2020 CriticalPoint's *QP503A™* Certification Program

In 2017 CriticalPoint launched its ***QP503A™*** Certification. QP stands for "qualified person" which is a technical term used in European Union pharmaceutical regulations and from which CriticalPoint has borrowed. Successful completion of these program requirements results in the acquisition of specific essential knowledge and skills that facilitate an individuals' ability to successfully plan, develop and operate a 503A pharmacy sterile compounding operation. This program may also be utilized 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.

There are two types of *QP503A™ Certification and the Certification is for a 3-year period.*

1. The traditional QP503A™ Certification***,*** *now retitled* ***QP503A, CO™*** is a program of home study, live training, practicum activities accompanied by traditional testing; observational competency verification as well as objective initial gloved fingertip sampling and media-fill testing (also accompanied by gloved fingertip testing and surface sampling in the DCA taken immediately after media-fill 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 core aspects of *best practice sterile compounding operations*. While the training is consistent with current USP 797 requirements, CriticalPoint's training focuses on ensuring the mastery of best practice compounding actions, thereby promoting the utmost in patient safety. After successfully achieving this credential, individuals are better prepared to oversee the development of comprehensive and detailed standard operating procedures (SOPs) as well as mentor, guide and inspire others working in the sterile compounding operation at their location. This program is intended for practitioners who currently perform or directly supervise sterile compounding activity.
2. The new ***QP503A, CQ™*** Certification is intended for those who work in sterile compounding operations but do not perform sterile compounding and are not direct pharmacy supervisors. Individuals seeking this certification are not required to be a licensed technician or pharmacist. These individuals may perform training or quality-related roles inside their organization. This program, which focuses on quality concepts, includes home study, live training, practicum activities accompanied by traditional testing; observational competency verification as well as objective initial gloved fingertip sampling and competency testing as a qualified evaluator. Those who have successfully attained the ***QP503A, CO™*** can seek the CQ certification as well, and requirements are described below.

QP503A, CO™ (Compounding Operations) Initial Certification Requirements:

Step 1: **Submit a completed application to ensure these requirements have been met**

- Licensed pharmacist or technician practitioner working in a licensed pharmacy
- Attestation from employer of at least 3120 hours (2 years averaging 30 hours per week) recent experience performing actual sterile compounding and associated activities

Step 2: **Complete the eCurriculum 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. The eLessons in all the Sterile Compounding eCourses (except Hazardous Drug) were updated in late 2019 or early 2020, so the new versions must be taken before attending the live training.

Step 3: **Attend the required live training at the CriticalPoint Center for Training and Research (CCTR)**

- Best Practices for Nonhazardous Sterile to Sterile Compounding (3 days)*
- Sterile Compounding Aseptics taking the Operations track (2 days)

Step 4: **Prior to leaving the CCTR successfully complete the following:**

- Pass the Hand Hygiene and Garbing Observational Competency
- Perform an Initial Gloved Fingertip Sampling (GFS): 1 instance both hands**
- Pass the Aseptic Technique Observational Competency
- Prepare 3 Media-Fill Units (MFUs)**
- Perform a subsequent GFS taken immediately after compounding MFUs**

- Take a Surface Sample from the direct compounding area immediately after MFT is complete**
- Pass 4 testing stations (1 visual inspection of bags, 1 visual inspection of syringes, 1 evaluation of compounding documentation, 1 identification of aseptic process mistakes in a video)

* Those who have attended previous "Boot Camp" or "Core Skills" must complete all the requirements outlined. The curriculum is continually revised and updated.

** CriticalPoint incubates and reads all samples and MFUs as well as documents competencies and the outcome of sampling. Candidates must pass all behavioral and objective sampling components.

Step 5: **Successfully pass all sampling associated with the certification.**

- No growth recovered on initial gloved fingertip samples
- No visible manifestations of growth in the MFU
- No more than 3 colony forming units recovered from both subsequent gloved fingertip samples
- No more than 3 colony forming units recovered from the DCA surface sample

Step 6: **Within 30 days of the end of the live training, take and pass the *QP503A, CO™* Post Test (80%)** administered through CriticalPoint's LMS covering all subjects from the Best Practices and Aseptics live training lectures and interactive experiences.

