USP <797> Chapter Official Date Countdown Tips

Days to Go	Tips
364	Read the chapter more than once before you change anything. You will pick up something new every time. Measure twice, cut once.
363	Have a PDF of the <797> Commentary open while you read the new chapter. With a quick search you can learn the Expert Committee's rationale for a change.
362	Do not rush garbing and hand hygiene training. Staff are now required to pass 3 successive garbing and hand hygiene competency evaluations, not just 3 total, initially.
361	Identify exceeded action levels for both gloved fingertip and surface samples collected during the aseptic manipulation competency. This information can help determine appropriate corrective actions.
360	Put Tables 2 and 3, which define the initial and ongoing competency requirements, in your SOPs. Fill in the column titled "Defined by Facility SOPs" with your requirements and break out the "Other" group further, if needed.
359	Require that your PEC and SEC certification be done according to CETA Application Guide-003. This ensures all necessary testing is conducted, including the tests that are not defined in the chapter.
358	Clearly identify the personnel with direct compounding oversight that do not compound. This could be in a job description, in their training records, or in another document.
357	Follow your certifier's lead on total particle count testing locations. Although the chapter indicates that sampling sites and procedures must be described in your SOPs, they understand the requirements of ISO 14644-1.
356	Collect surface samples on equipment in the PEC and staging/work areas near the PEC. Do a risk assessment to identify the best sample locations for frequently touched surfaces.

Pure Microbiology LLC.
6034 Hamilton Blvd #135 Allentown, PA 18106

Days to Go	Tips
355	Start the process for purchasing sterile agents and sterile cleaning supplies for use in the PEC. If you need to change agents, talk with the manufacturer about your options and what to expect with the change.
354	Choose a low-lint, presaturated sterile 70% IPA wiper to wipe critical sites. Traditional alcohol prep pads are not low lint and can leave fibers on critical sites, risking particle contamination of the CSP.
353	Triple clean new equipment before bringing it into the sterile compounding area. Apply an EPA-registered one-step bactericidal cleaner, followed by two applications of an EPA-registered one-step sporicidal cleaner.
352	If you are using tacky mats outside the SEC, define in your SOP when a layer is to be changed and how the mat is to be used. Position the tacky mat so a person gets at least two steps with each foot on the mat.
351	Place temperature and humidity sensing devices on an interior wall, but not near an air-handling return/exhaust or door. This ensures a representative reading in the sterile compounding area.
350	If you use TSA and a fungal media at a single sample location and only one of them exceeds the action level, resample the location with both types of media. This shows the complete picture of the microbial state of control.
349	Develop valuable, user-friendly SOPs. The SOP must have sufficient detail to ensure compliance, consistency, and repeatability. Process variability frequently results in noncompliance, which can lead to negative patient outcomes.
348	Identify those in your organization who may need to prepare immediate-use CSPs. Ensure they have read the necessary SOPs, are trained, and deemed competent.
347	Take full advantage of Section 1.4 Preparation Per Approved Labeling. This chapter addition can help reduce the sterile compounding workload.
346	Think of the entire chapter as a quality system. Use it as a base for SOPs and sprinkle in other quality elements to create a robust quality management system unique to your organization.

Days to Go	Tips
345	Spend time training new sterile compounding staff on first air. Use a smoke source so they can visualize airflow and identify proper compounding technique in different PECs.
344	Hold the plates vertically when collecting gloved fingertip samples with the hand hygiene and garbing competency. This ensures that those being tested apply appropriate pressure.
343	Label sample collection plates on the base of the plate, along the edge. This aids in counting colonies and eliminates sample mix ups in the event lids come off of a stack of plates.
342	Design media-fill tests based on the most challenging procedures staff may encounter. You will have multiple media-fill test procedures based on the equipment, components, and PECs used.
341	Store garb away from the sink and trash cans to prevent it from becoming contaminated. Consider using closed bins if the garb does not come individually wrapped.
340	Define reporting requirements in your certification provider vendor agreement. The chapter now has specific reporting requirements, as does CAG-003.
339	Have an SOP on documentation practices. Follow the ALCOA+ principles which are: attributable, legible, contemporaneous, original, and accurate + complete, consistent, enduring, and available.
338	Be sure to swirl media-fill test units before incubation and after the first incubation. This ensures that the media has come in contact with all interior surfaces of the container closure and that if there was contamination it will be recovered.
337	Reference USP <1163> Quality Assurance in Pharmaceutical Compounding for a list of SOPs. It's not an all-inclusive list, but it's a good starting point to ensure you have the necessary SOPs in place.
336	If you have a CAI or CACI in your SCA, seriously consider replacing it with an LAFW for non-HD compounding or BSC for HD compounding. CAIs and CACIs no longer afford full dating and they are challenging to work in.

Days to Go	Tips
335	Create an environment where staff are comfortable to notify others of garbing issues, like a torn gown or hair sticking out. This will drive compliance, process improvement, and patient safety.
334	Train staff to recognize the different microbial growth patterns that could be present in media-fill test units. You are not just looking for turbidity. Reach out to industry experts for training, if needed.
333	Don sterile gloves in the location that makes sense for your facility. Think through the process. Where are your contamination risks? Where are your risks to personnel safety?
332	Include frequently touched surfaces in your daily clean. You define what they are. Surfaces could include the workflow management system, keyboards, intercoms, scales, chairs, refrigerator handles, and pass-through handles.
331	After taking appropriate remediation actions in response to air and surface sample excursions, resample the location. Even though this is no longer required by the chapter, it is the only way to prove a return to a microbial state of control.
330	Read the chapter FAQs. If you still have questions about how to interpret the chapter, reach out to USP. Contact information is on the last page of the chapter PDF.
329	If you utilize a lab for antimicrobial effectiveness, stability, sterility, or bacterial endotoxin testing, do an onsite audit. Even if the lab has been inspected by the FDA, you are still responsible for ensuring it meets your testing needs.
328	If you need paper in the cleanroom, but are worried about particulate generation and regulatory scrutiny, purchase cleanroom paper. It is specifically designed for use in critical environments.
327	Visibly identify the perimeter of your SCA. This could be walls and a door or visible markings on the floor. This perimeter defines the garbing and material transfer process.
326	For those planning a cleanroom remodel with a wet anteroom, consider making the space controlled not classified (CNC). This would eliminate the need to collect viable samples in the wet anteroom.

Days to Go	Tips
325	Have one of your designated people become a CETA member. This provides access to all the CETA Application Guides (CAGs) and a semiannual publication.
324	Think of your pass-through as an extension of the cleaner ISO Classification and assign the stricter action level. Pass-throughs connected to the buffer room would have a surface sample action level of >5 CFU/media device.
323	Set a preventative maintenance schedule and include things like prefilter changes, residue removal, surface integrity evaluation, and silicone maintenance. Frequency is based on your facility's specific needs.
322	Determine how you will handle the storage of refrigerated single-dose containers after they are punctured in ISO Class 5. Place buffer room refrigerators close to returns/exhausts.
321	For those that compound multiple-dose containers, work closely with the lab that performs the antimicrobial effectiveness testing. Be sure they include a neutralization study and follow USP <51>.
320	Thoroughly read the manufacturer's use instructions for your incubators. Many incubators require back and side clearance to ensure proper function.
319	Before deciding on PEC placement, talk with your certifier. PEC location is critical to the proper function of the device. Proximity to doors, HEPA filters, and other PECs all need to be considered.
318	Category 1 and 2 compounders, ditch the isolation gowns. There are so many better options that are specifically designed for cleanroom use. Gown or coverall, your choice.
317	If you have a clean cart that is used to transfer materials into the HD buffer room, make sure you have a process to decontaminate the cart before it is brought back into the anteroom. This should include work surfaces and the wheels.
316	Make sure you have diffuser screens on all of your LAFWs. Diffuser screens create airflow uniformity and limit turbulent airflow on the deck of the PEC.

