process.
29)	Unanswered	Garbing and Gloved Fingertip observations and testing are completed every six (6) months in the classified areas or SCA.
30)	Unanswered	Garbing and GFT observations and testing are completed every three (3) months.

Aseptic Manipulation Competency Testing

31)	Unanswered	Facility has SOP for Aseptic Manipulation Competency Testing which includes procedures, documentation, incubation, and interpreting results.
32)	Unanswered	Aseptic Manipulation Competency which included observation, media fill testing, gloved fingertip testing, and surface sampling performed initially for compounding personnel or personnel who have direct oversight.
33)	Unanswered	Testing simulates the most challenging compounding procedures.
34)	Unanswered	Documentation includes:
35)	Unanswered	a) Name of the person evaluated.
36)	Unanswered	b) Evaluation date/time.
37)	Unanswered	c) Manufacturer, lot, and expiration numbers of media and components used.
38)	Unanswered	d) Incubation temperature intervals (20-25 degrees C for 7 days then 30-35 degrees C for 7 days).
39)	Unanswered	e) Dates of incubation.
40)	Unanswered	f) Results.
41)	Unanswered	g) Name of observer and the person who reads/documents the results.
42)	Unanswered	All failures of the Aseptic Manipulation Competency Testing documented along with corrective action taken that includes retesting the entire process.
43)	Unanswered	Certificate of Analysis is present for commercial growth media.
44)	Unanswered	In-house media demonstrates growth promotion in accordance with USP<71>.
45)	Unanswered	Aseptic Manipulation Competency is completed every 6 months.
46)	Unanswered	Aseptic Manipulation Competency is completed every 3 months.

Section B HD: USP <800> TRAINING PROGRAM

	Answer	Question
1)	Unanswered	Facility has a written Training Program and Competency assessment which includes:
2)	Unanswered	a. Review of facility’s HD list, dosage form, and risks .
3)	Unanswered	b. Review of facility’s SOPs related to HDs.
4)	Unanswered	c. Proper Use of PPE.
5)	Unanswered	d. Proper use of equipment and devices (e.g engineering controls).
6)	Unanswered	e. Response to HD exposure – known or suspected.
7)	Unanswered	f. Spill Management.
8)	Unanswered	g. Proper disposal of HDs and trace-contaminated materials.
9)	Unanswered	h. Personnel of reproductive capability must confirm in writing that they understand the risk of handling HDs.
10)	Unanswered	Initial and annual training documentation present for all personnel who handle HDs observed by Designated Person or Assigned Trainer, with proficiency demonstrated every twelve (12) months.

Section C: PERSONAL HYGIENE AND GARBING:

	Answer	Question
1)	Unanswered	Facility has written SOP on personal hygiene and garbing procedure logically based on location of hand hygiene sink (e.g. outside of ante room, dirty side of ante room, clean side of ante room).

Section C: PERSONAL HYGIENE AND GARBING:

	Answer	Question
2)	Unanswered	Prior to entering a compounding area, staff:
3)	Unanswered	a. Removes personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests).
4)	Unanswered	b. Removes all cosmetics because they shed flakes and particles.
5)	Unanswered	c. Removes all hand, wrist, and other exposed jewelry including piercings. Cover any jewelry that cannot be removed.
6)	Unanswered	d. Not wear earbuds or headphones.
7)	Unanswered	e. Not bring electronic devices that are not necessary for compounding or other required tasks into the compounding area.
8)	Unanswered	f. Keep nails clean and neatly trimmed to minimize particle shedding and avoid glove punctures. Nail products (e.g. polish, artificial nails, and extenders) must not be worn.
9)	Unanswered	g. Wipe eyeglasses, if worn
10)	Unanswered	h. Documentation by designated person for any permissible excursion that do not compromise the quality of the classified environment.
11)	Unanswered	Hand Hygiene:
12)	Unanswered	a. Wash hands and forearms up to the elbows, for at least 30 seconds, using soap containers that cannot be refilled.
13)	Unanswered	b. Use of nail picks.
14)	Unanswered	c. No scrub brush used in hand hygiene.
15)	Unanswered	d. Dry hands and elbows using low-lint towels or wipes (no hand dryers).
16)	Unanswered	e. Hands sanitized with alcohol based hand rub.
17)	Unanswered	Facility SOPs for hand hygiene/garbing address cleanroom suite sink placement
18)	Unanswered	Facility has SOP for garbing order and garbing materials.
19)	Unanswered	Garbing materials if Category 1 or 2 include
20)	Unanswered	a. Face mask and Beard cover, if applicable.
21)	Unanswered	b. Low-lint garb such as gowns/coveralls, disposable covers for shoes, head, and facial hair.
22)	Unanswered	Garbing Materials for Category 3 include:
23)	Unanswered	a. Face Mask and Beard Cover, if applicable
24)	Unanswered	b. Low lint garb that is sterile and not reused without resterilization.
25)	Unanswered	c. No exposed skin (fully garbed).
26)	Unanswered	Gloves must be powder free and sterile, donned inside SCA or Classified area.
27)	Unanswered	a. Sterile 70% IPA applied regularly throughout the compounding process.
28)	Unanswered	RABS (CACI and CAI) – Disposable gloves worn inside gloves attached to RABS sleeves, and sterile gloves donned over gloves attached to RABS.
29)	Unanswered	RABS sleeves changed per manufacturers' recommendations/SOPs.

Section C HD: USP <800>: Personal Protective Equipment:

	Answer	Question
1)	Unanswered	Facility has written SOPs for PPE use based on the risk of exposure and activities performed.
2)	Unanswered	a. Receipt
3)	Unanswered	b. Storage
4)	Unanswered	c. Transport
5)	Unanswered	d. Compounding (sterile and nonsterile)
6)	Unanswered	e. Deactivation/decontamination, cleaning, and disinfecting
7)	Unanswered	f. Spill Control
8)	Unanswered	g. Waste disposal

Section C HD: USP <800>: Personal Protective Equipment:

