**Qualified Person Certification Program for 503A and 503B Personnel**

**Executive Summary**

The quality and safety of compounded medications in the United States is influenced by several factors that include appropriately designed, built and controlled facilities; various state-of-control work practices as well as educated, engaged and highly proficient personnel. Over the last twenty years, many preventable compounding errors have resulted in patient harm and death. One of the root causes consistently identified in all of these events was the lack of knowledgeable, accountable and capable compounding personnel. In order to consistently achieve quality and safety, CriticalPoint has approached NABP as it wishes to work in concert with the State Boards of Pharmacy to establish a formal and standardized system for evaluating, educating and credentialing qualified persons for both 503A and 503B entities.

While licensed pharmacies performing sterile compounding have demonstrated measurable progress in their pursuit of USP 797 compliance, we all (the State Boards of Pharmacy, the NABP and ourselves) remain concerned that the improvements in practice are merely incremental in nature. To ensure consistency in practice, we are recommending that at least one pharmacist at each licensed pharmacy performing sterile compounding should be required to master specific curriculum and demonstrate their ability to act on this knowledge through objective testing and collection of certain personnel sampling metrics.

As a result of the requirements detailed in the Drug Quality and Security Act, Title I-Compounding Quality Act, Sec 503B. Outsourcing Facilities, the Federal Food, Drug and Cosmetic Act states that drugs compounded in 503B entities must be compounded by or under the direct supervision of a licensed pharmacist. We feel strongly that pharmacists should have to demonstrate knowledge and the ability to design sound compounding methodology and effective quality systems to supervise such operations.

Our program, the Qualified Persons Certification Program:

- **For 503A Personnel (*QP503A™* and *QP503A Master™*)** this offering **c**reates a national credentialing program leveraging CriticalPoint's existing Pharmacy Math and Sterile Compounding eLearning Curriculums, specific live training and practicum exercises (Sterile Compounding Boot Camp and Aseptic Technique Live Training), required Hand Hygiene and Aseptic Technique Competencies with accompanying personnel sampling and media fill testing; as well as pass a final exam administered through the CriticalPoint LMS. This program results in the acquisition of specific desired demonstrated knowledge and psychomotor skills. Persons who earn the QP503A™ credential have the option of pursuing the QP503A Master® credential by completing an additional project demonstrating their ability to facility measurable change in sterile compounding performance in their work setting.
- **For 503B Personnel (*QP503B™*)** this offering creates a national credentialing program created using a combination of three 503B eLearning courses to ensure level-setting for pharmacists and technicians as well as a 3.5-day live training course titled Strategies and Considerations Essential to the Operation of a 503B Outsourcing Facility. To be eligible to earn the ***QP503B™***, individuals would have to complete the eLearning within 12 months before attending the live training, complete the live training, successfully complete a sterile garbing competency with accompanying personnel sampling as well as pass a final exam administered through the CriticalPoint LMS.



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**History of the term Qualified Person (QP)**

The concept of the Qualified Person (QP) was first established in 1975. It is a unique regulatory requirement found in the European Union (EU) pharmaceutical regulations. The regulations specify that no batch of medicinal product can be released for sale or supply prior to certification by a QP that the batch is in accordance with the relevant requirements. The QP is typically a licensed pharmacist, biologist or chemist (or a person with another permitted academic qualification) who has several years' experience working in pharmaceutical manufacturing operations, and has passed examinations attesting to his or her knowledge.

The QP concept has also be embraced by The Occupational Safety and Health Administration (OSHA), a division of the US Department of Labor. OSHA has established requirements for both a Competent Person and Qualified Person in various industries where safety is paramount. The OSHA rules state:

- 29 CFR 1926.32(f) states: "Competent person" means on who is capable of identifying existing and predictable hazards in the surroundings or working conditions, which are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them.
- 29 CFR 1926.32(l) states: "Qualified" means one who, by possession of a recognized degree, certificate, or professional standing, or who by extensive knowledge, training and experience, has successfully demonstrated his ability to solve or resolve problems relating to the subject matter, the work, or the project.

The Qualified Persons Certification program would provide mechanisms to achieve the following objectives and outcomes:

1. To create a compounding quality and accountability platform for 503A pharmacists and pharmacies whereby the critical performance metrics desired by State Boards of Pharmacy may be met and patient safety improved.
2. To create a national credentialing program that all State Boards of Pharmacy could endorse, establishing confidence that 503B entities would have an identified individual that would have oversight responsibility and accountability to the quality of the medications shipped into any state.
3. To clearly delineate and establish the responsibilities of the Pharmacist working in a 503B Outsourcing Facilities as mandated by the DQSA. These responsibilities could be developed through the collaborative efforts of the FDA, State Boards of Pharmacy, NABP and industry experts at a Stakeholder's meeting.
4. To formalize and elevate 503B manufacturing quality through the application of accountability for patient safety to a specific individual.



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