Days to Go	Tips
315	Define "cosmetics" in your SOP. The chapter does not define cosmetics, but seems to infer it is only makeup. The FDA definition includes a variety of items, like deodorant, which we would definitely want people to wear.
314	Work with your certifier to show staff how many particles can be generated during certain activities. Have them collect samples while people walk quickly, push down trash, wave around paper, or scratch their head.
313	Sanitize the sterile 70% IPA spray trigger throughout the compounding day. Keeping the trigger clean can help minimize touch contamination.
312	Draft a compounding area visitor policy. Define to whom it applies, when an escort is required, and allowable "accommodations", if applicable.
311	Have hoods available for staff with full beards or who have hair on the neck. A typical beard cover is not sufficient. There are many cleanroom-appropriate options available.
310	Ensure everyone who cleans the sterile compounding area knows the dwell/contact time for the agents used. For the daily clean, use the bactericidal dwell/contact time.
309	If you incubate your own microbiological samples, read USP <1117> Microbiological Best Laboratory Practices. It provides guidance on incubators, cross contamination concerns, and training.
308	Have a negative control to which you can compare incubated media-fill units. Prepare an extra unit of each container type and put it in the refrigerator. This is really helpful for containers that are not quite clear.
307	Define in your SOP how to clean the PEC. Include the order the surfaces are cleaned and that irregular surfaces are cleaned by hand. Consistency is key. Everyone needs to clean the PECs the same way.
306	Validate your autoclaves and dry heat ovens. This is more than running biological indicates with each load. A proper validation includes installation, operation, and performance qualifications.

Days to Go	Tips
305	Read Strength and Stability Testing for Compounded Preparations by Loyd V Allen Jr, PhD, Gus S Bassani, PharmD, Edmund J Elder Jr, PhD,and Alan F Parr, PharmD. It clearly defines the difference between strength and stability.
304	Follow your lab's recommendations on how to ship plates with growth for identification. Each lab will be different, so if you switch labs, be sure to ask.
303	Develop a plan for an unexpected cleanroom shut down. Include what to do with in-process CSPs, where compounding occurs in the interim, and what is required to bring the cleanroom back into use.
302	Decontaminate the viable air sampler after sampling in the HD buffer room or C-SCA. As with all processes surrounding HD compounding, the goal is to mitigate the migration of HD residue.
301	Read the FDA's Insanitary Conditions at Compounding Facilities Guidance for Industry. As you make changes based on the new chapter, also address changes that can be made to limit your risk of insanitary conditions.
300	Remember, the chapter is a minimum standard written for a variety of practice settings. Minimum will meet the needs for some organizations but not others. Assess your risk and let patient safety be your guide.
299	Consider more conservative beyond-use dating for CSPs prepared from compounded single-dose CSPs and CSP stock solutions than what the chapter allows. Use your professional judgment to assess microbial risk.
298	Verify that your SCA really is clean, uncluttered, and dedicated to compounding. Many times there is a lot of other activity in and around the SCA resulting in piles of papers and stacks of boxes.
297	Define "personal hygiene" in your SOP. USP <797> requires that those entering a compounding area maintain proper personal hygiene, but does not define what that includes. Be sure to share your expectations with staff and vendors.
296	Review and retain the certificate of analysis for media used for gloved fingertip testing. The chapter only mentions this for viable air and surface sampling media, but it should be done for all media used.

Days to Go	Tips
295	Evaluate the sterile compounding area for ergonomic risks. Staff should be able to work in a neutral posture at a comfortable height, have items within easy reach, and limit the use of excessive force.
294	Make sure the certification report includes an identifying number of the equipment actually used in certification and not just a generic list. This is critical in the event a piece of their equipment comes back from calibration and is out of specification.
293	Have spare HEPA filters for your PECs and cleanroom on hand. If filter issues are noted during certification, having filters on hand can prevent downtime and an additional certifier visit.
292	Develop a procedure on how to wipe eyeglasses, including the agents to use. Have an eyeglass cleaning station set up outside the cleanroom or SCA with the agent to use on the frames and lens cleaning wipes for the lenses.
291	Have your BSCs certified to NSF ANSI 49 and confirm that individuals doing this certification hold the NSF BSC Field Certifier Accreditation. This ensures accurate and consistent testing done according to an industry standard.
290	Draft a plan for managing loss of water or contaminated water used for hand hygiene. If compounding must occur, define how hand hygiene will be performed and if additional precautions will be taken.
289	If you currently allow cell phones in the compounding area, prepare staff for this no longer being an option. Electronic devices not necessary for compounding or other required tasks must not be brought into the compounding area.
288	Allow your certifier to bring electronic devices necessary for data collection into the compounding area, including cell phones. Require cell phones be removed from their case and wiped with sIPA.
287	When possible, pair your certification with your monthly clean. If this isn't an option, clean all daily clean surfaces and any other possibly contaminated surfaces with your EPA-registered one-step sporicidal disinfectant cleaner.
286	If you are new to sterile compounding, Google Eric Kastango. You'll find an abundance of timeless articles, studies, and presentations dedicated to compounding compliance and patient safety.

Days to Go	Tips
285	Make sure your internal definition of "oversight" matches that of the chapter. Oversight is more than spot checking compounding. It's being responsible for the actions taken by personnel and being available for consultation.
284	Confirm that the media you use for gloved fingertip testing and viable sampling is double or triple bagged and irradiated. This testing is critical to compliance, so why risk starting with media that may be contaminated.
283	If you have a RABS, observe the dynamic airflow smoke pattern test during certification. Confirm it is done while your staff simulate compounding activities and that the smoke follows the compounder's movements.
282	Reserve the infamous "triple clean" for cleanroom shutdowns and when there's a total loss of the microbial state of control. Doing a triple clean after every microbial excursion is a waste of time, effort, and supplies.
281	Category 1 and 2 compounders, evaluate the cost/risk of reusing gowns during the same shift. Although allowed by the chapter, reusing a gown will release a buildup of particles and microorganisms when donned again.
280	If you are using TSA and a fungal media for your viable sampling, incubate the TSA at both temperatures. This provides you with the most complete picture of the microorganisms present in the compounding area.
279	Take time to explain to staff why jewelry is a contamination concern and needs to be removed. If you need to show them the evidence, use a contact plate to sample a ring or a watch.
278	Stop using sterile water to clean your PECs. Unless you have heavy soiling in the PEC, your EPA-registered one-step disinfectant cleaner will be able to handle a light to moderate soil load. Be sure to follow with sIPA.
277	For vendors, define the personal hygiene requirements in the contract or vendor quality agreement. If the onsite provider arrives and is not in a condition to enter the space, do not let them enter and contact the vendor.
276	Stop associating viable sampling with certification. They are two separate activities. It just so happens that the certification vendor can also provide viable sampling as a service.

Days to Go	Tips
275	Spot check how staff are using filter needles. The use of alternating pressure could result in result in breaking of the filter or inadvertently reintroducing the filtered particles back into the solution.
274	If you have a sliding pass-through window, it's time for an upgrade. Consider installing HEPA-filtered pass-through chambers from unclassified to classified spaces, in order to meet the FDA's insanitary conditions expectations.
273	As you plan for USP 800 to become compendially applicable, don't lose sight of the sterile compounding requirements. For things like garbing, cleaning, and compounding practice, both chapters must be referenced.
272	Choose sterile gloves that are long enough to cover the wrists and are tight enough so that the glove does not bunch up, risking skin exposure. Gowns with thumb loops can also help ensure proper skin coverage.
271	If you are due for new cleanroom shelving racks, choose one with a solid surface shelf. There is no requirement for wire shelving, as the cleanroom is turbulent flow, plus they are so much easier to clean.
270	Use your certifier as another set of eyes on your compounding area. Encourage them to share concerns, insanitary conditions, and suggestions for improvement with you. Agree on a means to relay this information.
269	Read "Choosing a Certification Professional to Evaluate Your Cleanroom and Engineering Control" By James T. Wagner. Written in 2009, it provides useful information and a really great certifier "should" list.
268	Evaluate the amount of "stuff' you keep in the compounding area. Limit supplies, materials, and components to what your organization needs for a few days. Too much stuff will result in it all not being cleaned during the monthly clean.
267	Check the viable sampling reports from your certifier to be sure the lab has not yet moved to the new incubation parameters. This could result in noncompliance with state regulations and your own SOPs.
266	For those who terminally sterilize CSPs using an autoclave, confirm you include a biological indicator (BI) in each cycle. Also consider incubating an unexposed BI as a control to prove that the lot of BIs is viable.

