# USP <797> Chapter Release Countdown Tips

| Days to Go | Tips |
|---|---|
| 18 | If you plan to incubate your own media-fill, gloved fingertip, viable air, or surface samples, you need two incubators. One must have refrigeration capabilities, so it can hold 20 to 25 °C. Start shopping now. |
| 17 | Be prepared to order sterile, EPA-registered one-step bactericidal and sporicidal disinfectant cleaners to clean your primary engineering controls. The agents you are currently using may not come in a sterile version. Do your research! |
| 16 | Determine the number of plates you need to perform gloved fingertip, viable air, and surface sampling for 3 months and set up a standing order. Don't forget you need to do a surface sample with every media-fill test. More media to store! |
| 15 | The "designated person" is mentioned 20 times in the body of the chapter. They are responsible and accountable for the entire sterile compounding operation, including personnel. Identify more than one designated person to cover all of the required responsibilities. |
| 14 | Define a maximum time for the incubation of gloved fingertip, viable air, and surface samples. Incubating for too long dries out the media, and growth may not be viable for ID. Example: 1st incubation 48 hours to 4 days 2nd incubation 5 to 7 days. A range provides process control! |
| 13 | Develop a process for assessing a garbing accommodation, including the associated documentation. Accommodations are only permitted if the quality of the CSP and the compounding environment will not be affected. Be ready to provide evidence! |
| 12 | If you decide to compound any Category 3 CSPs, you must continuously meet all Category 3 requirements. Even on days when you don't compound Category 3 CSPs. It's all or nothing! Plan accordingly! |
| 11 | If you plan on compounding Category 3 CSPs, all garbing materials must be sterile and low-lint. Start your search now. Remember, there can be no exposed skin, so look for items that have good coverage of the face and neck. And yes, you must wear goggles! |
| 10 | Read CETA Application Guide (CAG)-003 titled Certification of Sterile Compounding Facilities for USP Compliance. The latest version provides extensive detail on certification testing and reporting. Knowledge is power. |



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

| | |
|---|---|
| 9 | Start researching the "use time" of your sterile cleaning agents and materials once they are opened. The "use time" must be defined in your facility's SOPs. Contact the manufacturer. If they don't have a recommendation, you must decide. Base it on risk and usage. |
| 8 | Determine where equipment will be located in the PEC and be sure it is in that location when the certifier performs the dynamic airflow smoke pattern test. Staff must return the equipment to the exact same location after cleaning. Otherwise, the test must be repeated. |
| 7 | Check your SOPs to be sure roles, duties, and training for personnel responsible for the quality program are defined. This could be a huge undertaking if you have multiple people responsible for different aspects of the quality program. Quality is part of all operations! |
| 6 | Confirm you have procedures in place to evaluate components for defects at the time of receipt and use. If a defect is detected, any other lots of that component from that vendor must be examined for the same defect. Document the defect and investigation! |
| 5 | Describe in your SOPs how reusable cleaning tools are to be cleaned and disinfected before and after each use. Those who clean the controlled environment must be aware of this cleaning tool chapter requirement. Consider documenting this task! |
| 4 | Draft a process for conducting a second visual inspection if a CSP will not be released or dispensed the same day prepared. Run through the process with all necessary staff members and work out the details before implementation. Especially inspection documentation! |
| 3 | If you will be terminally sterilizing CSPs using steam heat, start shopping around for physicochemical integrators. Each sterilization run must be verified with a biological indicator AND another confirmation method, like an integrator. Check out USP <1229.9>! |
| 2 | Identify your assigned trainers and clearly define the training and observation each may perform. "Assigned trainer" is a new chapter term, which allows staff other than designated persons to train others. Use this to your advantage! |
| 1 | If you are not currently compliant with USP <800>, now is the time. USP <800> will become compendially applicable when USP <797> becomes official. From what we know right now, that will be May 1, 2023. States may enforce this differently! |
| 0 | Have multiple people read the new version of <USP 797>. Identify and prioritize the changes you need to make. Divide and conquer the workload, using industry experts, if needed. |