IQPP Quality Assurance Standard

Version 4.0
Approved June 25, 2014

PPTA
Plasma Protein Therapeutics Association

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 June 25, 2014. The current version of this standard supersedes version 3.0 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

PPTA Source represents various organizations that supply human plasma for further fractionation into vitally needed human therapies used world-wide. A prime responsibility of PPTA Source members is to adhere to applicable standards while generating the safest possible source material. PPTA Source supports these activities by interactions with regulatory authorities to help better define compliance statutes established by these groups. PPTA Source has voluntary standards that help PPTA Source members demonstrate their adherence to standards that are not simply set by those outside the industry but rather are set by members of the industry itself. The International Quality Plasma Program (IQPP) is a good example of this proactive approach.

For years, IQPP has been the proactive actions of the industry to compliance areas viewed as not being covered by governmental compliance activities. Although specific focal points may have varied, common to all IQPP actions is the goal of increased safety. Consistent with this goal, IQPP falls in step with today's compliance environment by adding a program based on Good Manufacturing Practices (GMP).

The principles of GMP add quality and safety factors to plasma production in many ways. Compliance with GMP is currently the basis for inspectional audits from Team Biologics (of the USFDA) as well as from European agencies (such as the German Health authorities). IQPP does not intend to duplicate the actions of these agencies. Instead, and consistent with past IQPP practices, a series of new programs have been introduced that will allow PPTA Source members to create an industry based functional definition of GMP principles that is consistent with third party compliance profiles as well as good plasma production business practices. Successful adherence to IQPP standards will support member activities based on third party (e.g. FDA) audits. In addition, it will also help other organizations/agencies understand the GMP issues as defined by PPTA Source members.

This GMP based IQPP component focuses on the most essential part of a regulated industry, its Quality Unit. This program establishes definitions and organization, which should be useful to help PPTA Source members establish "Quality" organizations within their plasma collection organization. There are a number of ways in which this goal can be met. IQPP does not intend to limit

members' options. Rather it intends to lay down a framework upon which a variety of organizations can be built. IQPP will assist, through audits and training, members with using their specific model of the Quality Unit to be in general compliance with recognized standards. As IQPP adds other GMP based standards, more attention will be placed on shaping each member's Quality Unit into a program consistent with PPTA Source programs and practices designed to make plasma collected by PPTA Source members 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 GMP principles that is consistent with third party compliance profiles as well as good plasma production practices. The requirements contained in this standard are intended to support member activities based on third party audits and to assist other organizations/agencies in understanding the GMP issues as defined by PPTA Source members.

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 ensure that manufacturing is consistently performed in such a way as 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. All facilities 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 or in the Pharmaceutical Inspection Convention Scheme (PIC/S) Guidance 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) BPDRs, Complaints, and Adverse Reactions;
h) Records Management;
i) Plasma Release Procedures;
j) QA Audits;
k) Tracking and Trending of Deviations;
l) Tracking and Trending of Viral Marker Rates;
m) Reactive Unit Management, where applicable;
n) Change Control; and
o) 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 Complaints and Release Procedures 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.