Days to Go	Tips
265	Reread the manufacturer's instructions for use of your cleaning agents. Changes may have occurred since your SOPs were last revised or you may find you've been using the incorrect dwell time for the desired outcome.
264	Pull some recent FDA 483s for 503A pharmacies and use them to assess your facility and operations. Pay particular attention to observations addressing insanitary conditions, media-fill testing, smoke pattern testing, and aseptic technique.
263	Identify the irregular surfaces in the cleanroom suite that must be cleaned by hand. Include instructions on how to clean these irregular surfaces in your SOPs and in the training for those who clean.
262	If you perform sterility testing on your CSPs, make sure you have method suitability data for all formulations. You can't have a valid sterility test without a method suitability test.
261	Read "Standardize a System-wide Master Formulation Record" by Amanda Wollitz, PharmD, BCPS, FISMP and Jessica Wendler, PharmD, BCSCP. Even if this isn't your ultimate goal, it provides some valuable insight.
260	Verify that your SOPs and training address food and drinks in the cleanroom and SCA. This includes gum, mints, and cough drops, which can create excessive saliva and result in a wet, ineffective mask.
259	Consider identifying all growth recovered in the PEC to the species level, even if the action level is not exceeded. This aids in trending and allows you to take appropriate actions to reduce the likelihood of recurrence.
258	Clean your PEC diffuser screens. When cleaning, wet the applicator instead of spraying onto the screen, as this prevents damage to the HEPA filter.
257	Confirm that your SOPs prohibit compounding during cleanroom or SCA cleaning activities. Although the new version does not address this, cleaning is a dirty activity and there must be clear procedures to prevent CSP contamination.
256	Check your cleanroom for transfer grilles. Although allowed by the chapter, their use indicates an air balancing/room pressure issue. Installation between a classified and unclassified area, is considered an insanitary condition.

Days to Go	Tips
255	Watch Patti Kienle's Pharmacy Purchasing & Products webinar titled "Maintaining USP Compliance through SOPs." It provides guidance on areas which require focus, such as personnel, facilities, and monitoring.
254	Determine how you will store your reusable cleaning tools. The chapter requires they be dedicated for use in the classified areas or SCA and not be removed from these areas except for disposal.
253	If you have ceiling returns in the cleanroom, get your certifier in as soon as possible to perform a visual smoke study to verify absence of stagnant air. If the room does not pass, it's time for a redesign.
252	Perform a gap analysis of your viable sampling program. Compare your program to USP <797>, CAG-009, and industry best practices. If you are coming up short and need guidance, reach out to your lab or an industry consultant.
251	Decide if you will be compounding Category 3 CSPs. Even if you compound Category 3 CSPs occasionally, you must meet the requirements for compounding Category 3 CSPs at all times.
250	Identify who needs to be trained on the difference between beyond-use dating and hang time. This can cause confusion on the patient floor, but a small change to labeling could be extremely helpful.
249	Confirm that your master formulation records include a physical description of the final CSP. This is essential to the visual inspection that is required to be completed for every CSP.
248	Read Adam West's Pharmacy Purchasing & Products article titled "Operational Compliance Drives Cleanroom Design." It provides insight as to why you don't want to just design your cleanroom to the minimum standard.
247	If you are sterilizing stoppered and crimped empty vials using steam heat, verify that the vials contain a small amount of sterile water. This water is necessary to generate steam within the vial and destroy microorganisms and their spores.
246	Check your manufacturer's instructions for the calibration/verification interval of your temperature monitoring equipment. If an interval is not specified, be sure it occurs at least every 12 months.

Days to Go	Tips
245	Define in your SOP how the ceilings of your SCA will be assessed to determine whether they need to be cleaned. Consider documenting a weekly visual assessment looking for dust, stains, or other soiling.
244	Define in your SOP the "servicing of facilities or equipment" activities that will prompt viable sampling. List the major ones and include language to allow the designated person to assess the sampling need for other situations.
243	For those designing a cleanroom for both HD and non-HD compounding, the sink must be in the anteroom, as required by USP <800>. Check your design plans to confirm compliance.
242	Develop a process for documenting garbing "accommodations." Consider a form that includes the staff member, accommodation, additional garbing requirements, start date and end date.
241	Inspect media devices before use. Be sure surface sampling media has a raised, convex surface. Devices that are desiccated, are cracked, show signs of being frozen, or had the agar fall out of the base must not be used.
240	If your organization is repeatedly having to document the same change in the CR to something specified in the MFR, consider creating a new MFR for that CSP variation. This can help prevent preparation errors.
239	Read Kimberly Coughlin's Pharmacy Purchasing & Products 3-part series on understanding certification reports. Each part tackles a different part of testing: cleanroom, PECs, and RABSs.
238	Make sure you are labeling gloved fingertip samples with a personnel identifier, right or left hand, and the date and time of sampling. These are chapter requirements and labeling can be done with marker or a printed label.
237	For those incubating their own viable air and surface samples and contracting with a lab for identifications, ask if they will determine the number of different colony types recovered. If not, you will be responsible for telling them which colonies to identify.
236	Verify that staff understand the purpose of the anteroom line of demarcation. It serves as the visible marking for where to don shoe covers and also defines the material transfer process for items that must enter through the anteroom.

Days to Go	Tips
235	Replace the term non-shedding with low lint in your SOPs related to garbing materials and cleaning/material transfer supplies. Nothing that is used is 100% non-shedding.
234	For those using bulk API to compound, know if your supplier is testing the bulk drugs before you purchase them for patient use. If testing results are not on the certificate of analysis (COA), audit your supplier.
233	Encourage staff to use an unscented, untinted moisturizer to help minimize the shedding of skin particles. Just be sure it is not applied to the hands and arms before garbing, as this does not allow for effective hand hygiene.
232	Read "USP <797> Immediate-Use CSPs: Small Changes, Big Impact" by Kevin N. Hansen, PharmD, MS, BCPS, BCSCP; Amanda M. Choi, PharmD, MBA; Annie Lambert, PharmD, BCSCP. It's a great resource on immediate-use CSPs, with helpful infographics.
231	Category 1 and 2 compounders, choose disposable garb over launderable garb, unless you are working with a vendor that specializes in cleanroom laundry services. Laundering garb comes with risks.
230	Category 3 compounders, leave the laundering and sterilization of garb to the professionals. There are numerous companies that can supply, launder, and sterilize garb, using robust, validated processes.
229	Be prepared to have staff available for the certification tests that require dynamic operating conditions. These tests include viable sampling, total particle count testing, and dynamic airflow smoke pattern testing.
228	If you are incubating your own microbiological samples, define in your SOPs how you will handle temperature excursions. This should include a documented assessment of whether the excursion affected the samples.
227	Confirm staff are moving equipment in the PEC to clean underneath it. Also, verify that the equipment is returned to the same location, as designated by dynamic airflow smoke pattern testing.
226	Ensure all personnel who "touch" a CSP receive appropriate training based on their interaction with the CSP. This includes those who receive sterile products and preparations, enter orders, clean compounding areas, or transport CSPs.