	Answer	Question
9)	Unanswered	Two pairs of powder-free chemotherapy gloves (ASTM D6978 or successor) must be used when compounding with the outer pair sterile when performing sterile compounding.
10)	Unanswered	a. Gloves are changed every thirty (30) minutes or according to the manufacturer's recommendation.
11)	Unanswered	b. Hands must be washed with soap and water after doffing gloves.
12)	Unanswered	Coated disposable gowns.
13)	Unanswered	a. Open in back
14)	Unanswered	b. Long-sleeved with cuffs
15)	Unanswered	c. Changed per manufacturer's information or every two (2) to three (3) hours or immediately after spill/splash
16)	Unanswered	Contaminated clothing must not go home under any circumstances.
17)	Unanswered	Head, hair, and shoe covers
18)	Unanswered	a. Protect against contact with HD residues
19)	Unanswered	b. Second pair of shoe covers donned before entering C-SEC and doffed before exiting C-SEC
20)	Unanswered	Goggles
21)	Unanswered	a. Must be worn when the risk for spill or splashes outside of a C-PEC
22)	Unanswered	b. Best practice – goggles with face shield

Section D: FACILITIES AND ENGINEERING CONTROLS:

	Answer	Question
Segregated Compounding Area (SCA)		
1)	Unanswered	The SCA and all surfaces in the SCA are clean, uncluttered, and dedicated to compounding.
2)	Unanswered	Surfaces are smooth, impervious, free from cracks and crevices, easily cleanable, and resistant to damage from cleaning and disinfecting agents.
3)	Unanswered	SCA is located away from unsealed windows and doors that connect to the outside and away from high-traffic flow areas. Must not be near restrooms, warehouses, or food preparation areas.
4)	Unanswered	SCA has a visible perimeter.
5)	Unanswered	SCA is clear of free-standing humidifiers/dehumidifiers or air conditioners .
6)	Unanswered	Sink located more than 1 meter from PEC .
Cleanroom Suite (Buffer and Ante Rooms)		
7)	Unanswered	ISO-classified Anterooms and buffer rooms are separated from unclassified areas by fixed walls, doors, etc.
8)	Unanswered	Buffer room maintains at least ISO 7 air quality.
9)	Unanswered	Anteroom providing access to a positive pressure ISO 7 buffer room maintains at least ISO 8.
10)	Unanswered	Anteroom providing access to a negative pressure ISO 7 buffer room maintains at least ISO 7.
11)	Unanswered	Primary Engineering Control (PEC) is located within ISO 7 positive pressure, provides unidirectional HEPA-filtered airflow, and maintains ISO 5 or better air quality during dynamic operating conditions.
12)	Unanswered	Sterile compounding facilities are well-light and comfortable (USP<1066>)
13)	Unanswered	Temperature and Humidity are monitored and documented in each room of the cleanroom suite each day compounding is performed (should maintain 20 degrees C or cooler and relative humidity below 60% to provide comfortable conditions for personnel who are garbed).
14)	Unanswered	Electronic documentation of Temperature and Humidity must be retrievable.
15)	Unanswered	Temperature and Humidity readings reviewed per facility SOPs.
16)	Unanswered	ISO-classified areas are clear of free-standing humidifiers/dehumidifiers or air conditioners
17)	Unanswered	Air supplied to the cleanroom suite is introduced by HEPA filters located in the ceilings of ante and buffer rooms.
18)	Unanswered	Air returns are located low on wall.
19)	Unanswered	a. Visual smoke study demonstrates no stagnant airflow if returns are not located low on walls.
20)	Unanswered	b. Visual smoke study and environmental monitoring is repeated when equipment placement is changed, HVAC

Section D: FACILITIES AND ENGINEERING CONTROLS:

	Answer	Question
		alterations are made, or HEPA filters are changed .
21)	Unanswered	All ISO classified rooms are equipped with pressure-differential monitoring, and electronic records are readily retrievable.
22)	Unanswered	Room pressures are documented at least daily.
23)	Unanswered	Room pressures are reviewed at least daily.
24)	Unanswered	Minimum 0.020-inch water column positive pressure differential between buffer room and anteroom.
25)	Unanswered	Pressure differential between anteroom and unclassified area not less than 0.020-inch water column .
26)	Unanswered	Anteroom has a line of demarcation that indicates a clean side for garbing.
27)	Unanswered	Procedures are in place to minimize the influx of lower-quality air ISO-classified areas.
28)	Unanswered	Both doors of pass-throughs are not opened at the same time.
29)	Unanswered	No tacky mats in ISO-classified areas.
30)	Unanswered	If compounding both sterile and nonsterile preparations (e.g weighing and mixing):
32)	Unanswered	a. PECs must be placed in separate rooms unless ISO 7 can be continuously maintained.
33)	Unanswered	b. If in the same room, respective PECs for sterile and nonsterile must be 1 meter apart and no particle-generating activities occur during sterile compounding.
34)	Unanswered	Surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, worksurfaces, counters, and cabinets in classified areas are smooth, impervious, free from cracks and crevices, and non-shedding.
35)	Unanswered	Anteroom does not contain a floor drain.
36)	Unanswered	Buffer room does not include plumbed water sources (sinks, eye washes, showers or floor drains)
37)	Unanswered	All surfaces are resistant to damage by cleaning agents, disinfectants, sporicidal agents, and tools used for cleaning.
38)	Unanswered	Walls are constructed of or covered with durable material (e.g. epoxy painted walls, heavy-gauge polymers)
39)	Unanswered	Junctures between ceilings and walls, and walls and floors are sealed to eliminate cracks and crevices.
40)	Unanswered	Floors include coving to the sidewall or juncture between floor and wall is caulked
41)	Unanswered	Ceiling panels caulked on all sides.
42)	Unanswered	Dust-collecting overhangs, pipes, and/or ledges are minimized. All such areas are easily cleanable, and cleaning is documented.
Facilities Preparing CSPs from Nonsterile Ingredients/Components:		
43)	Unanswered	Weighing and mixing before sterilization completed in ISO 8 or better environment (e.g. anteroom or buffer room) and in a single-use containment glove bag, containment ventilated enclosure (CVE), BSC, or CACI.
44)	Unanswered	CVE, BSC, CACI used for weighing and mixing must be certified at least every six months.
45)	Unanswered	Secondary engineering control used for weighing and mixing is certified under dynamic conditions.
Placement and Movement of Materials:		
46)	Unanswered	Classified area or SCA contain only furniture, equipment, and materials necessary for compounding which are low-shedding, promote easy cleaning & disinfecting, and do not impact environmental air quality
47)	Unanswered	Equipment removed from the classified area or SCA is cleaned and wiped with SIPA (or appropriate disinfectant) before returning to the area. (Should not be removed except for calibration, servicing, or required maintenance activity).
48)	Unanswered	No cartons, corrugated cardboard, or uncoated cardboard in classified areas or SCA
49)	Unanswered	Carts or equipment in classified areas are non-porous with cleanable casters and wheels. Carts do not cross to the opposite side of the line of demarcation unless the entire cart is cleaned and disinfected.
50)	Unanswered	Only equipment necessary for compounding is located in the PEC. Placement is verified by a dynamic airflow smoke pattern test initially and repeated if the equipment is moved.

