IQPP Personnel Education and Training Standard

Version 5.0
Implemented July 1, 2019

PPTA
Plasma Protein Therapeutics Association

Background

The IQPP Personnel Education and Training Standard is part of a series of standards that comprise the Plasma Protein Therapeutics Association (PPTA) IQPP Standards Program. PPTA's Voluntary Standards Program provides global leadership for the plasma protein industry's goal of continuous improvement with a focus on safety and quality from the donor to the patient.

This voluntary IQPP Standard was developed by the PPTA IQPP Standards Committee, and was approved by the PPTA Source Board of Directors on April 9, 2019. The current version of this standard supersedes version 4.0 in its entirety.

For questions about this PPTA Voluntary Standard contact IQPP@pptaglobal.org. For more information about the IQPP Standards Program or PPTA, visit www.pptaglobal.org.

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1. Introduction

This IQPP Standard is part of a series of standards that comprise the PPTA IQPP Voluntary Standards Program. For more information about the program, visit www.pptaglobal.org.

2. Scope

This standard applies to facilities that collect Source Plasma.

3. Purpose

The purpose of this standard is to establish minimum requirements for the education and training of personnel at a Source Plasma collection facility. The intention of the requirements is to facilitate the formation and retention of a knowledgeable and experienced workforce, with each individual being highly trained in their individual job responsibilities, and well-versed in current methods, safety measures and rationales for their implementation.

4. Terms and Definitions

Competent Education Authority (CEA): Competent Authority responsible for education in the country in which a Source Plasma collection facility operates

5. Personnel Education Requirements

5.1. All functional jobs of the plasma collection facility related to donor screening, plasma collection, product handling, or other similar functions, require at least:

A minimum of nine years of compulsory education as defined by the CEA, plus either:

a) fulfillment of all additional minimum education and training requirements as defined by the CEA for fulfilling the functional job assigned; or

b) where the CEA does not define any additional minimum education and training requirements for the functional job assigned, completion of at least three years of further general education beyond the initial compulsory nine years (or its equivalent as defined by the CEA).

NOTE Examples for fulfillment of this requirement using item b) above include, but are not limited to:

i. in the United States, achievement of a High School Diploma or General Education Development (GED) credential (A copy of the college degree or transcript would satisfy the requirement if the high school diploma or the GED credential is unavailable.);

ii. in Germany, certification of completion of

a. "Hauptschulabschluß" and a three-year vocational training, or
b. "Mittlere Reife" and a three-year vocational training;

iii. in Austria, achievement of

a. a degree of the "Hauptschule" or "Polytechnische Schule" and certification of completion from a three-year vocational training program,

b. certification of completion of 5 years of "Neue Mittelschule" and certification of completion from a three-year vocational training, or

c. certification of completion of the entire curriculum of the "Neue Mittelschule" or a "Höhere Technische Lehranstalt"; and

iv. in the Czech Republic, achievement of at least 9 years of "gymnázium" and a school-leaving examination (maturitní zkouška) or apprenticeship certificate (výuční list).

5.2. See *UNESCO International Standard Classification of Education (ISCED)* web page for guidance on determining national requirements for general education and training. [United Nations Educational, Scientific and Cultural organization (UNESCO) Institute for Statistics, http://www.uis.unesco.org.]

5.3. Existing personnel (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.

5.4. It is recognized that facilities that utilize interns as part of a community based educational experience should be able to do so on a temporary basis without the application of this education standard to these individuals. Such individuals shall be appropriately supervised.

5.5. Job descriptions will be maintained for every position in the Donor Center. Existing personnel are required to sign the job description associated with their position.

5.6. Each facility's Training Program shall:

a) require employees to perform tasks under direct supervision of designated trainers, who are physically present in the area until their competency in the tasks is established and documented in accordance with the competency requirements of the training program;

b) include documentation of:

i. initial training for each job responsibility within each position. (This may take the form of a matrix/checklist or other equivalent document.);

ii. competency for each job responsibility that has GMP, product quality or donor safety relevance. (This may take the form of an observation matrix/checklist, quiz, test, etc., that includes evaluation of both theoretical and practical knowledge.);

iii. annual refresher training and competency assessment; and

iv. on-going training or re-training and competency assessment;

c) 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.);

d) include a statement regarding the training hierarchy which addresses documentation of certified trainers and corporate requirements for trainer re- certification;

e) 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); and

f) ensure appropriate training is conducted and documented based on changes to job responsibilities.

5.7. Each facility shall 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.).

The description shall include guidelines for review and/or re-training and documentation in the case of incorrect responses in either verbal or written quizzes or tests. In addition, there shall 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.); and

h) description of the training documentation required to be retained as permanent records.

5.8. Where applicable, the following requirements shall be included in the training:

a) The PPTA IQPP Standards;

b) Exposure Control Plan: Biosafety Practices and Procedures;

c) Current Good Manufacturing Practices (cGMP); and

d) Specific training related to each individual's job requirements.

The level of training in each of the requirements (a-c) may be variable depending on the job requirements for each position.

6. Audit and Compliance Verification

6.1 During the IQPP Corporate Audit, the auditor should request and review the company's SOPs as related to the Standard. They should then review the procedures for compliance to the Standard.

6.2 During the IQPP Plasma Center Audit, the auditor shall review the plasma center's training program SOPs and applicable training records related to the Standard to ensure the plasma center is following its company's SOPs.