Days to Go	Tips
225	Read "Seamlessly Transition to a Cleanroom Suite" by Michael Winstanley, RPh, BCSCP. For those organizations looking to move away from the SCA, this article addresses training, work practices, and SOPs.
224	Verify that your lab is actually performing a genus-level identification. If you are getting "gram positive cocci" or "gram negative rod" on your report, you are not getting what you paid for, unless they were unable to get an identification.
223	Develop a training process and chart it out to create visual tool. Be sure to include hospital/company, pharmacy, and sterile compounding curriculum.
222	Define a process and time frame for closing out investigations. Sufficient time must be given to ensure any corrective actions were effective, but there must be a resolution to whatever prompted the investigation.
221	Teach and use chapter terms and language. This will help staff better understand articles, studies, and external training.
220	Watch Pure Microbiology's Webinar titled "Your USP <797> Viable Sampling Questions Answered." This hour long webinar answers frequently asked questions about viable air and surface sampling chapter changes.
219	Address the use of hair products with staff. Hair spray, mousse, gel and temporary hair coloring in spray, chalk, or powder form can all flake from the hair, introducing a particle risk.
218	Read "Choosing the Right Cleanroom Construction Approach" by Mark Bodnar, RPh. This article is a great tool to use when deciding between a traditional stick-built cleanroom and a modular cleanroom.
217	Plan a yearly audit of the designated persons' responsibilities. As part of the annual SOP review, confirm all designated person responsibilities are addressed in your SOPs and that they are executed.
216	Check out the FDA Compounding Quality Center for Excellence. In addition to information about the annual conference, there is live and on-demand training, stakeholder engagement opportunities, and annual reports on outsourcing facilities.

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215	Use the "peel and present" technique when opening needle and syringe packages in the PEC. Read "Generation of Particulate Matter During Handling of Needle and Syringe Packaging" in the American Journal of Health-System Pharmacy to learn more.
214	Consider choosing a rapid sterility test method that allows for the microorganism to be identified in the event of a failure. Inability to identify the microorganism responsible for the sterility test failure has been an observations on FDA 483s.
213	For those depyrogenating using a dry heat oven or by rinsing, read USP <1228> Depyrogenation. There are five sections covering everything you need to consider when depyrogenating CSPs and equipment.
212	Use the Parenteral Drug Association (PDA) as a resource. Although their focus is on pharmaceutical/biopharmaceutical manufacturing, these industries align in many ways with sterile compounding.
211	Read "Best Practices for Compounding Garbing" by Kate Douglass, MS, RN, QP503A qualified. This comprehensive article provides guidance on garbing for HD and non-HD compounding, as well as doffing HD garb.
210	Include a sterile compounding history lesson in your training curriculum. The Wolters Kluwer webinar titled "Lessons to be Learned from the NECC 483", provides relevant insight into the tragedy that changed compounding.
209	Read the General Notices and Requirements in USP-NF. This section presents the basic assumptions, definitions, and default conditions for the interpretation and application of USP and NF.
208	If you plan on performing your own viable air sampling, do your research on air samplers. Start by reading Pure Microbiology's blog post titled "Choosing a Viable Air Sampler for USP <797> Applications."
207	Confirm your certifier is performing dynamic airflow smoke pattern testing according to CAG-014 Airflow Visualization Study. As part of reporting, a video recording of the study is to be provided.
206	Use the American Society for Quality (ASQ) as a resource for all things quality. Their website has tons of articles and helpful resources you can use to develop SOPs and forms.

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205	Read the Infusion Journal study titled "An Investigational Study on The Use Of A Sporicidal Disinfectant To Decontaminate Hazardous Drug Residues On IV Bags." The study investigates the leaching of a popular agent into IV bags.
204	Spread your monthly clean out over the course of two or three days. You could do the buffer room one day and the anteroom the next. Just be sure you don't go more than 30 days between cleaning each space.
203	Stagger staff's aseptic manipulation competency assessments. This alleviates the need to stock media for all staff at one time and ensures there is sufficient space in the incubators for all the media-fill units, gloved fingertip samples, and surface samples.
202	Choose a lab that has expertise in the incubation and analysis of USP <797> viable air and surface samples. Microbiology is not microbiology and your lab should have staff experienced and knowledgeable in pharmaceutical microbiology concepts.
201	Verify that the certificate of analysis (COA) for media used for gloved fingertip testing and viable sampling has clear and specific results for growth promotion, sterility, and pH. If the COA is missing any of this information, contact the manufacturer.
200	For those looking to unify SOPs across an organization, set aside a few days to review the chapter changes with leadership from all locations. List the areas where changes need to be made and schedule smaller breakout meetings to tackle each topic.
199	Make the USP compounding chapters, state laws and regulations, and other industry standards, guidelines, and guidance documents your source of truth. Published articles and studies can sometimes twist the requirements to meet an agenda.
198	Ensure the manufacturer's approved labeling has all applicable information before applying the compounding exemption in Section 1.4. Labeling must include the diluent, resultant strength, container closure system, and storage time.
197	Reevaluate your viable sampling plan yearly. Evaluate trends and identify locations that may no longer be providing valuable insight into the microbial state of control. Also assess the need to add samples based on workflow changes.
196	Update your SOPs to include the cleaning and disinfection of reusable cleaning tools before and after use. This is a new chapter requirement and must be included in SOPs and staff training.

Days to Go	Tips
195	Consider using TSA with lecithin and polysorbate 80 contact plates for gloved fingertip testing. There is no requirement to use settle plates and using contact plates reduces the number of different types of media that need to be purchased and stored.
194	Stop using the term "terminal clean" to define the monthly clean. The CDC defines a terminal cleaning as "cleaning and disinfection after the patient is discharged or transferred." This is not what sterile compounding facilities do.
193	Implement a form of line clearance into your sterile compounding workflow. This manufacturing concept helps staff prepare for the next CSP or batch, avoid mislabeling, and prevent cross-contamination of finished CSPs.
192	Teach staff the difference between PEC unidirectional airflow and non-unidirectional airflow in the cleanroom suite. Both remove particles, but the airflow in the PEC is more efficient than in the SEC, emphasizing the importance of cleanroom behavior.
191	Learn about the different phases of bacterial growth. A minimal understanding of the bacterial growth curve aids in an understanding of the changes to immediate-use dating and the use time of single-dose containers.
190	Define in facility SOPs when staff are required to change garb or gloves during compounding. SOPs should address holes or tears in garb, wet facemasks, and replacing gloves after adjusting garb.
189	Discuss proper pants length with staff, visitors, and vendors. Pants should be long enough to cover skin on the leg at all times when in the compounding environment, but not so long that the pants' legs drag on the floor.
188	Verify that CSPs prepared from nonsterile components or that contact nonsterile surfaces are sterilized within 6 hours after completing preparation. This minimizes the generation of bacterial endotoxins in CSPs.
187	Review Section 17 SOPs when updating your training SOPS. In this section the chapter mentions that all compounding personnel must be trained to recognize and report potential or actual issues, failures, or errors to the designated person.
186	Avoid using anti-fatigue mats in the sterile compounding area, as they are huge contamination risk. If they must be used, ensure both sides of the mat and the area under the mat are cleaned daily as part of the floor cleaning.

Days to Go	Tips
185	Require staff to discard all garb worn during cleaning. Before they resume sterile compounding activities, new garb must be donned and hand hygiene procedures repeated.
184	If you are struggling with the removal of the "highly pathogenic organisms" from the chapter, read Pure Microbiology's blog titled "A Look at Highly Pathogenic Organisms." It discusses how pathogenicity is not an inherent property of the microorganism.
183	Check the condition and integrity of cleaning tools on a monthly basis. The chapter now requires that the cleaning tools be discarded based on their condition. Make sure the tool is not broken and look for rust, pitting, and corrosion.
182	Consider requiring that at least one certification technician onsite hold the CNBT Registered Certification Professional – Sterile Compounding Facilities (RCP-SCF) credential. This helps ensure testing is done to industry standards and guidelines.
181	Get the media certificate of analysis (COA) from your certifier if they do any viable sampling for you. If it doesn't come with your report, ask for it.
180	Read USP General Chapter <1029> Good Documentation Guidelines. This informational chapter is helpful for building the foundation of a quality system that will ensure proper documentation as well as record integrity and control.
179	Be sure you have two methods to confirm the effectiveness of your steam sterilization cycle. Biological indicators must be used along with another confirmation method, such as physicochemical indictors.
178	Read "Eye-Opener: Understanding Invisible Hazardous Drug Exposure" by Martha A. Polovich, PhD, RN, AOCN. Although written for the oncology nurse, this short article is a good reminder of the risks associated with HDs.
177	Consider eliminating the use of disposable preparation mats in the C-PEC. There are so many preventive HD cross-contamination measures taken that their use just ends up being costly and wasteful.
176	If a disposable preparation mat is used in the C-PEC, work with your certifier to ensure the mat itself does not interfere with the functionality of the device. And make sure you are using sterile mats!

