



International Quality Plasma Program Standard

for

Quality Assurance

2006

IQPP Quality Assurance Standard
May 1999
Revised April 2006

I. Introduction

PPTA Source represents a variety of 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.

IQPP has for years 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 current Good Manufacturing Practices (cGMP).

The principles of cGMP add quality and safety factors to plasma production in many ways. Compliance with cGMP 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 create an industry based functional definition of cGMP principles that are consistent with third party compliance profiles as well as good plasma production business practices. That is to say, successful IQPP adherence to standards will not just support member activities based on third party (e.g. FDA) audits. In addition, it will also help outside agencies understand what are, in fact, current cGMP issues as defined by PPTA Source members.

This cGMP 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 member's 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 cGMP 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.

II. Definitions

Quality Assurance -	Actions that are planned and performed by a facility to provide confidence that all systems and processes that would affect the product are working as expected.
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.
Quality Policy -	Policy stating objectives, management's commitment to quality, defined organizational goals and procedures to meet and exceed customers' expectations.
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.

III. PPTA Source Quality Assurance Principles

All facilities must have a documented Quality Assurance(QA) program in place.

Quality Assurance must report independently within the organizational structure.

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

The primary responsibilities of Quality Assurance are outlined in the FDA Guideline for Quality Assurance in Blood Establishments or in the

Plasmapheresis Inspection Convention Scheme (PIC/S) Guidance and include activities in the following areas:

- Standard Operation Procedures
- Training and Education
- Competency Evaluation
- Proficiency Testing
- Validation
- Equipment
- Error/Accident Reports, Complaints, and Adverse Reactions
- Records Management
- Lot Release Procedures
- QA Audits

IV. Audits and Compliance Verification

Auditors shall request the plasma center's Table of Organization. They shall then review documented procedures and plans for the maintenance of the Complaints and Release Procedures aspects of the Quality Assurance Program. Quality Assurance procedures should be separate from operational procedures. Mechanisms for the assurance of independence of Quality Assurance will be reviewed.