Section D HD: USP <800> FACILITIES & ENGINEERING CONTROLS:

	Answer	Question
1)	Unanswered	HD Handling areas located away from breakrooms, and refreshment areas for personnel, patients, or visitors.

Section D HD: USP <800> FACILITIES & ENGINEERING CONTROLS:

	Answer	Question
2)	Unanswered	Designated areas for: receipts & unpacking of HD in neutral or negative pressure relative to surrounding areas.
3)	Unanswered	HDs stored off the floor in a manner that prevents spillage or container breakage in negative pressure with 12 ACPH.
4)	Unanswered	Refrigerated antineoplastic HDs stored in a dedicated refrigerator in negative pressure with at least 12 ACPH (consideration of exhaust adjacent to refrigerator compressor).
5)	Unanswered	Facility has signs and spill kits readily available to identify and contain spills.
6)	Unanswered	C-PECs used for sterile compounding are externally vented and maintain ISO 5 or better-quality air (e.g. Class II BSC, Class III BSC, or CACI; Class II BSC types A2, B1, B2, and C acceptable).
7)	Unanswered	ISO 5 C-PEC is located in ISO 7 C-SEC with ISO 7 anteroom.
8)	Unanswered	ISO 7 Buffer is externally vented with fixed walls, HEPA filtered air with minimum 30 ACPH, and negative pressure -0.01 to -0.03 inches water column relative to all adjacent areas.
9)	Unanswered	ISO 7 anteroom has fixed walls, HEPA filtered air with minimum 30 ACPH, and positive pressure at least 0.02 inches water column relative to adjacent unclassified areas.
10)	Unanswered	ISO 7 handwashing sink is at least 1 meter away from ISO 7 buffer entry.
11)	Unanswered	Facility has negative pressure HD buffer entered from positive pressure non-HD buffer
14)	Unanswered	C-SCA is externally vented, has fixed walls, negative pressure between 0.01 and 0.03 in water column relative to all adjacent areas, and min 12 ACPH. The handwashing sink must be at least 1 meter away from C-PEC.
15)	Unanswered	Non-HD preparations made in BSC or CACI used for HD compounding are placed in protective wrappers and labeled to require PPE handling precautions.
CONTAINMENT SUPPLEMENTAL ENGINEERING CONTROLS		
16)	Unanswered	CSTD used if it is physically and chemically compatible with the HD.

Section E: CERTIFICATION AND RECERTIFICATION:

	Answer	Question
1)	Unanswered	PEC is certified initially and every six months under dynamic conditions.
2)	Unanswered	Certification report contains Airflow Testing, HEPA Filter Integrity Testing, Total Particle Count Testing, and Dynamic Airflow Smoke Pattern Test
3)	Unanswered	Certification report contains Airflow Testing, HEPA Filter Integrity Testing, Total Particle Count Testing, Dynamic Airflow Smoke Pattern Test, and when applicable, manufacturer specifications.
4)	Unanswered	All ISO Classified rooms and PECs are certified initially, at least every six months, and when changes occur (e.g. redesign, construction, relocation and/or replacement of PECs and any changes affecting airflow or air quality).
5)	Unanswered	Airflow testing is performed and documented under dynamic operating conditions.
6)	Unanswered	ISO 7 rooms maintain ≥ 30 ACPH during dynamic operating conditions.
7)	Unanswered	Minimum of 15 ACPH are supplied by HVAC via ceiling HEPA filters.
8)	Unanswered	PEC used to meet minimum ACPH is not turned off except for maintenance (rooms & PEC must be recertified following maintenance).
9)	Unanswered	Total ACPH, ACPH contributed from PEC, and ACPH from HVAC are documented in the certification report
10)	Unanswered	ISO 8 rooms maintain ≥ 20 ACPH during dynamic operating conditions.
11)	Unanswered	HEPA filter integrity testing is performed after installation and as part of recertification.
12)	Unanswered	Total Particle Count Testing is performed under dynamic conditions using calibrated equipment.
13)	Unanswered	ISO 8 ≤ 3,520,000
14)	Unanswered	ISO 7 ≤ 352,000
15)	Unanswered	ISO 5 ≤ 3,520
16)	Unanswered	All sampling sites and procedures are documented in facility SOPs
17)	Unanswered	Dynamic airflow smoke pattern tests performed in each PEC and demonstrated unidirectional airflow and sweeping action over & away from preparations (Video documentation required).

Section E: CERTIFICATION AND RECERTIFICATION:

	Answer	Question
18)	Unanswered	Number of personnel in PECs and SECs during total particle counts & dynamic smoke pattern tests are documented.
19)	Unanswered	Certification and recertifications are reviewed by the designated person(s).
20)	Unanswered	Corrective Action Plan is documented in response for out-of-range results. Corrective Actions are reviewed for effectiveness and documented.

Section F: MICROBIAL AIR AND SURFACE MONITORING:

