PPTA
Plasma Protein Therapeutics Association

Certification Program Description

Implemented 1991
Revised 2012

Version 2.1

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IQPP Certification Program Description

Contents

IQPP Certification Program
Overview

I. Purpose

The purpose of this document is to describe the policies and processes that control and standardize the way in which PPTA Source certifies plasmapheresis facilities. The certification program is known as the International Quality Plasma Program (IQPP).

II. Intended Audience

The intended audience for this document includes:

- Regulatory agencies interested in applicable policies;
- Association leadership responsible for high-level policy approval;
- Plasma collectors seeking certification;
- Association staff with responsibilities for steps in the certification process;
- Other parties (e.g., patient groups) interested in the certification process.

III. Contact

For further information about the PPTA Source IQPP Certification Program, contact the Association by phone at +1-410-263-8296, via email at pptaglobal@pptaglobal.org or in writing at:

PPTA Source
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IV. In this document

In this document you will find information on the PPTA Source IQPP Certification Program from two perspectives: the collector (Section A) and the IQPP Manager (Section B).

Section A: PPTA IQPP Certification of Plasma Centers Overview

I. In this document

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. Source Plasma quality is the highest priority of the Source Plasma Collection Industry. PPTA Source, on behalf of its industry members, supports efforts by regulatory bodies to establish minimum requirements to ensure the safety of these raw materials. The standards implemented by PPTA Source and enforced through its IQPP certification move beyond the minimum requirements to provide added value and quality to Source Plasma for the benefit of customers and patients.

In response to a changing public and regulatory environment in the late 1980s, PPTA Source, through its membership, developed the Quality Plasma Program (QPP). The original QPP Certification Program, implemented in 1991, had seven core standards.

In the years since its inception, new standards have been added to the QPP. In 2000, the QPP program was made available to plasma centers outside of the United States and was renamed the International Quality Plasma Program (IQPP). PPTA Source developed the Qualified Donor Standard, which led to a more comprehensive Viral Marker Standard. PPTA Source has also implemented Quality Assurance Standards for all IQPP-Certified plasma centers.

The IQPP Standards were reviewed in 2004 leading to the elimination of the Donor Screening for Drugs of Abuse Standard. This decision was based on the enhanced safety margin due to the global introduction of nucleic acid amplification testing (NAT).

In December 2004 the Pharmaceutical Inspection Convention Scheme (PIC/S) Guide to Inspection of Source Plasma Establishments and Plasma Warehouses and the Compliance Program Guidance Manual for the Inspection of Source Plasma Establishments were implemented. This prompted a full re-assessment of the IQPP Standards to avoid redundancies between mandatory and voluntary requirements. During this re-assessment, some Standards were updated, and the program continues to be revised over time to reflect changes in the industry.

The current Standards are as follows:

1. Qualified Donor
2. Community-based Donors
3. Use of PPTA Source's National Donor Deferral Registry (NDDR)
4. Donor Education
5. Personnel Education and Training
6. Professional Plasma Collection Facility
7. Quality Assurance
8. Viral Marker
9. Cross Donation Management

II. Purpose

The purpose of PPTA Source's IQPP Certification Program is to provide independent, third party evaluation and recognition of a collector's adherence to PPTA Source's global IQPP Standards.

III. Control of the Program

Control and standardization of IQPP certification is important to assure PPTA Source members, regulators and patients of the quality and consistency of the certification program. Control and standardization of certification is achieved through four primary mechanisms:

- Establishment of the IQPP Standards;
- Qualified Auditors;
- Review of audit reports;
- Adherence to a standardized evaluation process.

IV. In this Section

This section contains information on the following topics:

Section A: PPTA IQPP Certification of Plasma Centers
The Certification Process

I. Certification Definition

IQPP certification is recognition by PPTA Source that a plasma center adheres to PPTA Source's IQPP Standards, based on the findings of an independent auditor's assessment of the plasma center.

II. Eligibility

IQPP certification is available to plasma collectors worldwide that have been licensed by a competent national regulatory authority inspecting establishments based on FDA's Compliance Program Guidance Manual 7342.002 or PIC/S Guide to Inspection PI008-1.

NB: Plasma centers in a country lacking a competent national regulatory authority will first need to be inspected according to the PIC/S Guidance by an independent authority.