Days to Go	Tips
175	Consider implementing the use of pharmacy dedicated shoes that are only worn in the pharmacy and cleanroom suite. Even with shoe covers, "street shoes" greatly increase the microbial contamination that is brought into the cleanroom suite.
174	For those that have RABSs, have staff save the sterile paper from the glove packaging to use to open plates for gloved fingertip testing. This works for gloved fingertip testing after garbing and after the media-fill test.
173	Note in their personnel records if an individual has permanent makeup. This can be valuable documentation if inspectors or surveyors see staff in the compounding area that appear to be wearing makeup.
172	Read USP <1079.2> Mean Kinetic Temperature in the Evaluation of Temperature Excursions During Storage and Transportation of Drug Products. This informational chapter is a great resource for those involved in handling temperature excursions.
171	Define in your SOP how to wipe a critical site. The chapter only specifies that the critical site needs to be wiped with sterile 70% IPA and allowed to dry.
170	Watch the webinar titled "Meet USP <800> Requirements for CSTD Utilization" by Fred Massoomi, PharmD, BSCSP, FASHP and Seth Eisenberg RN, OCN, BMTCN. This comprehensive webinar reviews opportunities for appropriate CSTD adoption.
169	Take a picture of any plate with an exceeded action level that is being shipped to the lab for identification. This can help resolve conflicts in the number of CFU you counted versus what the lab counted.
168	If you sterilize CSPs using a sterilizing filter, read USP <1229.4> Sterilizing Filtration of Liquids. The removal of microorganisms depends on the solution's bioburden, properties of the solution, filtration conditions, and the filter itself.
167	Treat microblading the same as you would a tattoo. The skin must be fully healed before staff can enter the cleanroom suite or SCA.
166	Train staff to check the integrity of sterile glove packaging and to check the expiration date of the gloves. If the packaging is compromised or the gloves are expired, they must not be used.

Days to Go	Tips
165	Read "Maximize Airflow Efficiency in the Sterile Compounding Cleanroom" by Kimberly Coughlin, BS, Mary Nazzal, PharmD, BSCSP, and Mark Bodnar, RPh. This white paper breaks down factors that affect airflow and reviews PEC airflow dynamics.
164	Clean your incubators monthly or as recommended by the manufacturer. Plan your cleaning around the incubation of samples.
163	Know your HVAC system. Smoke detectors, if present, may need to be disabled for the duration of the HEPA-Filter Leak Test. Your certifier, especially if they are new to your facility, will likely ask if the system is shared with the rest of the building.
162	Train staff that hand rub is for hands and sterile 70% IPA is for gloves. Using IPA on hands can dry out the skin, resulting in cracking and increased shedding. Using hand rub on gloves can break them down, resulting in an increased chance of holes and tears.
161	Read "Develop a Cleanroom Certification Checklist" by Ashley Duty, PharmD, MS, BCSCP, and Joanna Robinson, PharmD, MS, BSCSP. They provide an example checklist that you can use as a template to make your own facility-specific checklist.
160	Position PECs so that the walls behind and beside the devices and the outsides of the devices can be easily cleaned. Also consider how you will clean the floor under the device.
159	Read "Development of a Sterile Compounding Training and Competency Program at a Large Academic Medical Center" in AJHP. It provides valuable insight for those looking to streamline this part of their operation.
158	Watch for people's heads entering the PEC. This commonly occurs in LAFWs and is considered an insanitary condition. If noted, retrain staff, and look for ways to change practice so this is no longer an issue.
157	Read USP <381> Elastomeric Components in Injectable Pharmaceutical Product Packaging/Delivery Systems. It discusses the testing of the self-sealing capacity of elastomeric closures and may make you question your practices!
156	Lead by example. Whether you hold a management role or not, your appropriate cleanroom behavior will have a positive impact on other's and help lead the way to safe CSPs!

Days to Go	Tips
155	Read "Prioritize FDA Inspection Readiness" by Karla L. Palmer. The FDA has full legal authority to inspect traditional sterile compounding pharmacies and this article helps you understand what to expect.
154	Verify that the certificate of analysis (COA) for media used for any microbiological testing contains a description of media appearance. If the media doesn't look right, don't use it for testing.
153	If you sterilize aqueous CSPs using moist heat, read USP <1229.2> Moist Heat Sterilization of Aqueous Liquids. This chapter discusses the process and validation considerations.
152	Read "Develop a Hazardous Drug Oversight Committee" by Jamie Tharp, PharmD, BCSCP. Oversight of HDs throughout their entire lifecycle is more than the "designated person" can likely handle and this article provides some unique solutions.
151	Draft an acronym list that staff can reference when reading SOPs or other sterile compounding documents. Include the acronyms in the chapter as well as any facility specific acronyms.
150	Develop a numbering system for your SOPs and forms that also includes version numbers. Having this system makes tracking changes so much easier to manage.
149	Define in an SOP if staff are allowed to wear their badge into the sterile compounding area. If they are, include how the badge is wiped down and that lanyards must be easily cleanable.
148	Create a dedicated, quiet space for those checking final CSPs. Place signage indicating that the area is an "interruption-free zone" and that staff cooperation helps ensure patient safety.
147	Ensure those evaluating staff truly understand the process and coach when needed. Coaching is a necessary component of competency evaluations, especially for new staff. Give them the support they need, without giving away the process.
146	Require staff and visitors to tie long hair back and define this in the garbing SOP. Twirling hair up and tucking it in the hair cover is not sufficient to keep hair contained. Have hair ties available to ensure compliance with your SOP.

Days to Go	Tips
145	If you are unsure of what you need in an incubator, read Pure Microbiology's blog titled "Choosing Incubators." It discusses what to look for in an incubator and how to determine what you really need.
144	Make sure materials are wiped and immediately transferred to the sterile compounding area. Items cannot be wiped and sit around in the unclassified space until they are transferred into the sterile compounding area later in the day.
143	Leave your PECs running in the SCA. LAFWs continuously clean the air in the space, helping to reduce airborne contamination in the SCA. Plus, no one wants to do a 3-time clean every time the PEC is turned back on.
142	Be careful with how you plan to use the "other technologies, techniques, materials, and procedures are not prohibited" blurb. You must be familiar with USP <1223> and <1225>, as validation is required and it must be done properly.
141	Read the April 2023 release of NIOSH's Managing Hazardous Drug Exposures: Information for Healthcare Settings. It contains useful information, but it is not a standard. Don't lose sight of the regulatory requirements that apply to your operation.
140	Contact the media manufacturer immediately if you notice microbial growth in the agar after the incubation of gloved fingertip, air, or surface test samples. This indicates a sterility issue with the media.
139	Look for HD gowns that are tested to ASTM F3267-22. This standard was released in December of 2022 and defines permeation resistance testing of the protective clothing and seams against seven specified chemotherapy drugs.
138	Verify that the contract lab you or the certifier use is ISO 17025 accredited for the testing they do for you. Ask for and review their scope of accreditation, specifically looking for USP <797> incubation and analysis and identifications.
137	Read USP <1113> Microbial Characterization, Identification, and Strain Typing. This informational chapter provides great information on the process of identification, including subculturing , staining, and identification techniques.
136	Educate staff on the importance of showering daily, and preferably just prior to their shift. This helps reduce the microbial bioburden that is brought into the sterile compounding area.