	Answer	Question
1)	Unanswered	Facility has developed and implemented written SOPs for microbiological air and surface monitoring
2)	Unanswered	A diagram of sampling locations is included in SOP
3)	Unanswered	Procedures for collecting samples included in SOP
4)	Unanswered	Size of samples (e.g. surface area, volume of air) is defined in SOP
5)	Unanswered	Time of day of sampling is included in SOP
6)	Unanswered	CFU counts that trigger corrective action
7)	Unanswered	a. Air (ISO 5 > 1/ISO 7 >10/ISO 8 >100)
8)	Unanswered	b. Surface (ISO 5 >3/ISO 7 >5/ISO 8 >50)
9)	Unanswered	The facility documents all microbiological air and surface monitoring test results
10)	Unanswered	Results are reviewed along with personnel data to assess state of control and identify potential risks for contamination
11)	Unanswered	Corrective action taken is documented in response to out-of-range results.
12)	Unanswered	Corrective actions are reviewed for effectiveness when completed and documented.
13)	Unanswered	Impaction samplers are serviced and calibrated as recommended by the manufacturer.
14)	Unanswered	Facility has access to C of A for media used during sampling.
15)	Unanswered	Facility personnel who perform sampling are trained and demonstrate competency in air and surface sampling .
		Monitoring Air Quality for Viable Airborne Particles:
16)	Unanswered	Volumetric active air sampling is performed at least every six months in all classified areas (ISO 5 PEC, ISO 7 and 8 rooms) during dynamic operating conditions.
17)	Unanswered	Volumetric active air sampling is performed within 30 days prior to starting Category 3 compounding and at least monthly in all classified areas (ISO 5 PEC, ISO 7 and 8 rooms) during dynamic operating conditions regardless of the frequency of Category 3 compounding.
18)	Unanswered	Volume of air sampled is 1 cubic meter (1000 L) for each sample location.
19)	Unanswered	Action levels for Viable Airborne Particles Sampling:
20)	Unanswered	a. >1 CFU for ISO 5 PECs;
21)	Unanswered	b. >10 CFU for ISO 7 rooms;
22)	Unanswered	c. >100 for ISO 8 rooms
23)	Unanswered	CFUs exceeding action levels are identified to the genus level (USP <1113>) and corrective actions documented.
24)	Unanswered	Results are reviewed and documented as described in facility SOPs.
25)	Unanswered	Does Facility Perform its own Viable Air Samples?
33)	Unanswered	C of A from media manufacturer verifies expected growth promotion, pH, and sterilization requirements.
34)	Unanswered	Media supports growth of bacteria and fungi.
		Monitoring Surfaces for Viable Particles:
35)	Unanswered	Surface sampling is performed at least monthly for all classified areas (ISO 5 PECs, ISO 7 and 8 rooms) and pass-throughs.
36)	Unanswered	Surface Sampling is performed on a regular schedule at least weekly for all classified areas (ISO 5 PECs, ISO 7 and 8 rooms) and pass-throughs (see USP<1116>: and

Section F: MICROBIAL AIR AND SURFACE MONITORING:

	Answer	Question
37)	Unanswered	Surface Sampling is performed for all classified areas (ISO 5 PECs, ISO 7 and 8 rooms) and pass-throughs before assigning a BUD longer than the limits set in Table 13
38)	Unanswered	Surface sampling is conducted in the PEC at the end of each batch before cleaning and disinfection occur (unless a self-enclosed robotic device is used)
39)	Unanswered	Surface sampling is conducted at least once daily at the end of compounding operations and before cleaning and disinfection for any PEC that is a self-enclosed robotic device
40)	Unanswered	All sampling sites and procedures are described in facility SOPs.
41)	Unanswered	Action Levels for Surface Sampling:
42)	Unanswered	a. >3 CFU for ISO 5 PECs;
43)	Unanswered	b. >5 CFU for ISO 5 rooms;
44)	Unanswered	c. >50 for ISO 8 rooms.
45)	Unanswered	CFU exceeding action levels are identified to the genus level (USP <1113>) and corrective action is documented.
46)	Unanswered	Results are reviewed and documented as described in facility SOPs
47)	Unanswered	Does perform its own Viable Surface Sampling?

Section G : CLEANING, DISINFECTING, AND APPLYING SPORICIDAL AGENTS IN COMPOUNDING:

	Answer	Question
1)	Unanswered	Surfaces are cleaned prior to being disinfected unless an EPA registered one step disinfectant cleaner is used to accomplish both cleaning and disinfection in one step.
2)	Unanswered	A sporicidal agent is applied to destroy bacterial and fungal spores.
3)	Unanswered	Cleaning and disinfecting surfaces and applying a sporicidal occurs at the minimum frequencies as described in the facility's SOP or, if compounding is not performed daily, cleaning and disinfecting is completed before initiating compounding.
4)	Unanswered	All cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility-approved agents and procedures, which is described in SOPs. Personnel are trained if there is any changes in the cleaning and disinfecting procedures.
5)	Unanswered	Cleaning is performed in the direction of clean to dirty areas. The frequency, method(s), and location(s) of cleaning, disinfecting, and sporicidal agent use is established in written SOPs, in accordance with the manufacturer's instructions, and followed by all cleaning personnel.
6)	Unanswered	All cleaning, disinfecting, and application of sporicidal agents is documented accordingly to facility SOPs.
		Daily Cleaning, Disinfecting, and applying Sterile IPA
7)	Unanswered	Equipment and all interior surfaces of the PEC and when surface contamination is known or suspected.
8)	Unanswered	The surface of the workbench tray inside PEC.
9)	Unanswered	Pass-through(s), Floor(s), and work surfaces(s) outside the PEC.
10)	Unanswered	Apply sterile 70% IPA to the horizontal work surface at least every 30 minutes if the compounding process takes 30 minutes or less.
11)	Unanswered	a. If the compounding process takes longer than 30 minutes, compounding not disrupted and the work surface of the PEC is disinfected immediately after compounding.
		Monthly Cleaning and Disinfecting
12)	Unanswered	Floor(s)Wall(s), door(s), door frame(s), and ceiling(s).
13)	Unanswered	Storage shelving and bins.
14)	Unanswered	Equipment outside the PEC(s).
15)	Unanswered	Underside of the workbench tray inside the PEC.
		Applying Sporicidal- Monthly
16)	Unanswered	PEC(s) and equipment inside the PEC(s)
17)	Unanswered	Surface of the workbench tray

Section G : CLEANING, DISINFECTING, AND APPLYING SPORICIDAL AGENTS IN COMPOUNDING:

	Answer	Question
18)	Unanswered	All surfaces and the area underneath the workbench tray
19)	Unanswered	Pass-Through(s)
20)	Unanswered	Work surfaces outside the PEC
21)	Unanswered	Floor(s)Wall(s), door(s), door frame(s), and ceiling(s)
22)	Unanswered	Storage shelving and bins
23)	Unanswered	Equipment outside the PEC(s)
Cleaning Supplies		
24)	Unanswered	All cleaning supplies (e.g., wipers, sponges, and mop heads) with the exception of tool handles and holders are low lint.
25)	Unanswered	Cleaning supplies used in PEC must be sterile.
26)	Unanswered	If disposable cleaning supplies are used, they are discarded after each cleaning activity.
27)	Unanswered	Reusable cleaning tools are made of cleanable materials (e.g., no wooden handles) and cleaned and disinfected before and after each use.
28)	Unanswered	Reusable cleaning tools are dedicated for use in the classified areas or SCA and not removed from these areas except for disposal.
29)	Unanswered	Cleaning, disinfecting, and sporicidal agents used in the PEC must be sterile.