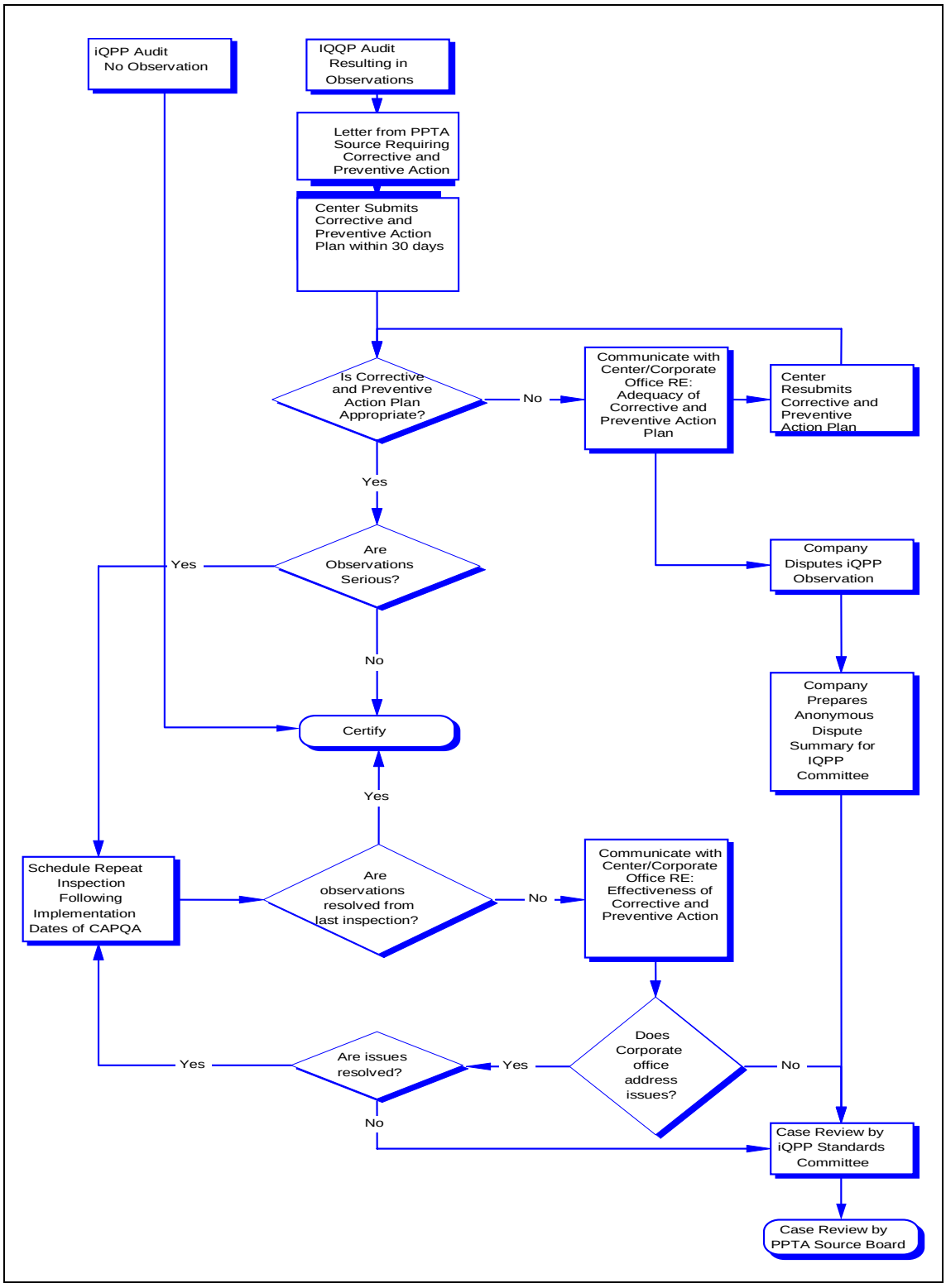
III. General Rules

The following general rules apply to the PPTA Source IQPP certification process:

- IQPP certifications of plasma centers are issued for a one to three-year period, based upon the outcome of the audit;
- IQPP corporate certifications are issued for a six month to two-year period, based upon the outcome of the audit;
- As new standards are developed, adherence will be confirmed at the next regularly scheduled audit following the implementation of the new Standard;
- PPTA Source must receive applications and fees before any audits are scheduled;
- Changes to the IQPP certification process, the IQPP Standards or the auditor qualifications are made under the procedures for change control, which require Board, IQPP Standards Committee and/or PPTA management approval.

IV. Certification Process Overview

The following flow chart provides an overview of the process by which plasma centers achieve IQPP certification. Failure to adhere to the IQPP Standards will result in a denial of certification according to the process described on the following pages and pages 17-20.


iQPP Audit
No Observation
IQQP Audit
Resulting in
Observations
Letter from PPTA
Source Requiring
Corrective and
Preventive Action
Center Submits
Corrective and
Preventive Action
Plan within 30 days
Is Corrective
and Preventive
Action Plan
Appropriate?
No
Communicate with
Center/Corporate
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Plan
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Resubmits
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Yes
Are
Observations
Serious?
Yes
Company
Disputes iQPP
Observation
No
Company
Prepares
Anonymous
Dispute
Summary for
IQPP
Committee
Certify
Yes
Schedule Repeat
Inspection
Following
Implementation
Dates of CAPQA
Are
observations
resolved from
last inspection?
No
Communicate with
Center/Corporate
Office RE:
Effectiveness of
Corrective and
Preventive Action
Does
Corporate
office
address
issues?
No
Yes
Are issues
resolved?
Yes
No
Case Review by
iQPP Standards
Committee
Case Review by
PPTA Source Board

Section A: PPTA IQPP Certification of Plasma Centers
The IQPP Standards

I. The IQPP Certification Process

IQPP certification recognizes a plasma center's adherence to PPTA's IQPP Standards[1]. Those Standards are outlined below; detailed descriptions of the Standards are found on the following pages:

- Qualified Donors: IQPP-certified plasma centers collect plasma only from Qualified Donors to ensure a committed, healthy donor population. A Qualified Donor is one who has successfully passed two donor medical history screenings and required viral testing and no more than six months has lapsed since their last donation.

- Community-based Donors: IQPP-certified plasma centers only accept donors who live within the community where the plasma center is located.

- Use of PPTA Source's National Donor Deferral Registry (NDDR): PPTA Source's NDDR is a database containing donor identification of permanently deferred donors on the basis of viral marker testing. Where applicable, IQPP-certified plasma centers use the NDDR to prevent inadvertent collection from a donor who has been permanently deferred from another plasma center.

- Donor Education: IQPP-certified plasma centers voluntarily initiate education and screening programs to educate donors about high-risk behaviors which could potentially lead to infections.

- Personnel Education and Training: IQPP-certified plasma centers employ staff that meet PPTA's educational standard and are fully trained to perform their duties.

- Professional Plasma Collection Facility: Each IQPP-certified plasma center is audited for interior and exterior appearance, maintenance and donor and staff safety and security.