Days to Go	Tips
135	Confirm that the designated person is responsible for addressing risk related to the placement and movement of materials in facility SOPs. The designated person may permit accommodations as long as the quality of the CSP and environment are not affected.
134	Make sure you read USP <797>'s glossary. We've gone from 29 glossary items to 116. This clarity helps eliminate some of the previous chapter interpretation.
133	Read USP <1116> Microbiological Control and Monitoring of Aseptic Processing Environments. It touches on training, selection of media, sample locations, and trending considerations.
132	Confirm you have comfortable working conditions in the SCA. The chapter requires that "sterile compounding facilities must be designed and controlled to provide a well lighted and comfortable working environment." This includes the SCA.
131	Define in your SOPs that the observer of the aseptic competency collects the surface sample and opens the plates for gloved fingertip testing. If performed in a RABS, the person being assessed would have to open the plates for gloved fingertip testing.
130	Read the June 2023 issue of Pharmacy Purchasing and Products. The issue has two Ask the Expert articles on USP <797> and viable sampling and an insightful article on remote observations.
129	Ask for help. If you are struggling with viable excursions, certification issues, or workflow challenges, there are industry experts available to assist. Reach out!
128	Plan media-fill tests so that the typical number of people who work in the compounding area at any given time are present. Focus on what is normal versus maxing out the space, when that might not be realistic or even achievable with every media-fill test.
127	If you have a Home Care Accreditation or Medication Compounding Certification through The Joint Commission, read the revised "Medication Compounding" chapter for home care and the Medication Compounding Certification (MDC). They are effective January 1, 2024.
126	Stop tossing items into the PEC. Items need to be slowly and carefully placed to avoid pulling outside air into the PEC.

Days to Go	Tips
125	Read Pure Microbiology's blog titled "Top 5 Things to Look for When Choosing a Lab for the Processing of USP <797> Viable Samples." All labs are not created equal.
124	Be careful with a "train the trainer" model. While this is a financially-friendly option, specialized topics may lose details in translation, resulting in diluted training. Evaluate your risk and determine the training format best suited for the topic.
123	Ensure staff are properly donning facemasks. The mask must fit snugly, sealing to the cheeks and being pulled fully under the chin. And make sure it's not on backwards!
122	Read "IV Beta-Lactam Therapy: Considerations from Diagnosis Through Sterile Compounding" in the May/June 2023 issue of Infusion. It touches on best practices for compounding these medications.
121	If your cleanroom has remote HEPA filters and you haven't started construction plans yet, ask your regulators about their compliance expectations. You may need to make alternate compounding plans.
120	Celebrate an individual's attention to detail. When someone takes time to focus on the small stuff, they truly have the bigger picture in mind.
119	Sign up for NHIA's 2023 USP Sterile Compounding Education Series. With 6 webinars and an Ask the Expert Panel Discussion, your chapter questions are sure to be answered!
118	Include the cleaning principles of clean to dirty and top to bottom in your cleaning SOPs. However, these are general concepts and there may be times when you can't exactly follow them. That's okay. Just document what is to be done in your SOP.
117	Embrace the risk assessment. The new chapter allows for many operating decisions to be based on risk. As you are updating procedures or identifying corrective actions, make decisions based on data instead of fear.
116	Verify that your terminal sterilization process meets chapter requirements. The SOP must include temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and use of biological indicators (BIs).

Days to Go	Tips
115	Read Pure Microbiology's blog titled "Unrealistic Certification Expectations." Certification is a dirty process. No amount of wiping down equipment or garbing is going to change that.
114	Instruct staff and visitors to tuck their shoelaces into the shoe covers. This helps reduce contamination and prevent a potential tripping hazard.
113	Teach staff how to properly sanitize gloves with sterile 70% IPA. There needs to be adequate IPA to cover the hands and wrists and the gloves must be allowed to dry.
112	Read the "not yet official version" of USP General Chapter <7> Labeling. Changes were made to the expiration date and beyond-use date section that take effect September 1, 2023.
111	Consider incorporating contamination recovery rates into your viable sampling trending. The contamination recovery rate is the rate at which viable samples are found to contain any level of contamination. USP <1116> discusses this metric in detail.
110	Sign up for the USP Healthcare Quality and Safety notifications. The compounding chapters fall under this group, so any information about USP <795>, <797>, or <800> will be distributed through their updates.
109	For those doing nonsterile-to-sterile Category 2 compounding, consider implementing Category 3 garbing practices. Reducing the human bioburden in the compounding area helps ensure a safer preparation.
108	Inventory your HD spill kits. Commercially available kits are one-size-fits-all and don't have everything you need. Check out Appendix I - Recommended Contents of an HD Spill Kit in ASHP Guidelines on Handling Hazardous Drugs.
107	Read USP <1211> Sterility Assurance. This informational chapter has everything you need to know about concepts and principles related to the preparation of materials that must be sterile.
106	Evaluate your organization's use of dispensing pins. They make huge holes compared to a needle, greatly increasing risk for microbial contamination. To better understand your risk, incorporate them into media-fill testing.

Days to Go	Tips
105	Teach staff to turn away from the face of the LAFW when speaking, coughing, or sneezing. Masks help catch exhalation droplets, but they aren't perfect.
104	Get in the habit of checking your certification stickers before the certifier leaves your site. Mistake can happen and the last thing you want is an incorrect sticker on a PEC when an inspector or surveyor visits.
103	Read the "not yet official version" of USP <1079> Risks and Mitigation Strategies for the Storage and Transportation of Finished Drug Products. Changes to this chapter take effect December 1, 2023.
102	If you are terminally sterilizing CSPs, verify that your SOPs include a filtration step utilizing a 1.2-micron filter prior to sterilization. This is required for both steam and dry heat sterilization to remove particulate matter.
101	Confirm your master formulation records include a list of equipment and supplies that are needed. And be specific! The goal of the master formulation record is to ensure preparation consistency.
100	Network, network, network. The more connections you make, the more information, knowledge, and resources you'll have access to. Totally worth it!
99	Read "Beyond-Use Dates for Parenteral Nutrition Must Take Compatibility and Stability Into Consideration" in Pharmacy Practice News. Too often sterility is the only focus when it comes to BUDs.
98	Stop calling USP <797> a guideline. It's a standard and the terms have two totally different meanings.
97	Read Pure Microbiology's blog titled "Determining How You Will Handle Viable Sampling and Incubation." If you're still not sure how you plan to tackle the increased sampling frequency and incubation, this blog can help.
96	Stack viable air, surface, and gloved fingertip samples in a bin for incubation. This keeps sample groups together and better secures the samples than just placing them on wire shelving. And don't forget to invert the plates!

Days to Go	Tips
95	Change RABSs gloves between compounders. Those compounding need properly fitting gloves to safely and precisely perform aseptic manipulations. Changing gloves ensures the proper glove size for whoever works in the RABS.
94	Read FDA's Guidance "Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance." It describes the conditions of Section 503A and information on regulatory action.
93	Emphasize to staff that sterile gloves must fit properly and that they must come to you if there are issues. If you need to order different gloves to ensure proper fit, do it. Ill-fitting gloves worn when compounding is a patient-safety concern.
92	If you perform nonsterile-to-sterile compounding, read USP General Chapter <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients. This chapter provides insight on the quality, facility, testing, packaging, and transportation of excipients.
91	Read USP General Chapter <1080> Bulk Pharmaceutical Excipients - Certificate of Analysis. Appendix 1 has a great example of a COA that can be applied to reviewing both an excipient or API.
90	Download USP's latest resource titled "Alternate suppliers and market share for impacted Pfizer medicines." Be sure to share with those in your organization who can use the information to address shortage concerns.
89	Consider using CSTDs for compounding HDs. Even though the use of CSTDs during compounding is a should, it reduces the risk of exposure by limiting aerosol generation during compounding.
88	Verify that your contract lab is applying the appropriate correction factor your viable air sample results, if applicable. Check the manufacturer's instructions for use for the correction factor tables and application.
87	Do not reuse empty IPA bottles for sterile water or cleaning agents. A handwritten label is not enough to avoid misuse or a regulator citation.
86	Use Glo Germ for hand hygiene and doffing HD PPE training. This powerful training tool provides visible feedback to learners and emphasizes why following facility procedures is so important.

