QSEAL Recovered Plasma Specification

Version 1.0
Approved June 13, 2013

PPTA
Plasma Protein Therapeutics Association

Background

The QSEAL Recovered Plasma Specification 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 Specification 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 Specification contact QSEAL@pptaglobal.org. For more information about the QSEAL Standards Program or PPTA, visit www.pptaglobal.org.

PPTA
147 Old Solomons Island Road, Suite 100
Annapolis, Maryland 21401

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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 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.

Plasma derivative manufacturers are successfully and safely using Recovered Plasma today. This specification is not intended to create any new acceptance criteria but to identify current common criteria. This specification is intended to ensure that plasma pools derived from either recovered or source plasma have comparable quality and safety.

The specifications under "Criteria for Collector" reflect what is standard for the industry today. Any unique requirements and/or acceptance criteria in order to use this material for further manufacturing are covered in the "Criteria for the Manufacturer."

The specification is focused on plasma safety. The goal is to assure the residual risk for Recovered Plasma including infrequent source plasma collected by blood establishments is comparable to that for Source Plasma.

2. Scope

The requirements contained herein are minimum acceptance criteria. Depending on where the final products are manufactured and marketed, there may be additional regulatory requirements and/or manufacturing specifications with which the collector of the Recovered Plasma and/or the manufacturer of plasma derivatives must comply. These additional regulatory requirements and/or manufacturing specifications will be addressed in the contract between the collector and the manufacturer.

This QSEAL Specification 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. CRITERIA FOR THE COLLECTOR

3.1. DONOR

3.1.1. IDENTIFICATION

A SYSTEM SHALL BE IN PLACE THAT ALLOWS THE UNIQUE IDENTIFICATION OF EACH DONOR FOR THE PURPOSE OF TRACEABILITY.

3.1.2. DONOR ELIGIBILITY

THE COLLECTOR SHALL HAVE PROCESSES FOR ASSESSING THE DONOR'S MEDICAL HISTORY AND GENERAL HEALTH AT THE TIME OF DONATION. PROCESSES SHALL INCLUDE, BUT ARE NOT LIMITED TO, VITAL SIGNS, HIGH-RISK BEHAVIOR AND MEDICAL HISTORY QUESTIONS.

3.2. CENTER

3.2.1. LICENSE/REGISTRATION

THE COLLECTOR SHALL BE INSPECTED, AUTHORIZED AND/OR LICENSED BY NATIONAL HEALTH AUTHORITIES.

3.2.2. LOOKBACK/RECALL PROCESSES

THE COLLECTOR SHALL HAVE PROCESSES IN PLACE FOR PERFORMING LOOK BACK PROCEDURES (E.G. FOR UNACCEPTABLE TEST RESULTS AND POST DONATION INFORMATION).

3.2.3. RECORD RETENTION

THE CENTER SHALL MAINTAIN DONOR HISTORY, COLLECTION AND TESTING RECORDS AS REQUIRED BY NATIONAL REGULATIONS.

3.3. PLASMA UNIT

3.3.1. SOFT-GOODS

SOFT-GOODS USED IN THE COLLECTION PROCESS SHALL BE APPROVED FOR THE INTENDED USE BY NATIONAL REGULATIONS.

3.3.2. AUTOLOGOUS AND DIRECTED DONATIONS

NO PLASMA DERIVED FROM AUTOLOGOUS DONATIONS MAY BE SHIPPED AS RECOVERED PLASMA. DIRECTED DONATIONS MAY BE SHIPPED AS RECOVERED PLASMA IF THEY MEET THE SAME REQUIREMENTS OF AN ALLOGENEIC DONATION.

3.3.3. LABELING

LABELING SHALL COMPLY WITH NATIONAL REGULATIONS. THE CONTAINER LABEL SHALL INCLUDE, AT MINIMUM, THE FOLLOWING INFORMATION:

A) A UNIQUE IDENTIFICATION NUMBER TO ENSURE COMPLETE TRACEABILITY FOR EACH UNIT BACK TO THE DONOR AND INDIVIDUAL DONATION,

B) NAME AND/OR IDENTIFICATION CODE OF COLLECTOR,

C) THE APPROPRIATE PRODUCT NAME,

D) VOLUME*,

E) STORAGE CONDITION*,

F) TEST RESULTS*,

G) COLLECTION AND/OR EXPIRATION DATE(S)*,

H) ANTICOAGULANT USED*.