- Quality Assurance: IQPP-certified plasma centers are audited for adherence to GMP in relation to Release Procedures and Complaint Resolution.

[1] IQPP-certified plasma centers are evaluated for adherence to these standards at each audit.

- Viral Marker: IQPP-certified plasma centers must meet a specific viral marker standard based upon data submitted to PPTA Source on a monthly basis.

- Cross Donation Management: Plasma donors may misunderstand the reasons for limiting the number of times that they can donate per week. Infrequently, a donor may attempt to donate more often than is allowed. While these are rare occurrences, it is necessary to take measures to protect the health of the donor and minimize the risk of cross donation.

II. Qualified Donor Standard

In 1997, PPTA Source members adopted the Qualified Donor Standard. This standard states that a new donor at any IQPP-certified plasma center will be classified as an Applicant Donor until that donor has been qualified for continued donations by successfully passing two donor medical history screenings and required viral testing. At that time, the donor is reclassified as a Qualified Donor.

The Qualified Donor Standard also stipulates that units of plasma from Applicant Donors who do not become Qualified Donors are not acceptable for use in further manufacturing into plasma therapeutics.

In this way, the Qualified Donor Standard helps to promote a donor's commitment to regular repeat donations and a healthy lifestyle. The Qualified Donor Standard helps to eliminate test-seekers and potential donors with high risk factors.

III. Community-based Donor Standard

IQPP-certified plasma centers accept only donors with proof of local residency. Donors with addresses known to be homeless shelters, hotels, motels or missions are not accepted. In addition, donors who reside outside of the Recruitment Area in which the plasma center is located will not be accepted. This does not include students at local colleges/universities, locally-stationed members of the military, or donors intentionally transported for the collection of source material for non-coagulation concentrate products for hyperimmune products (excluding tetanus) under a government-approved program for the collection of such donors.

IV. Use of the NDDR Standard

Government regulations require the testing of every unit of plasma. Plasma units that have positive test results for Hepatitis C (HCV), Hepatitis B (HBV) and Human Immunodeficiency (HIV) must be destroyed or diverted for non-

therapeutic use, and the donors permanently rejected from future donations. Each plasma center is required to keep a list of these permanently rejected donors.

In 1993, PPTA Source established the National Donor Deferral Registry (NDDR) as a means of notifying other plasma centers about a donor's reactive viral test status. Donor identification information about permanently rejected donors is added to the NDDR at a designated data entry site. When an Applicant Donor arrives at an IQPP-certified plasma center, the NDDR is queried to determine whether or not that donor has been rejected at another plasma center.

In addition, a separate certification is available for NDDR Data Entry Sites (see the National Donor Deferral Registry Data Entry Site Standard).

Additional standards were added in 2004 to recognize the changes to an internet-based NDDR system.

When NDDR is not permissible by law in a country, an in-house deferral registry must be used to share deferral information among different plasma centers of the same corporate entity.

V. Donor Education Standard

Each IQPP-certified company has developed educational materials to help donors recognize and avoid behavior that is believed to lead to an increased risk of infections. Donors are tested about the information in order to assure their comprehension and understanding of high-risk activity.

VI. Personnel Education and Training Standard

In 1995, PPTA Source defined minimum education standards for IQPP-certified plasma center functions. Additionally, standards were set for initial and recurrent training to ensure that IQPP certified plasma center personnel consistently follow only the approved procedures for plasma collection and processing. These standards were updated in 2004 to recognize improvements in plasma center operations.

Plasma center employees must meet basic education and training requirements as well as participate in routine training to maintain the most current and up to date knowledge of their jobs.

VII. Professional Plasma Collection Facility Standard

PPTA Source IQPP-certified plasma centers must maintain an appearance expected of a professional facility.

The Professional Medical Facility Standard helps to promote safe products by ensuring an environment where regular repeat donors feel comfortable as they approach from the outside and wait on the inside. Compliance with this Standard also helps promote the acceptance of the IQPP-certified plasma center by the surrounding community.

VIII. Quality Assurance Standard

IQPP-certified plasma centers are based on compliance with current Good Manufacturing Practices (GMP). This Standard is an enhancement to those requirements focusing on the aspects of Complaint Resolution and Lot Release Procedures.

IQPP requires that there be a person on staff who is responsible for evaluating customer and/or donor complaints and that those complaints be dealt with and investigated as quickly as possible.

Lot Release procedures must adhere to GMP rules. IQPP-certified plasma centers must have a system in place to both release shipments of plasma and stop them if necessary.

IX. Viral Marker Standard

With the implementation of IQPP in 1991, PPTA Source began to monitor the rates of detection of HCV, HBV, and HIV in plasma donors. The original standard was based upon simple prevalence within the entire donor population. Each plasma center was evaluated for adherence to the Viral Marker Standard at the time of re-certification. The Standard was revised and made more stringent in 1996. In 1999, following the implementation of the Qualified Donor Standard (see above), the Viral Marker Standard was again revised. As described by the Qualified Donor Standard, units from Applicant Donors are not acceptable for use in further manufacturing; therefore, the revised Viral Marker Standard was based upon the Qualified Donor reference rate. IQPP-certified plasma centers submit their data on a monthly schedule and it is compiled and analyzed every six months for adherence to the Standard. IQPP-certified plasma centers exceeding the Alert Limit must submit a corrective and preventive action plan (CAPA) to bring them into compliance with the Standard. If the plasma center is unable to comply, it may lose its IQPP certification.