Section G HD: USP <800> DEACTIVATING, DECONTAMINATING, CLEANING, DISINFECTING

	Answer	Question
1)	Unanswered	Reusable equipment and areas are deactivated, decontaminated, and cleaned according to facility's written procedures
2)	Unanswered	Procedures include agents used, dilutions (if applicable), frequency, and documentation requirements
3)	Unanswered	Agents used are compatible with facility surfaces and appropriate for the documented task(s) (List Agents used)
4)	Unanswered	C-PEC Deactivation, decontamination, and cleaning occurs daily and is documented
5)	Unanswered	C-PEC work tray is deactivated and decontaminated, cleaned at least monthly and is documented

Section H: INTRODUCING ITEMS INTO THE SEC AND PEC:

	Answer	Question
6)	Unanswered	All items are wiped with a sporicidal agent, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipes before they are introduced to the clean side of ante-rooms, pass-throughs, or brought inside the perimeter of the SCA. (Must adhere to contact time for sporicidal/disinfectant; sterile 70% IPA must be allowed to dry).
7)	Unanswered	All items are wiped with sterile 70% IPA and allowed to dry before entry to the PEC.
8)	Unanswered	Critical sites (e.g. vial stoppers, ampule necks, IV bag septum) are wiped with sterile 70% IPA is allowed to dry before entering or puncturing the container.
9)	Unanswered	Wiping of items does not render product labels unreadable.

Section I: EQUIPMENT, SUPPLIES, AND COMPONENTS:

	Answer	Question
Equipment and Supplies:		
1)	Unanswered	Equipment brought into classified space must be wiped down with a sporicidal agent, disinfectant, or sterile 70% IPA using low lint wipers.
2)	Unanswered	SOP's for calibration, maintenance, cleaning, and use of equipment based in manufacturer's recommendations are followed by compounding personnel
3)	Unanswered	Documentation of equipment calibration, verification, and maintenance is at the facility.
4)	Unanswered	Personnel conduct and record accuracy assessments on ACDs and similar equipment before the first use and again each day the equipment is used.
5)	Unanswered	Corrective action documented for accuracy measurements outside of manufacturers specifications

Section I: EQUIPMENT, SUPPLIES, AND COMPONENTS:

	Answer	Question
6)	Unanswered	Supplies (beakers, utensils, needles, syringes, filters, and tubing sets) that are in direct contact with CSPs are sterile and depyrogenated.
Components:		
7)	Unanswered	Compounding personnel follow SOP that addresses the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including ingredients, containers, and closures.
8)	Unanswered	API meets the following criteria:
9)	Unanswered	a. Comply with USP-NF monograph if one exists
10)	Unanswered	b. COA that includes specifications and test results showing API meets expected quality.
11)	Unanswered	c. In the United States, API must be manufactured by an FDA registered facility (If obtained from a non-FDA registered source the compounding facility is responsible for establishing identity, strength, purity, and quality of the ingredients by visual inspection, evaluation of COA, verification by testing a sample to determine conformance with COA. USP<1197>)
12)	Unanswered	Suitability for sterile compounding is assessed. API is not labeled with “not for pharmaceutical use”, “not for injectable use”, “not for human use”(unless the CSP is for non-human patients), etc.
13)	Unanswered	If facility uses commercially available sterile vials and container closure systems; a COA is on file for each lot.
14)	Unanswered	If facility sterilizes and depyrogenates its own vials and container closure systems; the efficacy of each process is verified and documented. (USP<1229>).
15)	Unanswered	Components are examined for deterioration and other aspects of unacceptable quality a when received and re-inspected before use.
16)	Unanswered	Unacceptable components are immediately disposed of or clearly labeled and segregated for disposal.
17)	Unanswered	Date of receipt is marked or added on each API that lacks expiration date. A conservative expiration date that does not exceed 1 year added to API packaging.
18)	Unanswered	Components are stored according to the official monograph or as specified by the manufacturer. (proper temperature, humidity, and lighting)
19)	Unanswered	Temperature in storage areas is monitored and documented at least once daily when facility is open. Documentation is readily retrievable

Section J: STERILIZATION AND DEPYROGENTATION:

	Answer	Question
1)	Unanswered	Does facility compound CSPs from one or more non-sterile components or nonsterile supplies or devices?
2)	Unanswered	Sterilization methods used do not degrade physical/chemical stability of CSPs (USP <1229>)
3)	Unanswered	SOPs include training and competency of personnel on all sterilization methods used at the facility
4)	Unanswered	SOPs describe the terminal sterilization and depyrogenation process that includes: temperature, pressure (if applicable), duration, permissible load, conditions, and use of Biological Indicators (BI) and endotoxin challenge vials (ECV).
5)	Unanswered	SOPs include a schedule and method for verifying the effectiveness of the terminal sterilization and depyrogenation methods selected and also includes methods for maintaining and cleaning the sterilization and depyrogenation equipment.
6)	Unanswered	Injectable CSPs that contain nonsterile components or that come into contact with nonsterile devices (e.g. containers or tubing) are sterilized within 6 hours after completing the preparation.

Section K: MASTER FORMULATION RECORD AND COMPOUNDING RECORDS:

	Answer	Question
Master Formulation Records:		
1)	Unanswered	Facility has Master Formulation records (MFR) for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s).
2)	Unanswered	Master Formulation Record includes name, strength or activity, and dosage form of the CSP.
3)	Unanswered	Identities and amounts of all ingredients.
4)	Unanswered	Type and size of container-closure systems(s).

