QSEAL Controls on Incoming Plasma Standard

Version 1.0
Approved June 13, 2013

PPTA
Plasma Protein Therapeutics Association

Background

The QSEAL Controls on Incoming Plasma Standard is part of a series of standards that comprise the Plasma Protein Therapeutics Association (PPTA) QSEAL 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 QSEAL Standard was developed by the PPTA QSEAL Standards Committee, and was approved by the PPTA Global Board of Directors on June 13, 2013.

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

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1. Introduction

Safety of plasma protein therapies is the top priority of the plasma fractionation industry. PPTA has adopted Voluntary Standards and other criteria that apply to the collection and fractionation of plasma for plasma protein therapies. These standards are in addition to formal regulatory requirements and are intended to promote the safety and quality of plasma protein therapies. The International Quality Plasma Protein (IQPP) voluntary standards address collecting, processing and testing of Source Plasma. The Quality Standards of Excellence, Assurance and Leadership (QSEAL) program addresses the manufacture and fractionation of plasma protein therapies, regardless of the source of plasma. QSEAL certification provides recognition of a company's adherence to the voluntary standards to address product safety during the manufacture of life-saving plasma protein therapies.

The Controls on Incoming Plasma Standard was established to delineate responsibilities of the manufacturer with respect to the quality and safety of incoming plasma used for manufacturing plasma protein therapies.

2. Scope

This standard applies to all plasma that is used in the manufacture of plasma protein therapies, regardless of its source.

This QSEAL Standard is not applicable for toll fractionation (i.e., where plasma from a specific country is only manufactured under contract into final products that are delivered for distribution in that country). If products (or intermediates used for manufacture of such products) are intended to be marketed outside the jurisdiction where the plasma was collected, this standard will apply.

3. Requirements

3.1. THE MANUFACTURER SHALL DEMONSTRATE THROUGH PROCESS CONTROLS THAT PLASMA POOLS MEET EQUIVALENT QUALITY AND SAFETY PARAMETERS, REGARDLESS OF THE SOURCE OF INCOMING PLASMA USED.

3.2. ALL FINAL THERAPIES USING PLASMA COMPONENTS SHALL BE MANUFACTURED IN COMPLIANCE WITH THE QSEAL VOLUNTARY STANDARDS AND OTHER CRITERIA THAT ARE APPLICABLE AT THE TIME. THE APPLICABLE VOLUNTARY STANDARDS ARE OUTLINED IN TABLE 1.

3.3. WHERE MANUFACTURE OF AN INVESTIGATIONAL OR LICENSED PRODUCT REQUIRES THE USE OF NON-CONFORMING PLASMA (E.G., SEROPOSITIVE PLASMA) THEN THE APPLICABLE REQUIREMENTS OF THE QSEAL STANDARDS AND SPECIFICATIONS SHALL NOT APPLY.

TABLE 1

APPLICABLE PPTA STANDARDS AND OTHER CRITERIA, DEPENDING ON TYPE OF PLASMA USED IN MANUFACTURING

	TYPE OF PLASMA		
	FROM IQPP-CERTIFIED CENTERS	**NOT FROM IQPP-CERTIFIED CENTERS**	
		Source Plasma	**Recovered Plasma**
APPLICABLE STANDARD OR OTHER CRITERIA	QSEAL NAT Testing Standard	QSEAL NAT Testing Standard	QSEAL NAT Testing Standard
	QSEAL Inventory Hold Standard	QSEAL Inventory Hold Standard	
	All other requirements for IQPP certification, including: • IQPP Standard for Community Based Donors; • IQPP Cross Donation Management Standard; • IQPP Standard for Donor Education; • IQPP Standard for Use of the National Donor Deferral Registry; • IQPP Standard for Personnel Education and Training Programs in Plasmapheresis Establishments; • IQPP Standard for Professional Plasma Collection Facility; and • IQPP Standard for Quality Assurance	IQPP Standard for Qualified Donors	
		IQPP Standard for Viral Markers	
		Where the requirements in IQPP standards are not specifically included in the requirements of the competent regulatory authority in which the product is fractionated, the following requirements of IQPP standards apply: • Unique donor identification • Traceability; and • Tracking	QSEAL Recovered Plasma Specification