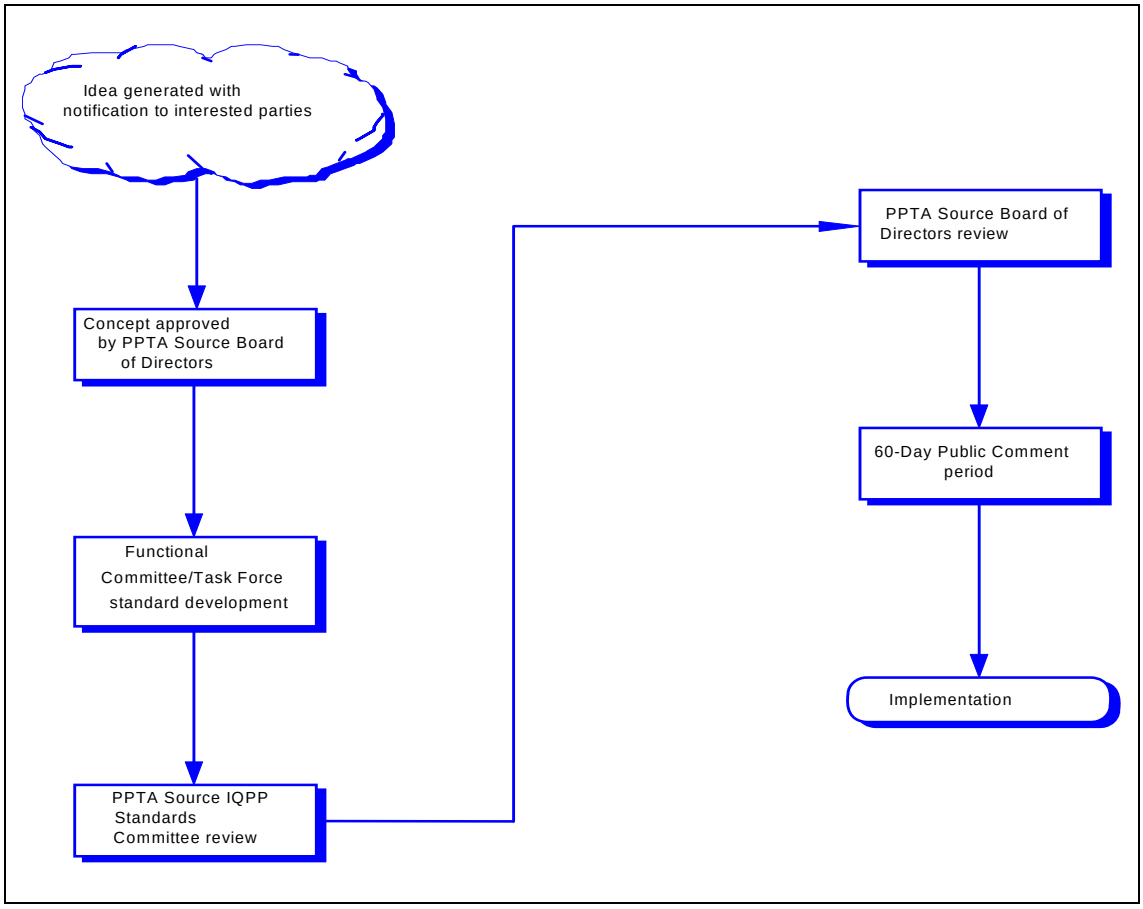
X. Cross Donation Management Standard

This standard was implemented in 2010 to address the potential risk of cross donation. Any donor who is found to be actively donating in more than one center but not exceeding the maximum allowable limits will be informed about the health risks of donating more frequently than is allowed by regulation and the reasons for the center's concerns for the donor's health if cross donating should occur. Plasma collection centers must have a policy in place stating how they will prevent a donor found to be an active donor in more than one center from donating more often than allowed. A donor who is found to be cross donating will be permanently deferred.

Section A: PPTA IQPP Certification of Plasma Centers
IQPP Standard Development Process

I. Overview

The IQPP certification program strives to be a reflection of current Industry Standards. The following flow chart provides an overview of the process by which PPTA Source develops Standards.



II. Discussion

The process for the development of a new standard or changes to an existing Standard starts with ideas from a number of sources, including staff, auditors, plasma centers, fractionators, and regulatory authorities. PPTA Source's Board of Directors must approve any proposed standard. The functional committee that develops the ideas into workable standards is comprised of representatives from PPTA member companies. Draft standards are forwarded from the functional committee to the IQPP Standards Committee, comprised of broader high-level corporate representation. The Standards Committee will either recommend

further development of the standard or recommend approval of the standard by the PPTA Source Board of Directors. Following Board approval, the 60-Day Public Comment Period allows other stakeholders to review and provide input in the proposed standard. The proposed standard is also posted on the Association website, inviting comments from interested parties.

Section A: PPTA IQPP Certification of Plasma Centers
PPTA Source Auditors

I. Auditor Qualifications

The PPTA Source auditor is essential to the IQPP certification process. Minimum qualifications for PPTA Source IQPP certification auditors are:

- Bachelor's degree from an accredited college or university, preferably in a scientific or engineering discipline;
- Minimum three years auditing experience, preferably in the pharmaceutical, biologics, or the blood/plasma industry;
- Professional certification by a recognized certifying organization is required (eg, ASQ, ISO). These may include ISO Lead Assessor, examiner for the national Baldridge Award or a state award equivalent, certification by the Regulatory Affairs Professional Society or any certification society for quality.

