



International Quality Plasma Program Standard

for

**Personnel Education and Training Programs in
Plasmapheresis Establishments**

**Implemented 1995
Revised 2008**

Version 3.1

**IQPP Personnel Education & Training Programs
in Plasmapheresis Establishments Standard
Implemented November 1995
Revised February 2008**

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I. Personnel Education Requirements

All functional jobs of the plasma collection facility related to donor screening, plasma collection, product handling, or other similar functions, require a minimum of a High School diploma or General Equivalency Diploma (GED) to satisfy the education requirement.^{1 2}

NOTE: Two exceptions to this rule are:

1. Existing employees (those employed prior to November 1995) who have successfully completed the appropriate job function training are “grandfathered.” These individuals are exempt and may be employed by other companies provided they can provide documentation of previous employment and training in the industry and job functions they are performing.
2. It is recognized that facilities that utilize interns as part of a community based educational experience should be able to do so without the application of this education standard to these individuals. Such individuals shall be appropriately supervised.

¹ If the employee has a vocational certification/degree that requires a high school diploma or GED, documentation of this requirement from the vocational institution with a copy of the diploma or certification will be acceptable.

² A copy of the college degree or transcript will satisfy the requirement if the high school diploma or the GED is unavailable.

II. General Requirements

Each facility's Training Program must:

- A. Provide for training in the following general job functions/responsibilities, if applicable:
1. Medical Receptionist/Donor Screening/Processing Technician
 2. Phlebotomist/Donor Collection Technician
 3. Plasma Processing Technician
 4. Physician and Physician Substitute
 5. Area Supervisor
 6. Designated Trainer
 7. Center Management
 8. Quality Assurance Personnel
 9. Specialty Product Coordinator as applicable (such as an assistant manager, etc.)

NOTE: This list of job functions is not intended to represent the responsibilities of single individuals, since a single individual may be trained in one or more of the functions listed. Conversely, a single individual may be trained in only some of the responsibilities of a job function. The job description and training documentation for an individual should accurately reflect the scope of their responsibilities.

- B. Include documentation of initial training for each job responsibility within each position. (This can take the form of a matrix/checklist or other equivalent document.)
- C. Include documentation of competency for each job responsibility. (This can take the form of an observation matrix/checklist, quiz, test, etc., that includes evaluation of both theoretical and practical knowledge.)
- D. Require trainees to be under supervision until their competency is established and documented in accordance with the competency requirements of the training program.
- E. Include documentation of annual refresher training.

General Requirements, continued

- F. Include documentation of on-going training or re-training.
- G. Utilize a documented system to summarize the status of each individual's training, wherever they are in their training experience (i.e., initial training, re-training, annual refresher training, cross-training, etc.).
- H. Include a statement regarding the training hierarchy which addresses documentation of certified trainers and corporate requirements for designated training personnel.
- I. Provide translation of training materials and competency evaluations for non-native language speakers if necessary (e.g. non-English speakers in the US, non-German speakers in Germany).
- J. Ensure appropriate training is conducted based on changes to job responsibilities.

III. Program Description

Each facility must have a document that describes their training requirements, including:

- A. Identification of all job positions for which the facility is designed to provide training.
- B. Identification of reference materials that will be used during the course of training (i.e., SOPs, Training Manuals, etc.).
- C. Identification of training documents that will be used (i.e., checklists, other tracking/certification forms, quizzes, tests, etc.).
- D. Description of how and when training documents are to be completed.
- E. Description of how competency is to be established for each job responsibility/task (i.e., observed to be performing correctly and able to answer questions; observed to be performing correctly X times; passes a quiz or test with a score of X%, etc.).

NOTE: *The training program must include guidelines for review and/or re-training and documentation for incorrect responses in either verbal or written quizzes or tests. In addition, there should be guidelines for re-taking quizzes and/or tests if permitted.*

- F. Description of annual refresher training requirements.
- G. Description of when ongoing or re-training will be conducted (i.e., new or modified procedures, in response to internal audit or inspection by an outside agency or customer, etc.).
- H. Specification of what training documentation must be retained as permanent records.

IV. General Training Requirements

Where applicable, the following requirements must be included in the training:

- A. General Recordkeeping Requirements (i.e., traceability, concurrent documentation, proper error corrections, etc.)
- B. System of Donor and Unit Identification
- C. Handling Non-Conformances
- D. Quality Assurance Program
- E. Infectious Waste Management
- F. Exposure Control Plan: Biosafety Practices and Procedures
- G. Chemical Safety (MSDS)
- H. Hepatitis B Vaccination Program
- I. Emergency/Disaster Management
- J. Maintenance/Cleaning of Work Area
- K. Quality Control, as applicable
 - 1. Use of Reagents/Controls
 - a. Reference to Manufacturer's Package Insert for use, dating and storage
 - b. Documentation
 - c. Handling performance defects
 - 2. Use of Instruments
 - a. Reference to Manufacturer's Operator Manuals for calibrations and/or standardization, repairs and maintenance
 - b. Documentation
 - 3. Supplies Management
 - a. First in-First out system
 - b. Receipt and inspection
 - c. Handling and reporting defects
 - 4. Aseptic Techniques

General Training Requirements, continued

- L. Customer Service and Donor Management
- M. Introduction and Understanding of the Plasma Industry and Uses of Final Products
- N. Current Good Manufacturing Practices
- O. Qualified Donor Program
- P. NAT Testing Requirements
- Q. Automated Donor Management Systems, as applicable
- R. Donor Health Education
- S. Labeling and Inventory Control
- T. NDDR and entry of known positives into NDDR, as appropriate
- U. Viral Marker Standards
- V. Corrective & Preventive Action Program (CAPA)

IQPP PERSONNEL EDUCATION AND TRAINING STANDARD

Revision History

Date	History
11/1993	Standard implemented.
7/2004	More stringent requirements added to compliment the Quality Assurance Standard.
1/2006	Added wording to make a more internationally-focused standard.
6/2007	Changes made to reflect training for the Viral Marker Standard and Corrective and Preventive Action plans
6/2007	Separated out specific position requirements and created Personnel Education and Training Appendix.