EXPLANATORY NOTE: STARRED (*) INFORMATION ABOVE, IN SOME REGIONS, MAY BE PROVIDED IN DOCUMENTATION (E.G., ELECTRONIC RECORDS, SHIPPING DOCUMENTS, SUPPLIER AGREEMENTS) OTHER THAN THE CONTAINER LABEL.

3.4. FREEZING/STORAGE AND TRANSPORTATION

3.4.1. FREEZING/STORAGE AND TRANSPORTATION SHALL BE IN COMPLIANCE WITH APPLICABLE NATIONAL AND/OR INTERNATIONAL REGULATIONS.

3.4.2. SYSTEMS FOR FREEZING, STORAGE AND TRANSPORTATION SHALL BE VALIDATED.

3.5. PLASMA UNIT TESTING

3.5.1. SEROLOGY TESTING - (ANTI-HIV-1/2, ANTI-HCV & HBSAG)

THE COLLECTOR (OR DESIGNATED CONTRACT LABORATORY) SHALL PERFORM SEROLOGY TESTS USING LICENSED OR APPROVED TEST KITS IN COMPLIANCE WITH NATIONAL AND INTERNATIONAL REQUIREMENTS. THE COLLECTOR SHALL REPORT TEST SYSTEMS (INCLUDING DEVICE MANUFACTURER AND ASSAY NAME) TO THE MANUFACTURER AS WELL AS RESULTS AND/OR CERTIFICATION THAT ALL UNITS ARE NEGATIVE. THE ACTUAL FORM FOR REPORTING RESULTS WILL BE JOINTLY AGREED TO BY THE COLLECTOR AND MANUFACTURER.

3.5.2. NAT TESTING

MANUFACTURERS SHALL USE RECOVERED PLASMA THAT HAS BEEN TESTED IN ACCORDANCE WITH THE QSEAL NAT TESTING STANDARD.

3.5.3. VIRAL MARKER REPORTING

EPIDEMIOLOGICAL DATA SHALL BE COLLECTED ON THOSE BLOOD-BORNE INFECTIOUS AGENTS FOR WHICH A POTENTIAL TRANSMISSION BY BLOOD PRODUCTS IS WELL RECOGNIZED AND ROUTINE TESTING OF BLOOD AND PLASMA DONATIONS IS MANDATORY. THESE INFECTIOUS AGENTS CURRENTLY INCLUDE HUMAN IMMUNODEFICIENCY VIRUS (HIV), HEPATITIS B VIRUS (HBV) AND HEPATITIS C VIRUS (HCV). THE COLLECTOR SHALL COLLECT DATA FOR VIRAL MARKER RATES FOR EACH MARKER PERFORMED AND REPORT THE VIRAL MARKER RATES TO THE MANUFACTURER IN A MUTUALLY AGREED UPON FORMAT.

THE MANUFACTURER SHALL HAVE A PROCESS FOR PERIODICALLY EVALUATING THESE DATA, LOOKING FOR COLLECTION CENTERS THAT ARE ABOVE DEFINED ACCEPTABLE RATES FROM THE DONOR POPULATION WITHIN A GEOGRAPHIC AREA. THE MANUFACTURER, IN CONSULTATION WITH THE COLLECTOR, SHALL ESTABLISH EPIDEMIOLOGICAL IN-PROCESS CONTROLS (RATES, ALERT LEVELS, CORRECTIVE AND PREVENTIVE ACTION PLANS) AND MONITOR THE COLLECTOR'S PERFORMANCE.

4. CRITERIA FOR THE MANUFACTURER

4.1. SUPPLIER APPROVAL

THE MANUFACTURER SHALL HAVE A PROCESS TO EVALUATE AND APPROVE RECOVERED PLASMA SUPPLIERS.

4.2. CONTRACTUAL SUPPLY AGREEMENT

THE MANUFACTURER SHALL HAVE A CONTRACTUAL SUPPLY AGREEMENT AND QUALITY AGREEMENT WITH THE RECOVERED PLASMA COLLECTOR.