II. Auditor Training – Initial

Prior to becoming an official PPTA Source auditor, all candidates must be trained, either individually by PPTA Source and another IQPP auditor, or by attending an official PPTA Source training workshop, which includes the following topics:

- PPTA Source's IQPP Standards
- The audit process
- Documentation of Audits
- PPTA Source's auditor agreement, including the confidentiality agreement

III. Auditor Training – Ongoing

PPTA Source will convene training workshops for auditors to introduce a new IQPP Standard and ensure consistent interpretations of the standard. These training programs will take place at a minimum of every other year. Attendance at these workshops is mandatory. Auditors are reimbursed for expenses incurred while participating in mandatory training however they are not compensated for their time.

IV. Auditor Continuing Education

To maintain one's qualification as a PPTA Source auditor, each auditor must participate in and provide documentation of participation in at least one continuing education event every two years. These events may include:

- Industry or government workshops relevant to auditing, quality assurance, quality management, good manufacturing practices, validation, or other relevant government regulation;
- Completion of courses required for maintenance of a professional certification;
- Completion of one class toward an advanced degree;
- Teaching a college-level course related to auditing.

V. Auditor's Objectives

IQPP certification auditors have two very specific objectives:

- Assess a firm's adherence to PPTA Source IQPP Standards and report this to the Association;
- Assist facilities in interpretation and adherence to PPTA Source IQPP Standards, where appropriate.

Section A: PPTA IQPP Certification of Plasma Centers Audits and Audit Reports

I. Types of Audits

The PPTA Source IQPP Certification Program conducts four types of audits:

1. Plasma Center Audits – conducted for the purpose of initial certification or renewal of certification of a plasma center.

2. Corporate Audits – conducted for the purpose of reviewing corporate policies and procedures in reference to IQPP Standards.

3. Combined Corporate/Plasma Center Audits – conducted for the purpose of reviewing corporate policies and procedures in reference to IQPP Standards and certification or renewal of certification of the plasma center. These audits are conducted at a designated plasma center when no separate corporate facility exists.

4. Issue-Driven Audits – All plasma centers may be subject to an issue-driven audit that may occur at any time.

II. Audit Rules

Plasma Center Audits – Plasma Center audits are performed on a one to three-year cycle, determined by the outcome of the audit.

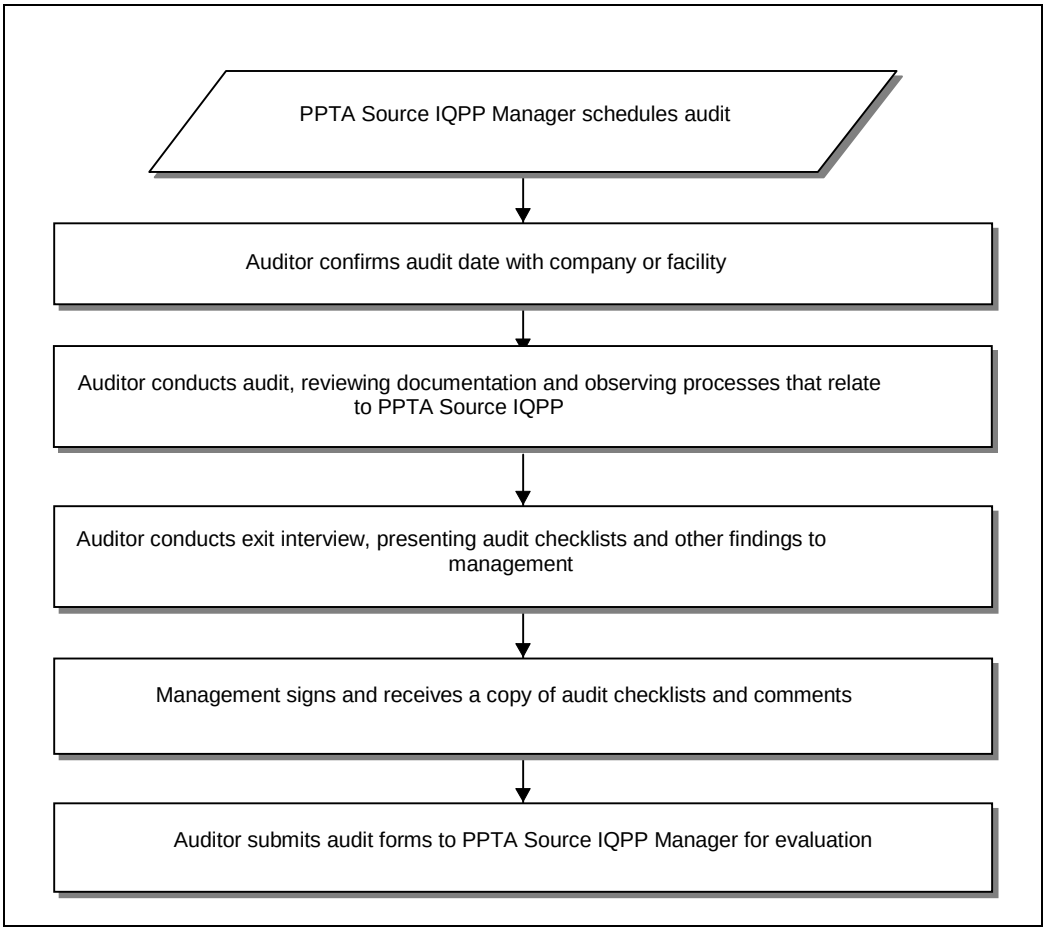
Corporate Audits – Corporate audits are performed on a six-month to two-year cycle, determined by the outcome of the audit. For those companies with a separate corporate office from which policies and procedures regarding plasma center operations are generated, the corporate audit will be performed at that location.

Combined Corporate/Plasma Center Audits – Combined Corporate/Plasma Center audits are performed on a six month to two-year cycle, determined by the outcome of the audit. For companies that do not have a separate corporate office, the Corporate audit will take place at a designated plasma center and will be combined with the Plasma Center audit.

