



IQPP Donor Education Standard

Version 3.0
Approved September 11, 2014



Background

The IQPP Donor Education 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 September 11, 2014. The current version of this standard supersedes version 2.0 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

People around the world depend on therapeutics derived from human plasma proteins to treat conditions such as hemophilia, immune disorders and other diseases or injuries. The ultimate safety of these therapeutics is critically dependent upon the quality of the source material from which they are derived.

PPTA Source IQPP-certified plasma centers must initiate education and screening programs to exclude donors who may be at increased risk of possible infections.

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

This Standard focuses on educating donors not only on risk behavior but also on other aspects of general well-being.

The purpose of this standard is to establish minimum requirements for education and screening of donors to:

- a) exclude those who are at increased risk of possible infectious diseases, and
- b) encourage donors to follow a healthy lifestyle.

4. Terms and Definitions

4.1. Risk Behavior

Activities that increase an individual's risk of contracting HIV, HCV or HBV

4.2. Well-being

A state of good health

5. Requirements

5.1. Each plasma center shall have an electronic, paper or video-based education system (or materials) of their choosing, to help donors recognize and



avoid risk behavior. In their educational materials, companies shall address activities related to the possible contraction of infectious disease.

5.2. The donor's comprehension of the information shall be assessed initially in order to assure their understanding of risk behavior. The comprehension assessment methods may be determined by the individual company.

5.3. Educational materials shall also be provided to educate donors, on their initial visit, on general well-being practices for plasma donation (e.g., staying hydrated, eating low-fat foods, staying well-rested, smoking cessation).

6. Audit and Compliance Verification

6.1. During the IQPP Corporate Audit, auditors shall request the company's SOPs that relate to the Donor Education Standard. They shall then review the procedures for compliance to the Standard.

6.2. During the IQPP Plasma Center Audit, auditors shall review records that relate to the Donor Education Standard to ensure the plasma center is following the company SOPs.