Days to Go	Tips
85	Read "Develop a System-Wide Compounding Committee" by Amanda Wollitz, PharmD, BCPS, FISMP and Jessica Wendler, PharmD, BCSCP. Having a team dedicated to compounding compliance may also benefit your organization.
84	Ensure staff are removing items from their pockets before entering the sterile compounding area. Items left in pockets are a contamination risk and possibly a distraction.
83	Make sure staff understand that even though administration is out of the scope of the chapter, stability during administration matters. The drug must still deliver the intended effect while it's being administered, not just up until the BUD.
82	Verify that initial training for personnel who clean (and are not compounders) includes demonstrating competency in maintaining the quality of the sterile compounding environment. Training must focus on cleanroom behavior for these individuals.
81	Check your cleanroom ceiling panels to confirm they are caulked around each panel and sealed to the support frame. If you're not sure what type of ceiling system you have, talk with facilities or your certifier.
80	Visit ASHP's Compounding Resource Center for news, guidance documents, tools, and past presentations. It includes a ton of FREE information on USP <795>, <797>, and <800>.
79	Train staff to keep the area around the PEC in the SCA dedicated to compounding. Although the chapter says the area within 1 meter of the PEC "should" be dedicated for sterile compounding, this really is a best practice.
78	If you are doing Category 3 compounding, choose a sterile coverall as your outer garment. The chapter indicates that "all low-lint outer garb must be sterile" but it does not indicate what type of garment must be worn. Better to be conservative.
77	Read "Audience Q&A: From Legal Considerations when Interacting with the FDA Webinar" with Neil DiSpirito. This easy read Q&A provides insight into what to expect before, during, and after an FDA inspection.
76	Revise your SOPs if you use "line of demarcation" (LOD) to define the line in the anteroom and the HD doffing line in the HD buffer room. USP 797 now defines the LOD as the visible line on the floor that separates the clean and dirty sides of the anteroom.

Days to Go	Tips
75	Choose the right biological indicator (BI). You must consider the type of sterilization, the load contents (liquid, oil, solid), the volumes, and the spore population. Talk with the BI manufacturer. They can help.
74	Make reading AIHA's Hazardous Drug Surface Contamination Guidance Document a priority. It provides technical clarity and best practice approaches to effectively evaluate the potential for HD surface contamination in healthcare environments.
73	Review the safety data sheets for the drugs your organization handles. Not only do you need to consider the NIOSH list for HDs, but also OSHA requirements for safe drug handling.
72	Take a look at the FDA's Draft Guidance for Industry Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act. It clears up some confusion with 503As selling/transferring the drug as part of administration.
71	If you are planning on doing stability studies, read USP's Formulation and Stability Reference Document for Pharmaceutical Compounding. It's a great resource to better understand stability studies, including antimicrobial effectiveness testing.
70	Educate staff on the importance of checking the integrity of cleanroom finishes and promptly reporting any issues. Even if you have a preventive maintenance program in place, issues arise between planned inspections and need to be addressed.
69	Plan your SCA workflow to ensure everything that is needed to compound is within the perimeter of the SCA. If you reach across the perimeter of the SCA to grab an item, at a minimum this would require changing gloves.
68	Define in your SOPs that staff must completely change garb (including the garment) after performing the daily, weekly, and monthly cleans before resuming compounding. You won't find this in the chapter, but this best practice mitigates patient risk.
67	If you are in the cleanroom suite design phase, have a discussion with the designers, architects, and compliance inspectors about the direction of the door swings. The "ideal" door swing direction may not meet certain codes or regulations.
66	Read "Going Beyond the New USP <797> Standards for Parenteral Nutrition" from Pharmacy Practice News. It highlights the importance of stability, compatibility, and order review.

Days to Go	Tips
65	If you use TSA and a fungal media or another TSA plate for surface sampling, collect the surface samples side-by-side. If you collect the sample in the exact same location, the first sample will likely have picked up all the surface contamination.
64	Define timeframes in your SOPs. This is especially important for calibration, verification, and certification. If a task is to be completed every 6 months or yearly, give yourself the entire final month to complete it.
63	If you utilize pH-modifiers, be sure you update your SOPs and BUDs. Section 14.3 clarifies that there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components.
62	Get rid of your pass-through refrigerator. They are particulate generators, cause room-to-room pressure issues, and are a huge microbial contamination risk. If a refrigerator is a must, choose a freestanding model that is positioned by a return or exhaust grille.
61	Keep the area outside the anteroom door and any pass-throughs clean and uncluttered. Cardboard boxes, workstations, printers, and piles of paper can all be a contamination risk to the cleanroom.
60	Find out what system your lab uses to identify microorganisms. An identification to the genus or species level is not always necessary to perform an investigation, but a wrong identification could waste resources and result in unnecessary corrective actions.
59	If you choose to use aseptically-filled plates for viable and personnel sampling, pre-incubate the plates before use. This step allows any contamination to be visible at the time the plates are used for sampling.
58	Embrace the freedom. The chapter provides the destination, but you are in the driver's seat. Just be sure your choices are defendable.
57	Talk to your certifier before you choose a HEPA-filtered pass-through. Depending on the design, some are easy to test, some are more challenging, and some might not be able to be tested at all.
56	Keep non-essential compounding activities outside the cleanroom suite. If you are designing a new cleanroom, consider creating space outside the cleanroom for staging, final checks, and supply/component storage.

Days to Go	Tips
55	Train staff to cross off blank spaces on paper documentation and complete the required fields in electronic documentation systems. To help ensure compliance, design documentation to minimize blank fields.
54	Incorporate a pest control program. In the cleanroom, check the light fixtures and corners of the room regularly for insects. Outside the cleanroom, insect lights and traps should be considered to prevent pest entry into the cleanroom.
53	Stop using the brush/sponge/soap/nail pick combined product. By doing so you eliminate the chance of noncompliance by using the brush. Plus, it's wasteful considering all you need is some soap and a nail pick.
52	If you will be performing Category 3 compounding, consider more personnel monitoring. Collecting gloved fingertip samples on the compounder after every batch can provide additional data when making batch-release decisions.
51	If you are the designated person, consider attending the Eagleson Institute's Certification of Sterile Compounding Facilities and Aseptic Isolators training. It's designed for the certifier, but you will learn everything you need to know about certification.
50	Read the July/August 2023 issue of INFUSION Magazine. It has articles on drafting immediate-use SOPs, implementing IV workflow systems, viable sampling, and writing quality SOPs.
49	Determine how you will define a media-fill test failure. According to the chapter "failure is indicated by visible turbidity or other visual manifestations of growth." This definition only considers microbial growth, not particulate contamination.
48	Subscribe to Cleanroom Technology's newsletter. There's always some great information that can be applied to the sterile compounding cleanroom.
47	Use HD wipe sampling as a tool to better understand your deactivation/decontamination procedures. USP <800> states that wipe sampling "should be done to document the effectiveness of any agent used for decontamination of HD residue from work surfaces."
46	Talk with your sampling vendor and the contract lab if you get strange viable sampling results. You might need details from both providers to perform a robust investigation and rule out sampling, handling, or analysis errors.