Issue-Driven Audits – All plasma centers may be subject to an Issue-Driven audit that may occur at any time for the following reasons: plasma center is placed on the Viral Marker Alert List, plasma center changes owners, plasma center relocates, plasma center receives an FDA Warning Letter, at PPTA's discretion due to prior poor audit, formal complaints, etc.

II. Audit Process

The following flow chart provides an overview of the PPTA Source audit process.



III. Audit Findings

IQPP Audits are graded on an Observation Ranking System. All questions are assigned an Observation Level. Should a corporation or center fail to comply with any question or questions on the Audit Checklist, the points associated with that question will be assigned and the final score will impact when the next audit will be scheduled to take place.

Critical Observations are worth 50 points each
Major Observations are worth 10 points each
Minor Observations are worth 2 points each

For Plasma Center Audits, the following Scoring Guidelines will be used:

- 0 – 20 points – Next IQPP audit will take place in three (3) years.
- 21 – 50 points – Next IQPP audit will take place in two (2) years.
- 51 points or more will trigger a procedure in which a re-audit in less than two years may occur.

For Corporate Audits a score of 51 points or more will trigger a procedure in which a re-audit in less than one year may occur.

IV. Types of Auditor Recommendations

Audit reports may result in three types of recommendations by the Auditors, based on their observations during the audit:

- For Certification – the company or plasma center demonstrates adherence to the PPTA Source IQPP Standards.

- Provisional For Certification – the company or plasma center demonstrates a need for improvement in its implementation of some aspects of the PPTA Source IQPP Standards.

- Not For Certification – the company or plasma center demonstrates significant non-compliance with PPTA Source IQPP Standards.

V. Evaluation of Audit Reports

The PPTA Source Certification Manager evaluates all audit reports. The flow chart on page 8 describes the review process for audit results. The PPTA Source IQPP Certification Manager reviews the audit reports and determines the validity of the auditors' observations. Observations requiring CAPAs are then communicated to the company or plasma center in a letter from the IQPP Certification Manager. The plasma center then submits its CAPA, which is also reviewed by the IQPP Certification Manager, as described in the Certification Process flow chart found on page 8.

VI. Corrective and Preventive Action Plan (CAPA)

The outcome of all audits is communicated to the company. Companies receiving plasma center audits resulting in "Provisional Certification" or "Not For Certification" recommendations are provided the opportunity to develop CAPAs to correct the deficiencies. Responses must be submitted to PPTA Source no later than 30 days after receipt of the notification letter. In "Not For Certification" situations, PPTA Source may conduct an Issue-Driven audit to assure the CAPAs were implemented and effective.

Review of certification status may be escalated to the IQPP Standards Committee by the PPTA Source IQPP Certification Manager in any situation where CAPAs to audit findings are not adequately resolved within 60 days of the plasma center or company receiving the PPTA Source report.

VII. Conflict Resolution

In the event that a company disagrees with an audit report and PPTA Source review of that report, the company may enter into a dispute resolution process. The IQPP Standards Committee will consider each circumstance individually; identifying information will be blinded. The Standards Committee may uphold the company position, recommend acceptable CAPAs, or review the appropriate Standard for its applicability or interpretation. The company has 30 days to notify PPTA Source and provide evidence that it has made corrective and preventive action or that the company disputes the decision of the IQPP Standards Committee. If so, the dispute is escalated to the PPTA Source Board. If the PPTA Source Board upholds the IQPP Standards Committee determination, the company has 15 days to provide evidence that it has corrected the observation or certification is revoked.

Section B: How PPTA Administers the Certification Program Overview

I. Background

PPTA Source's International Quality Plasma Program (IQPP) has been certifying plasma centers in the U.S. since 1991 and in Europe since 2002. Processes and procedures that have been successfully used by other certification programs are incorporated into the PPTA Source certification program.

II. Control of the Program

Control and standardization of IQPP certification is important at the administrative level, as well as the audit level. Control and consistency at the administrative level is achieved through four primary mechanisms:

- a standardized administrative process;
- established rules which govern the administrative process;
- established authorities and responsibilities; and
- established procedures and document control system.

III. In this Section

This section covers the following topics relating to the areas of control and standardization for the administrative processes of the IQPP Certification Program.