Section K: MASTER FORMULATION RECORD AND COMPOUNDING RECORDS:

	Answer	Question
5)	Unanswered	Documentation of complete instructions for preparing the CSP, including equipment, supplies, a description of the compounding steps, and any special precautions.
6)	Unanswered	Physical description of the final CSP.
7)	Unanswered	BUD and storage requirements.
8)	Unanswered	Reference source to support the stability of the CSP.
9)	Unanswered	Quality control (QC) procedures (e.g., pH testing, filter integrity testing).
10)	Unanswered	Other information as needed to describe the compounding process and ensure repeatability (e.g., adjusting pH and tonicity, sterilization method (e.g., steam, dry heat, irradiation, or filter).
11)	Unanswered	An SOP that describes who is responsible for making changes to the MFR
Compounding Record:		
12)	Unanswered	A Compounding Record must be created for all CSPs.
13)	Unanswered	Compounding Record includes Name, strength or activity, and dosage form of the CSP.
14)	Unanswered	Date and time of preparation of the CSP.
15)	Unanswered	Assigned internal identification number (e.g., prescription, order, or lot number).
16)	Unanswered	A method to identify the individuals involved in the compounding process and verifying the final CSP.
17)	Unanswered	Name of each component.
18)	Unanswered	Vendor, lot number, and expiration date for each component for SCP's prepared for more than 1 patient and for CSPs prepared from nonsterile ingredient(s).
19)	Unanswered	Weight or volume of each component.
20)	Unanswered	Strength or activity of each component.
21)	Unanswered	Total quantity compounded.
22)	Unanswered	Assigned BUD and storage requirements.
23)	Unanswered	Results of QC procedures (e.g., visual inspection, filter integrity testing, pH testing).
24)	Unanswered	Master Formulation (MF) reference for the CSP and any deviations from MF are approved.
25)	Unanswered	Calculation made to determine and verify quantities and/or concentrations of components.

Section L: ESTABLISHING BEYOND USE DATES (BUD):

	Answer	Question
Parameters to Consider in Establishing a BUD		
1)	Unanswered	When establishing a BUD for a CSP, compounders must consider factors that may affect stability, including but not limited to:
1)	Unanswered	a. The chemical and physical properties of the drug and/or its formulation
1)	Unanswered	b. The compatibility of the container-closure system with the finished preparation (e.g., leachables, interactions, and storage conditions).
Establishing a BUD for a CSPs		
2)	Unanswered	A shorter BUD assigned when the stability of the CSP or its components is less than the hours or days stated above.
3)	Unanswered	The BUD does not exceed the shortest remaining expiration date or BUD of any of the starting components, regardless of the source.
4)	Unanswered	BUD Controlled Room Temperature (20-25 degree Celsius) ≤ 12 hours or refrigerator (2-8 degree Celsius) ≤ 24 hours. Prepared in a Segregated Compounding Area.
No Sterility Test Performed		
5)	Unanswered	Aseptically processed, no sterility testing, prepared from one or more non-sterile starting components: 1 day at controlled room temperature, 4 days refrigerated, 45 days frozen.
6)	Unanswered	Aseptically processed, no sterility testing, prepared from only sterile starting components: 4 days at controlled room temperature, 10 days refrigerated, 45 days frozen.

Section L: ESTABLISHING BEYOND USE DATES (BUD):

	Answer	Question
7)	Unanswered	Terminally sterilized, no sterility testing: 14 days at controlled room temperature, 28 days refrigerated, 45 days frozen.
		Sterility Test Performed and Passed
8)	Unanswered	Aseptically processed, with sterility testing: 30 days at controlled room temperature, 45 days refrigerated, 60 days frozen.
9)	Unanswered	Terminally sterilized, sterility testing: 45 days at controlled room temperature, 60 days refrigerated, 90 days frozen.
10)	Unanswered	Aseptically processed, sterility tested, and pass all applicable tests for Category 3: 60 days at controlled room temperature, 90 days refrigerated, 120 days frozen
11)	Unanswered	Terminally sterilized, sterility tested, and passing all applicable tests for Category 3: 90 days at controlled room temperature, 120 days refrigerated, 180 days frozen.
12)	Unanswered	Category 3 CSP must be prepared using the exact formulation from which stability data was derived.
13)	Unanswered	Documentation of the stability study, including methodology, validation of the method, stability-indicating analytical method, container closure, and all results of the study.
14)	Unanswered	If Category 3 is an injection or ophthalmic, particulate matter testing is conducted in accordance with USP <788> or <789>.
15)	Unanswered	CSP Category 3 that are prepared are sterility tested and if required endotoxin tested .

Section M: RELEASE INSPECTIONS AND TESTING:

	Answer	Question
1)	Unanswered	All release testing procedures (e.g., visual inspections and testing) must be included in the facility's SOP documentation. Any out-of-specification results must be investigated, and a corrective action plan must be implemented and documented as part of the quality assurance (QA) and QC program.
		Visual Inspection:
2)	Unanswered	Before release and dispensing, the CSP is visually inspected for visible particulates, other foreign matter, discoloration, or other defects.
3)	Unanswered	The CSP and its labeling match the prescription or medication order.
4)	Unanswered	Container-closure integrity inspected for leakage, cracks in the container, or improper seals.
5)	Unanswered	(any observed defect must be discarded, or marked and segregated from acceptable units in a manner that presents them from being released or dispensed.)
6)	Unanswered	When a CSP will not be released or dispensed on the day of preparation, a visual inspection must be conducted before it is released or dispensed.
		Sterility Testing :
7)	Unanswered	Does facility perform sterility testing Y or N.
		Bacterial Endotoxins Testing
17)	Unanswered	Injectable CSPs made from one or more non-sterile component(s) and assigned a BUD that requires sterility testing are tested in accordance to USP <85> to ensure that they do not contain excessive bacterial endotoxins.
18)	Unanswered	CSPs endotoxin testing is performed with every batch , if using non-sterile ingredients or components.
19)	Unanswered	In the absence of a bacterial endotoxins limit in an official monograph or other CSP formula source, the CSP must not exceed the endotoxins limit calculated as described for the appropriate route of administration for humans.
20)	Unanswered	CSPs for non-human species must not exceed the endotoxin reference limits based on the weight of the target animal unless a different limit is scientifically supported.