QP503A, CQ™ (Compounding Quality) Initial Certification Requirements:

Step 1: **Submit a completed application to ensure this requirement is met**

- Attestation from employer of at least 3120 hours (2 years averaging 30 hours per week) recent experience working in a sterile compounding operation

Step 2: **Complete the eCurriculum 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. The eLessons in all the Sterile Compounding eCourses (except Hazardous Drug) were updated in late 2019 or early 2020, so the new versions must be taken before attending the live training.

Step 3: **Attend the required live training at the CriticalPoint Center for Training and Research (CCTR)**

- Best Practices for Nonhazardous Sterile to Sterile Compounding (3 days)*
- Sterile Compounding Aseptics taking the Quality track (2 days)

Step 4: **Prior to leaving the CCTR successfully complete the following:**

- Pass the Hand Hygiene and Garbing Observational Competency
- Perform an Initial Gloved Fingertip Sampling (GFS): 1 instance both hands**
- Pass the Qualified Evaluator Competency
- Pass 4 testing stations (1 visual inspection bags, 1 visual inspection syringes, 1 evaluation of compounding documentation, 1 identification of aseptic process mistakes in a video)

* Those who have attended previous "Boot Camp" or "Core Skills" must complete all the requirements outlined. The curriculum is continually revised and updated.

** CriticalPoint incubates and reads all samples as well as documents competencies and outcome of sampling. Candidates must pass all behavioral and objective sampling components.

Step 5: **Successfully pass all sampling associated with the certification.**

- No growth recovered on initial gloved fingertip samples

Step 6: **Within 30 days of the end of the live training, take and pass the *QP503A, CQ™* Post Test (80%)** administered through CriticalPoint's LMS covering all subjects from the Best Practices and Aseptics live training lectures and interactive experiences.

If an individual with a ***QP503A, CO™*** wants to attain a ***QP503A, CQ™*** certification, they must return to the CCTR to take the Quality Track (Day 2) as well as complete Steps 4 through 6 during the time their ***QP503A, CO™*** is current.

QP503A, CO™ and ***QP503A, CQ™ Recertification Requirements***

Three months prior to the expiration of the QP503A credential, follow these steps:

Step 1: **Visit the CriticalPoint QP503A™ 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 as is appropriate to the type of Certification (CO or CQ).

Step 2: **Complete all eCurriculum required for the type of Certification (CO or CQ) 6 months before 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 or quality (submit the article and the citation).
- Complete a teaching project 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 6 ***live*** hours (from one or several courses within the recertification period) obtained through live training. The training will be accepted provided it was at least 6 ACPE-approved credit hours and was related directly to sterile compounding operations or quality. If live training presentations are not ACPE-approved, the curriculum and learning objectives may be submitted to CriticalPoint for evaluation and potential approval.

Step 4: **Visit the CriticalPoint QP503A™ Recertification Application Page and complete the following**:

- QP503A™ Recertification Application to provide some basic demographic and contact information as well as confirming all Sterile Compounding eLessons and required math lessons 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 was accepted. If accepted, the ***QP503A, CO™*** or the ***QP503A, CQ™ Post Test*** will be loaded into the Applicant's CriticalPoint LMS account.

Step 5: Take the ***QP503A™ Post Test*** and pass with a score of at least 80%. The Post Test is comprised of over 200 questions of which approximately 85 are pulled randomly reflecting each topic from the sterile compounding and aseptic training either in operations or quality. Be aware that the questions are updated each year to reflect current practice and passing this test demonstrates that 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 3 times and may use any training materials at their disposal while taking it.

Step 6: When an applicant passes the Post Test, a temporary certificate will be available for download from the LMS. Within 6 weeks CriticalPoint will send a raised seal certificate that is suitable for framing.