CriticalPoint's *QP503A™* and *QP503A Master™* Certification and Recertification

QP503A™ Basic Sterile Compounding Training and Competency Certification Program

In 2017 CriticalPoint launched its ***QP503A™*** and ***QP503A Master™*** Certifications. 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. QP stands for "qualified person" which is a technical term used in European Union pharmaceutical regulations and from which CriticalPoint has borrowed.

Eligible participants for the ***QP503A™ 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 are currently performing sterile compounding.

CriticalPoint has shared this vision with the National Association of Boards of Pharmacy as well as State Boards of Pharmacy to identify if these programs 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 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.

The ***QP503A Master™ Certification*** is earned after obtaining the basic QP503A™ Certification and requires that individuals demonstrate their ability to put the knowledge gained through training to use in actual work settings by making measurable changes to sterile compounding processes resulting in improved patient safety.

This ***QP503A™ Certification*** also provides the foundation necessary for individuals to successfully complete the requirements necessary to obtain the ***QP503B™*** credential which is described later in this document.

QP503A™ Initial Certification Requirements:

Step 1: Submission of application for ***QP503A™*** with the following prerequisites:

- 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: 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 the Sterile Compounding eLessons and Post Tests

(continued on the next page)

CriticalPoint Center for Training and Research
11B Commerce Way
Totowa, NJ 07512-1154

Tel: 973.256.6500
Fax: 866.538.4783
www.criticalpoint.info

Step 3: 3.5 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 2.5-day Sterile Compounding Boot Camp® live training*
- Attendance at the 1-day Aseptics Class live training immediately following the Sterile Compounding Boot Camp® as well as successful completion of the following during the Aseptics Class:
  - Hand Hygiene and Garbing Observational Competency
  - Initial Gloved Fingertip Sampling (total of 1 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)**

*For previous Boot Camp attendees only, you still must complete all the requirements outlined. The Sterile Compounding Boot Camp® 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%) to be administered through CriticalPoint's LMS covering all subjects from the Boot Camp and Aseptic Technique Live Training Lectures and Labs within 30 days subsequent to the live training.

QP503A™ Certification: 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.

Step 2: **Complete all CriticalPoint Sterile Compounding eLessons and the 3 required math lessons 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 or inspection (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*** CPE hours (from one or several courses within the recertification period) obtained through live training in sterile compounding. Examples may include CriticalPoint's Aseptic Training Class or Environmental Sampling Class. Other CPE may be accepted provided it was at least 6 ACPE-approved credit hours and was related directly to sterile compounding. If live training

CriticalPoint Center for Training and Research
11B Commerce Way
Totowa, NJ 07512-1154

Tel: 973.256.6500
Fax: 866.538.4783
www.criticalpoint.info

presentations are not ACPE-approved, the curriculum and learning objectives must be submitted to CriticalPoint for 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™ Post Test*** will be loaded into the Applicant's CriticalPoint LMS account.

Step 5: Retake the ***QP503A™ Post Test*** and pass with a score of at least 80%. The Post Test is comprised of over 200 questions of which 87 are pulled randomly reflecting each topic from the sterile compounding and aseptic training. 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.

QP503A™ Master Initial Certification Requirements

1. Complete and submit an approved ***QP503A™ Master*** Sterile Compounding Change Project within 24 months of earning the ***QP503A™*** certification.
2. The project must demonstrate the ability of the individual to use the information and behaviors learned during ***QP503A™*** Certification training to produce a measurable change in sterile compounding related performance in the work setting. The individual would identify a specific area of their sterile compounding operation where improvement is required in order to achieve consistent quality and reduce risk to patients.
3. The candidate designs a plan for remediation, implements the plan, measures the outcome of the plan as well as any alterations to the plan and submits documentation of these elements and the outcomes in measurable terms.
4. Specific project requirements and elements of performance will be clearly communicated to participants.
5. This project must be identified, implemented and submitted to CriticalPoint within 24 months from earning the ***QP503A™*** certification.

QP503A Master™ Certification: Recertification

Completion of the requirements for QP503A™ recertification outlined above ***and any one*** of the following every 3 years:

- Evidence of a published article regarding sterile compounding practice
- Submission of another Sterile Compounding Change Project (as above)
- Teaching project on sterile compounding with evidence of provision of teaching to 10 or more individuals by submitting the PowerPoint slide deck and evaluations from participants

CriticalPoint Center for Training and Research
11B Commerce Way
Totowa, NJ 07512-1154

Tel: 973.256.6500
Fax: 866.538.4783
www.criticalpoint.info