Section N: LABELING:

	Answer	Question
1)	Unanswered	The label on the immediate container of the CSP must, at a minimum, display prominently and legibly the following information:
2)	Unanswered	a. Assigned internal identification number (e.g., barcode, prescription, order, or lot number)

Section N: LABELING:

	Answer	Question
3)	Unanswered	b. Active ingredient(s) and their amounts, activities, or concentrations
4)	Unanswered	c. Storage conditions if other than controlled room temperature
5)	Unanswered	d. BUD
6)	Unanswered	e. Dosage form
7)	Unanswered	f. Route of administration
8)	Unanswered	g. If it is a single dose container (if space permitting)
9)	Unanswered	h. If it is a multidose container (if space permitting)
10)	Unanswered	i. Special Hanging instructions, (if applicable)
11)	Unanswered	j. Warning statements, (if applicable)
12)	Unanswered	k. Compounding facility and contact information if sent outside of facility
13)	Unanswered	l. Labeling indicates it is a compounded preparation.

Section N HD: USP <800>

	Answer	Question
14)	Unanswered	USP <800>: HD handling precautions must be clearly labeled at all times during transport.
15)	Unanswered	Personnel ensure that the labeling process for compounded preparation do not introduce contamination into the non HD areas.

Section O: USE OF COVENTIONALLY MANUFACTURED PRODUCTS AS COMPONENTS:

	Answer	Question
Single-Dose Containers:		
1)	Unanswered	Single-dose vial entered or punctured in only ISO 5 or cleaner air.
2)	Unanswered	Single-dose vial used within 12 hours after initial entry or puncture.(e.g.: labeled with date and time)
3)	Unanswered	Opened single-use ampules are used immediately and not stored for any time period once opened.
Multiple Dose Containers:		
4)	Unanswered	Once entered or punctured not used for more than 28 days (e.g labeled with date and time) unless otherwise specified by the manufacturer on the labeling. (USP<51>)
Use of Conventionally Manufactured Pharmacy Bulk Packages:		
5)	Unanswered	Contents of conventionally manufactured Bulk Packages punctured only in ISO 5 PEC.
6)	Unanswered	Used according to manufacturer’s labeling. (USP<659>)
7)	Unanswered	Does the facility use CSPs as components for final CSPs?

Section P: QUALITY ASSURANCE AND QUALITY CONTROL:

	Answer	Question
1)	Unanswered	Facility has written SOP Quality Assurance and Quality Control Program for non-sterile compounding procedures. The Program must be able to identity the following:
2)	Unanswered	a. That procedures were followed
3)	Unanswered	b. Prevention and Detection of Errors and other quality problems.
4)	Unanswered	c. Evaluation of Complaints and Adverse Events
5)	Unanswered	d. Appropriate Investigations and Corrective Actions
6)	Unanswered	Facility has a designated person(s) responsible for QA and QC program for non-sterile compounding.
7)	Unanswered	Designated QA and QC person has documented training for non-sterile compounding.
8)	Unanswered	QA and QC program reviewed annually and documented.
Notification About and Recall of Out -of – Specifications Dispensed CSPs:		
9)	Unanswered	Facility has procedures in place to immediately notify prescriber of a failure of specifications with the potential to

Section P: QUALITY ASSURANCE AND QUALITY CONTROL:

	Answer	Question
		cause patient harm (sterility, strength, purity, bacterial, endotoxin, or other quality attributes).
10)	Unanswered	Facility has procedures to determine whether a recall is necessary.
11)	Unanswered	Facility has SOP for recall of out-of- specification dispensed CSPs that contain:
12)	Unanswered	a. Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall.
13)	Unanswered	b. Procedures to determine the distribution of any affected CSP, including the date and quality of distribution.
14)	Unanswered	c. Procedures to identify patients who have received the CSP.
15)	Unanswered	d. Procedures for disposition and reconciliation of the recalled CSP
16)	Unanswered	Facility documents the implementation of the recall procedures.
17)	Unanswered	Facility reports recalls to state board of pharmacy.
Complaint Handling and Adverse Event Reporting:		
18)	Unanswered	Facility has an SOP for Complaint handling and adverse Event reporting.
19)	Unanswered	Facility has a designated person who is responsible for reviewing of complaints to determine if the complaint indicates a potential quality problem with CNSP.
20)	Unanswered	Facility does an investigation into the complaint if a quality problem is identified.
21)	Unanswered	Facility has a readily retrievable record keeping system of all complaints with CNSPs that include:
22)	Unanswered	a. name of patient
23)	Unanswered	b. prescription number
24)	Unanswered	c. name and strength of CNSP
25)	Unanswered	d. date of complaint
26)	Unanswered	e. nature of complaint
27)	Unanswered	f. results of the investigation and follow-up

Section Q: CSP HANDLING, STORAGE, PACKING, SHIPPING, AND TRANSPORT:

	Answer	Question
1)	Unanswered	Facility has SOPs for handling, storing, packaging, and transporting CSPs
2)	Unanswered	Facility staff trained in accordance with SOPs; this is documented
Handling and Storing CSPs:		
5)	Unanswered	Facility monitors storage conditions for temperature daily and is documented. (USP<659>)
6)	Unanswered	Temperature and monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer.
Packaging of CSPs:		
7)	Unanswered	Facility selects appropriate shipping containers and packing materials based on information from vendors and modes of transport to protect CSPs from damage, leakage, contamination, degradation, and absorption
8)	Unanswered	IF USP <800>: Packaging materials must protect the healthcare worker from exposure.
Shipping and Transporting CSPs:		
9)	Unanswered	Facility selects modes of transportation expected to deliver properly packed CSPs in an undamaged, sterile, and stable condition.
10)	Unanswered	Special handling instructions included on exterior of container when applicable.

Section R: COMPOUNDING ALLERGENIC EXTRACT:

	Answer	Question
Personnel Qualifications		
1)	Unanswered	A designated person, trained and has expertise in allergen immunotherapy, is responsible for training, evaluation and supervision.
2)	Unanswered	Personnel demonstrate knowledge of principles and skills for sterile compounding before being allowed to

Section R: COMPOUNDING ALLERGENIC EXTRACT:

