

## Using the CriticalPoint USP 797 and 800 Electronic Gap Tool

Please complete the USP 797 and/or 800 Compliance Survey for the ***busiest*** sterile compounding location at your facility/organization (in the event your facility has more than one compounding location).

As the survey starts, you will be asked a series of questions in the “Demographic Information” and “General Compounding” domains. Many of these questions are used to determine which items will be presented to you in the rest of the survey. Therefore, it is very important that you answer those questions accurately.

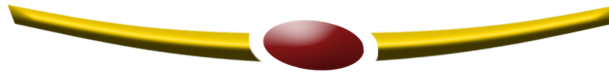
**At the end of the “General Compounding” domain, you will be asked if you want to answer questions for USP 800 only. If you answer “Yes” then USP 797 questions will not be presented. You may return at any point and change your answer to “No” to make the USP 797 hidden domains and items available.**

To simplify completion of the survey, all the measured compliance items require a simple “yes” or “no” answer. There are no “not applicable” answer choices provided. That is deliberate. If you are presented with a question, it means that the question ***does apply*** to your practice based upon the answers you provided in the “General Compounding” section though you may not be aware of those particular USP 797 & 800 requirements.

Also, please remember that a “yes” answer means that the location you are answering for is fully compliant and meets ***all*** the requirements outlined in the question. Rate your compounding location honestly. Don't answer the questions based on what your location “will be” or has “started” but on what is currently happening at your location on the date the survey is completed. It's really important that you are objective and don't overstate your compliance or rate your practice based on what you wish it to be. That's one of the dangers of a self-report study, and it is why we developed the tool the way we did. A lot of work and testing has gone into developing a tool that presents users with questions that apply to their practice based on the types of compounding they perform. This tool presents you with a snap shot of where you are today.

This electronic Gap Tool provides a detailed action plan for compliance, which is generated based on the answers you provided. If you go easy on your location and rate yourself as complying with the requirement/s when you don't, the Action Plan you receive will not be as comprehensive or helpful to you. Remember, all individual facility results are kept confidential – only aggregate data are reported in the study. To receive a comprehensive, detailed and individualized Action Plan, it is critical that you do not answer “yes” unless your location is fully compliant with the details of each item.

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## Detailed Instructions

1. The first sections you **MUST** complete are the Demographic Information followed by the General Compounding domains. Your answers to these questions will determine your access to other USP 797 & 800 content domains and the questions within those domains. Based on your answers to these questions, certain domains will be “greyed out” (not available).
2. As each question is completed, a percentage bar (% bar) will display your progress through the current domain. When all questions in a domain are completed, you will have the following options:
  - a. Continue to the next domain
  - b. Print out the offline survey OR
  - c. Go back to the Home page where you can
    - i. Select any domain to work on
    - ii. View the location’s action plan report (only available after all domains are completed)
  - d. Logout and return later to complete the survey
3. To view your location’s Action Plan, go the survey home page. Click on the PDF icon for “view full report.” You will be able to view, save or print the information. You also have the option of viewing the report on an individual domain by clicking the PDF icon for the specific domain of interest.
4. Completing all items in the CriticalPoint Gap Tool takes about 1 to 2 hours depending on the types of compounding your location performs and your answers to the “General Compounding” domain items. The entire Gap Tool does not need to be completed at one time. If you need to stop, you can log out. When you log back in, you will be able to review your answers and pick up where you left off.

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## Disclaimer

This tool is designed to sample high-level compliance with USP General Chapter 797 (2019) Pharmaceutical Compounding - Sterile Preparations & USP General 800 Hazardous Drugs – Handling in Healthcare Settings. It is not intended to replace a detailed first-hand review and application of the Chapters contents by pharmacy leadership. As such, the tool measures compliance with selected concepts and requirements that are considered fundamental to compliance with USP 797 & USP 800 and does not purport to measure every required compliance action. Measuring compliance with USP 797 & USP 800 is dependent upon the professional judgment and interpretation of the practitioner due to the uniqueness of each pharmacy’s role in compounding sterile preparations.

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