Section B: How PPTA Administers the Certification Program Administrative Process

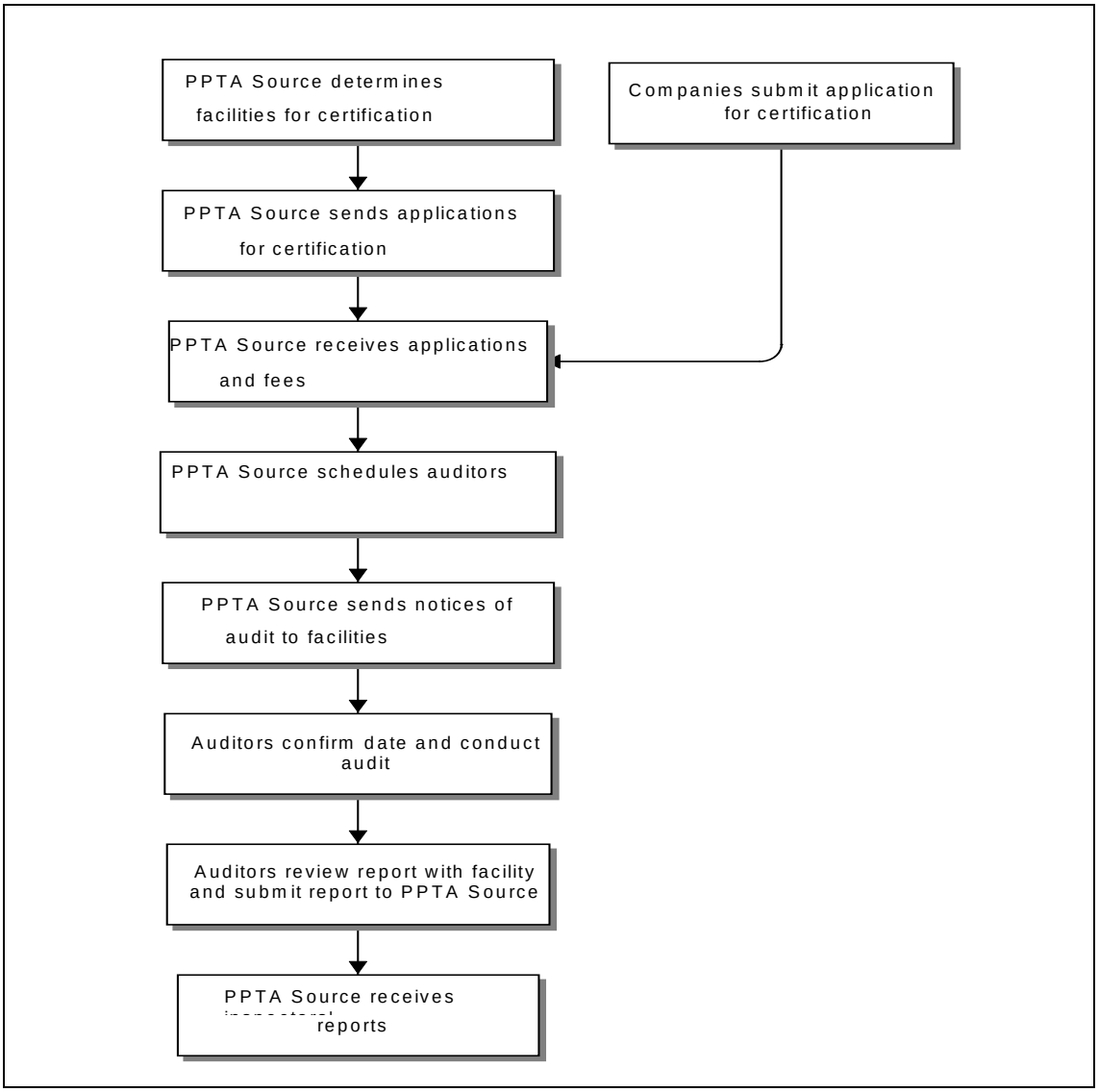
I. Introduction

Administration of IQPP certification can be divided into two parts:

- Coordination of the audits;
- Review of audit reports.

II. Administrative Process

The following flow chart provides an overview of the coordination of Audits.



Section B: How PPTA Administers the Certification Program Rules

I. Introduction

A number of rules apply to the issuance and maintenance of IQPP certification. These include:

- Eligibility for initial certification;
- Term for certification;
- Eligibility for recertification.

II. Eligibility for Initial Certification

Facilities are eligible for IQPP certification when they are licensed by a competent national regulatory authority and have submitted a complete certification application. Plasma centers not inspected according to FDA's Compliance Program Guidance Manual 7342.002 or PIC/S Guide to Inspection PI008-1 will first need to be inspected according to the PIC/s Guidance by an independent authority.

Initial IQPP certifications are usually scheduled to take place within 90 days of receipt of a completed application form.

III. Certification Term

IQPP Plasma Center certification is valid for a one to three-year period, determined by the outcome of the audit.

IQPP Corporate certification is valid for a six month to two-year period, determined by the outcome of the audit.

IQPP Combined Corporate/Plasma Center certification is valid for a six month to two-year period, determined by the outcome of the audit.

IV. Observation Rankings

All Corporate and Plasma Centers audits are based on a ranking scale of Critical Observations, Major Observations and Minor Observations. Each observation is given a score according to the following point system:

Critical Observations = 50 points each
Major Observations = 10 points each
Minor Observations = 2 points each

Corporate Audits that receive a score of 51 points or more may be subject to a re-audit that will occur in less than one year.

Plasma Centers that receive a score of 0 – 20 points are granted a three-year certification. Plasma Centers that receive a score of 21 – 50 points may be subject to a re-audit in two years. Plasma Centers that receive a score of 51 points or more may be subject to a re-audit in less than two years.

V. Scheduling for Recertification

PPTA Source tracks the date of initial certification.

Plasma Center audits are scheduled in cycles three times per year. At least 90 days before the beginning of a cycle, all plasma centers that will observe their anniversary of certification are identified in PPTA Source's database as due for re-certification in that cycle. PPTA Source will schedule the audit to occur within approximately 30 days of the certification anniversary. A plasma center undergoing renovation or relocation may request that the audit be postponed until renovations or relocation is completed; the audit must occur no more than 60 days past the anniversary date.

Corporate Audits and Combined Corporate/Plasma Center Audits are scheduled at the beginning of each cycle. At least 90 days before the beginning of the year, all companies due for their Corporate Audit will be notified by PPTA. The audit will be scheduled to occur within approximately 30 days of the certification anniversary.

In the event of an FDA or other regulatory authority audit on the same day as the scheduled IQPP audit, PPTA Source will postpone and reschedule the IQPP audit.

Weather and/or travel delays or auditor illness may result in the postponement and rescheduling of an audit.

VI. Plasma Center Relocation

1. An IQPP-certified plasma center that re-locates will be subject to an IQPP Plasma Center audit within six (6) months of that relocation, regardless of the certification anniversary date.