	Answer	Question
		compound. This training and competency include passing written or electronic testing before they can be allowed to compound allergenic extract prescription sets.
3)	Unanswered	Annual personnel training and competency must be documented. Personnel who have not compounded in more than six months retrained and tested on core competencies.
4)	Unanswered	Garbing and Hand Hygiene Competency (Gloved Fingertip Testing) observed and documented initially and every twelve (12) months. Documentation must include:
5)	Unanswered	a. Name of person evaluated.
6)	Unanswered	b. Evaluation date/time.
7)	Unanswered	c. Manufacturer, lot and expiration numbers of media and components used.
8)	Unanswered	d. Starting temperature for each interval of incubation.
9)	Unanswered	e. Dates of incubation.
10)	Unanswered	f. Results.
11)	Unanswered	g. Name of observer and person who reads/documents the results.
12)	Unanswered	Aseptic Manipulation Competency (Media Fills) performed initially and every 12 months.
13)	Unanswered	a. Testing simulates the most challenging compounding procedures
14)	Unanswered	b. COAs present for commercial growth media
15)	Unanswered	c. In-house media must demonstrate growth promotion in accordance with USP<71>
16)	Unanswered	All failures documented along with corrective actions taken.
Personnel Hygiene and Garbing		
17)	Unanswered	Before beginning compounding of allergen immunotherapy prescription sets, personnel perform hand hygiene and garbing procedures according to facility SOPs.
18)	Unanswered	Hand hygiene procedures include:
19)	Unanswered	a. Wash hands and forearms up to the elbows, for at least 30 seconds, using closed system soap and nail picks.
20)	Unanswered	b. No scrub brush used in hand hygiene.
21)	Unanswered	c. Dry hands and forearms to elbows completely with low lint disposable towels.
22)	Unanswered	The minimum garb requirements include:
25)	Unanswered	a. Low-lint garment with sleeves that fit snugly around the wrists and that is enclosed at the neck (e.g., gowns or coveralls).
26)	Unanswered	b. Low-lint, disposable covers for head that cover the hair, ears and facial hair.
27)	Unanswered	c. Face mask.
28)	Unanswered	d. Sterile powder-free gloves.
29)	Unanswered	Sterile 70% IPA rubbed onto all surfaces of the gloves and allowed to dry thoroughly throughout the compounding process.
Facilities for Compounding Allergenic Extract Prescription Sets		
30)	Unanswered	The compounding occurs in an ISO Class 5 PEC or in a dedicated allergenic extracts compounding area (AECA). Located away from unsealed windows, doors that connect to the outdoors, restrooms, warehouses, food preparation areas, and traffic flow.
31)	Unanswered	The PEC or the work surfaces in the AECA located at least 1 meter away from a sink.
32)	Unanswered	PEC if used is certified every 6 months.
33)	Unanswered	A visible perimeter establishing the boundaries of the AECA.
34)	Unanswered	Access to the AECA during compounding restricted to authorized personnel and no other activity is permitted in the AECA.
35)	Unanswered	The surfaces of walls, floors, fixtures, shelving, counters, and cabinets in the AECA are cleanable. No carpet in AECA.
36)	Unanswered	Surfaces in the AECA used to prepare allergenic extract prescription sets are prepared must be smooth, impervious, free from cracks and crevices, and non-shedding to allow for easy cleaning and disinfecting.

Section R: COMPOUNDING ALLERGENIC EXTRACT:		
	Answer	**Question**
37)	Unanswered	If ledges are present, they must be easily cleanable.
38)	Unanswered	AECA must be well-lit with temperature and humidity controls.
Cleaning and Disinfecting		
39)	Unanswered	PEC cleaned and disinfected daily and when surface contamination is known or suspected.
40)	Unanswered	Sterile 70% IPA applied to the horizontal work surface between each prescription set.
41)	Unanswered	Work surfaces in the AECA where direct compounding is occurring cleaned and disinfected daily and when surface contamination is known or suspected. Sterile 70% IPA applied to the horizontal work surface between each prescription set.
42)	Unanswered	Walls, doors, and door frames within the perimeter of the AECA cleaned and disinfected monthly and when surface contamination is known or suspected.
43)	Unanswered	Ceilings within the perimeter of the AECA cleaned and disinfected when visibly soiled and when surface contamination is known or suspected.
44)	Unanswered	Vial stoppers on packages of conventionally manufactured sterile ingredients wiped with sterile 70% IPA and allowed to dry before they are used to compound allergenic extracts prescription sets.
Establishing BUDs		
45)	Unanswered	BUD for the prescription set no later than the earliest expiration date of any allergenic extract or any diluent in the prescription set. BUD must not exceed 1 year from the date the prescription set is mixed or diluted.
46)	Unanswered	Prescription Set stored in vials not syringe.
Labeling		
47)	Unanswered	The label of each vial of an allergenic extract prescription set displays:
48)	Unanswered	a. Patient name
49)	Unanswered	b. Type and fractional dilution of each vial, with a corresponding vial number
50)	Unanswered	c. BUD
51)	Unanswered	d. Storage conditions
Shipping and Transport		
52)	Unanswered	Allergenic extract prescription sets are shipped and transported in an undamaged, sterile, and stable condition.
53)	Unanswered	Allergenic extract prescription sets that require special handling during shipping or transport, include specific handling instructions on the exterior of the container.
Documentation		
54)	Unanswered	SOPs describing all aspects of the compounding process
55)	Unanswered	Personnel training records, competency assessments, and qualification records including corrective actions for any failures
56)	Unanswered	Certification reports of the PEC, if used, and any corrective actions for failures
57)	Unanswered	Temperature logs for refrigerator(s)
58)	Unanswered	Information related to complaints and adverse events including corrective actions taken
59)	Unanswered	Investigations and corrective actions
Compounding Records:		
60)	Unanswered	Compounding Record includes Name, strength or activity, and dosage form of the CSP.
61)	Unanswered	Date and time of preparation of the CSP.
62)	Unanswered	Assigned internal identification number (e.g., prescription, order, or lot number).
63)	Unanswered	A method to identify the individuals involved in the compounding process and verifying the final CSP.
64)	Unanswered	Name of each component
65)	Unanswered	Vendor, lot number, and expiration date for each component for SCP’s prepared for more than 1 patient and for CSPs prepared from nonsterile ingredient(s).
66)	Unanswered	Weight or volume of each component
67)	Unanswered	Strength or activity of each component

Section R: COMPOUNDING ALLERGENIC EXTRACT:

	Answer	Question
68)	Unanswered	Total quantity compounded
69)	Unanswered	Assigned BUD and storage requirements
70)	Unanswered	Results of QC procedures (e.g., visual inspection, filter integrity testing, pH testing)
71)	Unanswered	Master Formulation (MF) reference for the CSP and any deviations from MF are approved.
72)	Unanswered	Calculation made to determine and verify quantities and/or concentrations of components.