



IQPP Quality Assurance Standard

Version 5.0
Approved January 24, 2020



Background

The IQPP Quality Assurance 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 January 24, 2020. 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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PPTA
147 Old Solomons Island Road, Suite 100
Annapolis, Maryland 21401



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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.

The International Quality Plasma Program (IQPP) includes requirements based on current Good Manufacturing Practices (cGMP). The cGMP based component of IQPP focuses on the most essential part of a regulated industry, its Quality Unit. This program establishes definitions and organization which help plasma collection companies establish “Quality” organizations within their organizations. IQPP does not intend to limit companies’ options. Rather it lays down a framework upon which a variety of Quality organizations can be built. IQPP assists companies with using their specific model of the Quality Unit to be consistent with PPTA Source programs and practices designed to make plasma collected by IQPP-certified centers the safest plasma in the world.

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 IQPP standard applies to facilities that collect Source Plasma.

3. Purpose

The purpose of this standard is to provide an industry-based functional definition of cGMP principles that is consistent with third party compliance profiles as well as good plasma production practices. Compliance with cGMP is currently the basis for inspections from Team Biologics (of the USFDA) as well as from European agencies (such as the European Medicines Agency). The requirements contained in this standard are intended to support activities based on third party audits and to assist other organizations/agencies in understanding the cGMP issues as defined.



4. Terms and Definitions

4.1. Quality Assurance

Actions that are planned and performed by a facility to provide confidence that all systems and processes that would affect the product quality and donor safety are working as expected

4.2. Quality Assurance Program

(1) A documented system, designed and implemented to confirm that manufacturing is consistently performed in such a way as to ensure donor safety is not compromised and to yield a product of consistent quality; and (2) the sum of all Quality Assurance activities, both planned and performed

4.3. Quality Policy

Policy stating objectives, management's commitment to quality, defined organizational goals and procedures to meet and exceed customers' expectations

4.4. Quality System

The company-wide work structure utilized to produce a cost effective, high- quality product, including quality control, quality assurance, and quality manufacturing practices

5. Requirements

5.1. Each facility shall have a documented Quality Assurance (QA) program in place.

5.2. Quality Assurance shall report independently within the organizational structure. The responsibilities for Quality Assurance shall be separate from operations.

5.3. Quality Assurance responsibilities and mechanisms for the maintenance of QA independence shall be documented.

5.4. Primary responsibilities of Quality Assurance are outlined, for example, in the FDA Guideline for Quality Assurance in Blood Establishments, the Pharmaceutical Inspection Convention Scheme (PIC/S) Guidance, EU Directive 2005/62 "Community standards and specifications relating to a quality system for blood establishments" and include activities in the following areas:

- a) Standard Operation Procedures;
- b) Training and Education;
- c) Competency Evaluation;
- d) Proficiency Testing;



- e) Validation;
- f) Equipment;
- g) Qualification and Quality Control
- h) BPDRs, Complaints, and Donor Adverse Events;
- i) Data Integrity (NDDR, CDCS) and Records Management;
- j) Plasma Release Procedures;
- k) QA Audits (internal);
- l) Tracking and Trending of Deviations;
- m) Tracking and Trending of Viral Marker Rates
- n) Reactive Unit Management, where applicable;
- o) Change Control; and
- p) Risk Management.

6. Audit and Compliance Verification

Auditors shall request the plasma center's Table of Organization as well as defined Quality Assurance responsibilities and job descriptions related to the Center Quality Assurance procedures. They shall then review documented procedures and, plans for the maintenance of the aspects of the Quality Assurance Program. The auditor shall confirm that the responsibilities for Quality Assurance are separate from Operations. Mechanisms for the assurance of independence of Quality Assurance will be reviewed.