



QUALITY STANDARDS OF
EXCELLENCE, ASSURANCE
& LEADERSHIP

QSEAL Inventory Hold Standard

**Version 1.0
Implemented 2000**



Background

The QSEAL Inventory Hold 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 implemented in 2000.

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 Inventory Hold Standard was established as an added protection at the manufacturing stage to allow for retrieval of single units of Source Plasma prior to preparation of the manufacturing pool. Compliance with this standard allows for the retrieval of units as a result of post-donation information (information that was not known at the time of donation) that would have disqualified the donor had it been known at the time of donation. Post-donation information could include anything from delayed admission of high-risk behavior, becoming reactive for HIV, HBV or HCV, or providing new information about international travel.

2. Scope

This standard applies to all units of source plasma that are released for further manufacturing.

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. ALL SOURCE PLASMA SHALL BE HELD IN INVENTORY FOR AT LEAST 60 DAYS FROM THE TIME OF COLLECTION.**
- 3.2. COMPANIES SHALL DOCUMENT AND VERIFY THAT EACH UNIT OF SOURCE PLASMA WAS NOT RELEASED FOR FURTHER MANUFACTURE UNTIL AFTER THE EXPIRATION OF THE 60-DAY HOLD PERIOD.**