CriticalPoint's

Designated Person(s) Certification and Recertification

Designated Person(s) Basic Sterile Compounding Training and Competency Certification Program

In 2017, CriticalPoint launched its QP503A Certification. Successful completion of the program requirements results in the acquisition of specific, essential knowledge and skills that facilitate an individual's ability to effectively plan, develop, and operate a 503A pharmacy sterile compounding operation. QP stands for "qualified person," which is a technical term used in European Union pharmaceutical regulations and which CriticalPoint has borrowed. In 2021, CriticalPoint updated the QP503A Certification program to the Designated Person(s) Certification.

Eligible participants for the Designated Person(s) Certification successfully complete a didactic program of home study, live training, and practicum activities accompanied by required objective personnel and cognitive testing. The goal of this program is to provide an immediate opportunity for all pharmacies performing sterile compounding to train *at least one individual* in the common aspects of pharmacy sterile compounding. This individual would be able to oversee the development of comprehensive and detailed standard operating procedures (SOPs) and mentor, guide, and inspire others performing sterile compounding at their location. This program is intended for practitioners who currently oversee or perform sterile compounding.

CriticalPoint has shared this vision with the National Association of Boards of Pharmacy and State Boards of Pharmacy to identify whether this program will be supported by regulators, either through mandates to licensed provider pharmacies or encouragement of licensees to pursue this type of credentialing program. This program may also be used by State Boards of Pharmacy as one of the elements of a state-mandated "Directed Plan of Correction" for licensees requiring significant remediation in their sterile compounding practices.

Designated Person(s) Initial Certification Requirements

Step 1: Register for Best Practices for Nonhazardous Sterile-to-Sterile Compounding live training and the Sterile Compounding Aseptics Class. Select the Certification Add-on in the Aseptics registration page.

It is highly recommended that Certification recipients have the following prerequisites:

- licensed pharmacist or technician practitioner working in a licensed pharmacy
- have at least 3120 hours (two years averaging 30 hours per week) recent experience performing actual sterile compounding and associated activities

Step 2: Successful completion of the following eLessons within 12 months *prior to* attending the required live training:

- selected eLessons and post tests from CriticalPoint's Pharmacy Math Calculations (Calculations Required for Dosing, Dilution, and Reconstitution; and Sterile Compounding Calculations)
- all sterile compounding eLessons and post tests

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Step 3: Five days of live classroom and practicum activities (ACPE-approved, live CE) at the CriticalPoint Center for Training and Research (CCTR) consisting of:

- attendance at the three-day Best Practices for Nonhazardous Sterile-to-Sterile Compounding live training*
- attendance at the one-and-a-half-day Aseptics Class live training immediately following the Best Practices for Nonhazardous Sterile-to-Sterile Compounding live training, and successful completion of the following during the Aseptics Class:
  - hand hygiene and garbing observational competency
  - initial gloved fingertip sampling (total of one instance)**
  - aseptic technique observational competency
  - preparation of media-fill units (MFUs)**
  - ongoing GFS (taken immediately after compounding MFUs)**
  - surface sampling (taken immediately after compounding MFUs)**

*Previous Best Practice attendees must still complete all the requirements outlined. The Best Practices for Nonhazardous Sterile-to-Sterile Compounding live training curriculum is continually revised and updated.

**CriticalPoint will incubate and read all samples and MFUs as well as complete documentation of competencies and outcome of sampling. Candidates must pass all behavioral and objective sampling components.

Step 4: Pass a post test (80%) administered through CriticalPoint's LMS and covering all subjects from the Best Practices and Aseptic Technique Live Training Lectures and Labs within 30 days subsequent to the live training.

Designated Person(s) Certification: Recertification Requirements

Three months prior to the expiration of the Designated Person(s) credential, follow these steps:

Step 1: **Visit the** CriticalPoint Designated Person(s) Recertification landing page. This location houses all information related to the recertification process. **Download the Attestation Form,** which must be completed. The Attestation Form is where the applicant's work supervisor confirms employment and attests that the applicant continues to perform sterile compounding duties.

Step 2: **Complete all CriticalPoint Sterile Compounding eLessons and the three required math eLessons within one year of the recertification due date.** This is to ensure that the applicant has likely completed the most recent versions of the eLearning regardless of whether they have previously completed them in the recertification period.

Step 3: **Prepare *one* of the following**:

- Author a published article regarding sterile compounding practice. Submit the article and the citation.
- Provide documentation of a change in sterile compounding practice you initiated and oversaw. Include the change, the planning and research that was required to make the change, obstacles that were encountered, and the SOP created or revised as part of the change.
- Perform a GAP analysis of your organization and provide a legitimate plan to bring forward improvements to facilities or work practices.

- Complete a teaching project (internal or external) on sterile compounding work practice to 10 or more individuals. Submit the PDF slide deck, learning objectives, and evaluations from participants.
- Provide proof of completion of six CPE hours (from one or several **live** courses within the recertification period) obtained through sterile compounding training. Examples may include CriticalPoint's Aseptic Training Class or Environmental Monitoring Class. Other CPE may be accepted provided it was at least six ACPE-approved credit hours and was related directly to sterile compounding. If live training presentations are not ACPE-approved, the curriculum and learning objectives must be submitted to CriticalPoint for approval.

Step 4: **Visit the** CriticalPoint Designated Person(s) Recertification application page **and complete the following**:

- Designated Person(s) Recertification Application to provide some basic demographic and contact information and to confirm all sterile compounding eLessons and required math eLessons have been completed.
- Upload the completed Attestation Form.
- Upload the evidence gathered for Step 3 (uploaded files may be PDF, doc, docx, jpg, bmp).
- Pay the $279 recertification fee.

Within 10 business days of uploading this material, applicants will be notified whether submitted material is accepted. If accepted, the Designated Person(s) post test will be loaded into the applicant's CriticalPoint LMS account.

Step 5: Retake the Designated Person(s) post test and pass with a score of at least 80%. The post test is comprised of over 200 questions from which 87 are randomly pulled and representing each topic from the sterile compounding and aseptic training. The questions are updated each year to reflect current practice, and passing this test demonstrates the applicant understands the application of current material. Applicants will have 30 days after the day the post test is activated in their account to retake it. Applicants may retake the post test up to three times and may use any training materials at their disposal while taking it.

Step 6: When an applicant passes the post test, a certificate will be available for download from the LMS.