Days to Go	Tips
45	Subscribe to Pharmacy Purchasing & Products and Pharmacy Practice News. Both publications provide insightful articles, useful tools, and information on the latest technology and products.
44	Read "Waste Handling: Doing Right by Employees, Patients" by Charlotte A. Smith, RPh, MS, Kathleen Skibinski, RPh, MS, and Monica Livingston in Pharmacy Practice News. It helps fill some gaps not covered by USP <800>.
43	Train staff to keep the counter or cart in the general pharmacy area used to stage CSPs free from totes, shipping cartons, and anything else that could contaminate the surface. Just because the surface looks clean doesn't mean it is clean.
42	Read USP <71> Sterility Tests if you will be performing sterility testing on your CSPs. You might not understand all the technical content, but it will give you an idea of what is actually required and provide you with knowledge to better evaluate your lab.
41	Choose carts, tables, shelves, equipment, etc., that are on casters. This makes cleaning the sterile compounding area so much easier. Just be sure you also clean the casters as part of the monthly clean, or more frequently, if needed.
40	Check out "Tips for Monitoring and Responding to Cleanroom Excursions" in Pharmacy Practice News. This short article provides some great tips to include in your investigation arsenal.
39	Consider having two viable sampling plans. You must have a routine plan that is collected under dynamic conditions. The other consists of only surface samples that are collected after cleaning under static conditions. This plan provides insight into cleaning efficacy.
38	Do not round your positive pressure results. A reading of 0.019" w.c. does not meet the chapter requirements 0.020"w.c. That hanging zero is there for a reason.
37	Make sure you include cleanroom refrigerators in your preventative maintenance plan and cleaning program. Any buildup of condensate beyond what is normal is a breeding ground for microorganisms.
36	Read Sequential Wipe Testing for Hazardous Drugs: A Quality Improvement Project by Seth Eisenberg. The study evaluated the benefits of performing wipe testing, implementing any necessary changes, and evaluating the change effectiveness.

Days to Go	Tips
35	If you do not wear coveralls, consider using shoe covers that come up the leg. These taller shoe covers ensure skin on the leg is not exposed in the compounding area.
34	Review the USP chapters referenced in <797>. Not all 20 chapters that are mentioned will apply to your compounding operation, but you want to be sure you are not missing out on any requirements or valuable guidance.
33	Choose locking lid plates. You can purchase both settle plates and contact plates with locking lids. Taping or using parafilm comes with contamination risks.
32	Read USP <1058> Analytical Instrument Qualification if you plan on having incubators. This informational chapter defines the different categories of instruments and describes everything that should be included to ensure function and quality.
31	Check out Technician Talk in NHIA's September/October 2023 Infusion Magazine. The best practice tips can be applied to any sterile compounding facility's viable sampling program.
30	Thoroughly vet cleanroom design vendors. Just because they have experience with laboratory or healthcare design does not mean they know how to properly design a sterile compounding cleanroom suite.
29	Make sure your microbial excursion SOP goes beyond just identifying the source. You want to identify contamination sources, points of entry, and areas for proliferation.
28	Renew your USP subscription. Even if you've saved PDFs of the chapters you use most, you may need access to additional chapters in the future. And there's always the possibility a chapter may be updated, making your copy obsolete.
27	Verify you have a COA or conformance documentation for each lot of commercially available sterile, depyrogenated containers and container closure systems. If sterilization and depyrogenation are performed onsite, check out <1228> and <1229>.
26	Get your information about microorganisms recovered in your facility from peer-reviewed publications. When you find that a bug was isolated from the space station or an ocean trench, question the identification.

Days to Go	Tips
25	Watch work practices. This can include physically being present in the compounding area or installing cameras to watch remotely. You can't oversee compounding without laying eyes on actual practice.
24	Get the PEC cords off the floor. By purchasing magnetic hooks and sticking them to the PEC, you can get the cord off the floor and make cleaning the floor so much easier.
23	Track deviations from SOPs. The chapter requires adherence to procedures. When procedures are not followed, the incident needs to be documented and evaluated as part of the CAPA program. Tracking the issues helps identify negative trends.
22	Be conservative with document retention. USP <797> only addresses retention time for "documentation for a particular CSP", which is 2 years. Hang on things like certification and EM reports that long. And don't forget to review other applicable laws and regulations for document retention.
21	Make sure the sink is cleaned and disinfected each day of use and that a sporicidal disinfectant is applied at least monthly. This information in section 4.4 Water Sources and not in Table 10, which covers the cleaning frequency and agent requirements.
20	Verify that staff are aware that single-dose containers may be used up to 12 hours once opened/punctured inside an ISO Class 5 PEC if the storage requirements are met. And remind them that the container doesn't need to stay in the PEC.
19	Choose a pass-through with interlocking doors. USP <797> and <800> have conflicting definitions of pass-through when it comes to the need for the doors to be interlocked. Pass-throughs with interlocking doors are a contamination control best practice.
18	If you need to fill in some gaps from USP <800>, check out the 45 references listed at the end of the chapter. There's some great information from associations, government agencies, and industry experts.
17	If you outsource your viable sampling, review your sampling plan, as you are responsible for the quality of the locations. The sampling locations must provide valuable data and insight to the risk to the final CSP.
16	Ship your viable samples or plates for identification to the lab in sterile bags. Some plate manufacturers include sterile bags in the pack of irradiated plates. You can also purchase sterile bags.

Days to Go	Tips
15	If you struggle with exceeded action levels on viable air samples, consider performing a room recovery study. Discuss this option with your certifier and request they follow the room recovery rate testing outlined in CAG-003.
14	Read the definition of "dynamic operating conditions" in the glossary. You need compounding personnel, simulated or actual compounding, and as close to routine operations as you can get.
13	Remind staff that they need to check their garb during the compounding process. Garb must be replaced immediately if it becomes visibly soiled or if its integrity is compromised. This is more than just gloves.
12	Verify that temperature, humidity, and other monitoring equipment are calibrated or verified for accuracy as determined by the manufacturer or every 12 months. Don't assume the frequency is every 12 months. Read the user manual.
11	Keep floor cleaning in the HD buffer room and C-SCA simple. Use the EPA-registered one-step disinfectant cleaner daily to meet USP <797> requirements. Decontaminate the floor weekly or at a frequency that makes sense based on your HD workload.
10	Investigate deviations from approved SOPs. USP Chapter <1163> Quality Assurance in Pharmaceutical Compounding indicates that it is the responsibility of the quality assurance personnel to investigate and implement appropriate corrective action.
9	Remind staff that slow and controlled movements in the PEC or immediately adjacent to a PEC are a must. Inappropriate movement can lead to the disruption of unidirectional airflow, which according to the FDA is an insanitary condition.
8	If you have a RABS, consider replacing it with an LAFW or BSC, as appropriate. RABS are much harder to clean, maintain, and work in. They also provide a false sense of security when it comes to the sterility of the CSP.
7	Take a hard look at your workflow and facility design. Be honest about what you see. If you turn a blind eye now, not only will the organization get cited, you will put your patients at risk.
6	Make sure you are not storing a vial where the septum or metal septum ring was removed. Vials that have the septum or metal septum ring removed are treated like ampules and must not be stored for any time period.

Days to Go	Tips
5	Have your contract lab report the total bacterial count, total fungal count, and total microbial count on your viable reports. Even if you don't exceed the action level, this gives you a general idea of what was recovered, allowing you to take action if you choose.
4	Research training opportunities through your vendors. Some provide comprehensive training, both remote and in person, in their area of expertise.
3	Focus on contamination control. Every decision you make must be evaluated for how it affects the compounding environment and the CSP. Find the right procedure for YOUR facility. For some things, there is more than one "right" way.
2	Plan out next year's live training for yourself and your staff. Whether at a conference or through a training company, there are a variety of training opportunities available. And some companies will come to you!
1	Sign up for Pure Microbiology's monthly newsletter, The Pure Observer. Every issue will contain USP <797>-related topics, including a main article and informational sections titled Question of the Month and Best Practice Makes Perfect.
0	Celebrate the progress you made over the last year. Smile at what you have learned. Your dedication to patient safety and sterile compounding compliance not only benefits your facility today but brightens the future for those that follow you.