2. Re-locating centers shall notify the Association in writing at least sixty working days prior to the date on which the center begins operation in its new location. The notification shall include:
   a) the date on which the re-located center will begin operation;
   b) the new center address and contact information;
   c) a statement indicating whether the center's new address falls within the Donor Recruitment Area according to the center's SOPs; and
   d) a completed Application for Recertification-Relocation Form.

3. Upon receipt of the notification, the Association shall schedule an audit to occur within thirty days after the date on which the re-located center begins operation. An alternative date for the audit may be selected upon mutual agreement of the Association and the company.

4. Upon re-location, if the center has stated on its Application for Recertification-Relocation Form that its new address falls outside the Donor Recruitment Area, the center will be assigned a new NDDR number, and the history of viral marker data reported by the center at the previous address will not be transferred to the new center for purposes of compliance with the IQPP Standards Program.

   If the center has stated on its Application for Recertification-Relocation Form that the new address falls within the Donor Recruitment Area, the center will not be assigned a new NDDR number, and the history of viral marker data reported by the center at the previous address will be transferred to the new center for purposes of compliance with the IQPP Standards Program.

Upon completion of a successful audit, the re-located center will be given a new certification period that begins with the date on which the re-located center began operation.

VII. Company Mergers, Buy-outs and Center Purchases

All IQPP-certified plasma centers affected by company mergers, company buy-outs and individual plasma center purchases will be required to submit the PPTA Transition Plan Form to PPTA no later than thirty (30) days before the sale is implemented, yet not until after the transaction has been made public. PPTA may conduct a corporate audit, determined by PPTA with oversight by the IQPP Standards Committee. A sampling of the plasma centers affected will be subject to an IQPP audit should the SOPs under which those plasma centers operated during the previous IQPP audit change. Plasma centers continuing to operate under the same SOPs will not be subject to a re-audit.

IQPP certification will continue. The NDDR number(s) related to the plasma center(s) will remain the same.

VIII. Plasma Center Closures

All IQPP-certified plasma centers that cease operations and then reopen will be considered new centers and must follow Eligibility for Initial Certification rules as stated under Section B.II. Plasma centers that open under new ownership will be assigned a new NDDR number. Starting in September 2006, plasma centers that open under the same ownership will keep the NDDR number previously assigned to that location. Plasma centers that closed prior to September 2006 will be assigned a new NDDR number.

All IQPP-certified plasma centers that temporarily close (due to renovations, etc.) for a period of no longer than six (6) months may be subject to an IQPP Plasma Center audit within six months of re-opening. IQPP certification(s) and the current NDDR number(s) will remain in effect.

All IQPP-certified plasma centers that temporarily close (due to renovations, etc.) for more than six (6) months will be required to apply for new IQPP certification. The current NDDR number assigned to that plasma center will remain in effect.

IX. Regulatory Censure

Should an IQPP-certified plasma center undergo regulatory censure, (i.e., be issued an FDA Warning Letter, or have their licensed revoked) IQPP status will be dealt with according to the following formula:

- Plasma Center closed: IQPP status revoked until regulatory approval and subsequent IQPP audits completed.
- Warning Letter or equivalent: IQPP audit will take place 90 days subsequent to the company receiving a “cleared” status notification, to assure IQPP compliance.

X. Government Regulatory Compliance

In the event that the plasma center's government regulatory license is suspended or revoked, IQPP Certification is automatically revoked.

A plasma center that is issued an FDA Warning letter or a license suspension will be subject to re-audit for IQPP compliance with IQPP standards. If such an instance occurs, this should be communicated to PPTA within five (5) working days.

Section B: How PPTA Administers the Certification Program Authorities and Responsibilities

I. Management Structure

Authority and responsibility for administrating the PPTA Source IQPP Certification Program is distributed in the management structure of PPTA Source, as follows:

Title	Responsibility
President, PPTA	Policy development
Vice President, PPTA Source	Policy development; Source Board of Directors relations; Standards development
Director, PPTA Source Europe	Policy development; EPCC relations regarding Standards; Standards development
Project Manager, Standards and Programs	Monitor, track, coordinate and provide oversight; IQPP Standards Committee/Task Force relations
Manager, Certifications	Administration of Certification Program; oversees Auditors, scheduling, fees, audit process; maintain program database
Manager, Data	Oversee Viral Marker data; input data; produce and distribute reports; evaluate data for plasma centers on Alert List; review corrective and preventive action plans

II. Governance Structure

The following governing bodies provide guidance for the PPTA Source IQPP Certification Program.

Governance Units	Comprised of	Responsibilities
Functional Committees or Task Forces	High level member representatives of a particular function	Develops ideas for new standards; develops details of new standards
Review Committee	IQPP Standards Committee, plus additional parties	Reviews issues appealed as a result of a PPTA Source audit; Reviews new standards and recommends standards to the Board
Board of Directors		High-level policy and standards approval

Section B: How PPTA Administers the Certification Program Procedures and Document Control

I. Procedures

PPTA Source uses the administrative procedures to manage certification programs. These procedures cover all aspects of administration of the IQPP Certification Program – from application to awarding of certification.

II. Document Control

PPTA Source has a defined system for document control. Documents are numbered, indexed and stored to provide traceability and easy retrieval. Confidential files are kept in locked files and placed in archives after appropriate intervals.

IQPP Certification Program Description

Revision History

Date	Version	Description
January 2001	1.0	
April 2001	1.1	
September 2002	1.2	
Jan 2003	1.3	
July 2003	1.4	
August 2004	1.5	
April 2005	1.6	
February 2006	1.7	
August 2007	1.8	
November 2008	1.9	
January 2009	2.0	
January 2012	2.1	
January 2013	2.1	Document format change ONLY