IQPP Corporate Audit Report Form and Checklist

Version 9.0
Effective April 1, 2018

PPTA
Plasma Protein Therapeutics Association

IQPP Corporate Audit Report Form
Version 9.0

Auditor _____

Company _____

Address _____

_____

Government Authority Identification _____

_____

Telephone _____

Person Responsible for Quality Assurance _____

Date of audit _____ Start Time _____

(approx.) End Time _____

Auditor Recommendation:

[ ] For Certification/Recertification

[ ] For Certification/Recertification, pending resolution of issues listed on report form,

Section(s) Page(s) _____

[ ] Recommend Re-audit within _____ days.

PPTA Review _____ **Date Reviewed** _____

Auditor's Statement

As an Auditor for the International Quality Plasma Program (IQPP), I shall not, either directly or indirectly, for myself or for the benefit of or in conjunction with any other person, corporation, partnership, association, agency, department, or other legal entity, use, communicate or otherwise disclose, or permit to be disclosed, any Confidential Information relating to this audit or company without prior written consent of such company; provided, however, Auditor may, only to the extent reasonably necessary or appropriate to the performance of Auditor's duties, disclose such Confidential Information to PPTA or an employee of PPTA for use in the IQPP Certification or a person to whom disclosure is otherwise required by applicable state or federal law or regulation.

All information obtained during audit will be forwarded to PPTA to be made a part of the company's IQPP certification file.

As a consultant appointed by PPTA to perform this company's IQPP audit, I hereby attest that to the best of my knowledge no conflict of interest exists between my current clients and the audited company and/or PPTA.

I also attest that I have employed reasonable, good faith efforts to protect the personal health information of any and all individual plasma donors, and have requested, reviewed, and incorporated such data only to the limited extent necessary to carry out my duties as an IQPP Auditor.

As a consultant for the purposes of performing the IQPP audit of said company, I certify that the attached audit findings and comments are true and accurate findings based on my observations and record review during the audit.

Auditor Signature _____Date_____

POST AUDIT REVIEW

I acknowledge that the Auditor has reviewed the observations listed in this report. My signature does not constitute concurrence or denial of any of the observations made by the Auditor.

Company Representative_____Date_____

Title_____Center Name/Location _____

IQPP Corporate Audit Checklist
Version 9.0

A – Qualified Donors, Donor Record File (DRF) Review & Donor Privacy				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the company have written procedures in place, or, in the case of automated donor process, functional documentation (specifications/validation) in place that conforms to the IQPP Qualified Donor Standard?			Critical
2.	Does the company have written procedures to track Applicant Donor Units (orphan units) as to their final disposition?			Critical
Auditor Comments on Section A:				

B – Community-Based Donor Population				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the company have written procedures in place that conform to the IQPP Community-Based Donor Standard?			Critical
Auditor Comments on Section B:				

C – Use of the National Donor Deferral Registry or centralized donor deferral registry usage				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the company have written procedures in place that conform to the IQPP Use of the NDDR Standard?			Critical
Auditor Comments on Section C:				

D – Donor Education				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the company have written procedures in place that conform to the IQPP Donor Education Standard?			Major
2.	Can the company show evidence of donor education material that is provided to the plasma centers to educate donors?			Minor
Auditor Comments on Section D:				

E – Personnel Education and Training				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the company have a written training program with instructions or procedures to be performed by the trainee for each relevant plasma center job function?			Major
2.	Does the company have a written procedure in place which requires annual Good Manufacturing Practices (GMP) training for all plasma center employees?			Major
3.	Is there a policy and process in place to verify that plasma center employees (with a functional job related to donor screening, plasma collection, product handling or other similar functions) have attained the minimum level of education required in the Standard?			Minor
Auditor Comments on Section E:				

F – Professional Plasma Collection Facility
NOTE: There are no questions from this section that are applicable for the Corporate Audit.

G – Complaints				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the company have written procedures available for receiving, recording and evaluating customer and/or donor complaints?			Major
Auditor Comments on Section G:				

H – Quality Assurance Standard				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the company have written procedures in place that conform to the IQPP Quality Assurance Standard?			Critical
2.	Does Quality Assurance/responsible person have the authority and responsibility as outlined by the plasma center SOP or job description to stop a) the release of plasma for shipment, if necessary? b) plasma center production, if necessary?			Critical
3.	Does the company have written procedures that outline and instruct Quality Assurance/responsible person on the specific checks that must be verified as acceptable before plasma units are released?			Critical
4.	Is final plasma release controlled by Quality Assurance personnel or a qualified alternate?			Critical
Auditor Comments on Section H:				

I – Viral Marker Standard				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the company have written procedures in place that conform to the IQPP Viral Marker Standard?			Critical
2.	If the data are computer-generated, is the query set up to classify Applicant and Qualified Donors according to the IQPP Qualified Donor Standard?			Major
Auditor Comments on Section I:				

J – Cross Donation Management Standard				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the company have written procedures that conform to the IQPP Cross Donation Management Standard?			Major
2.	Do the written procedures include how it will prevent an individual from donating more often than allowed by regulation?			Major
3.	Do the written procedures include a notification process to inform all known plasma centers within a center's Donor Recruitment Area ("DRA") of the opening of a new center and provide all required information to the Cross Donation Check System ("CDCS") no later than 30 days prior to the scheduled opening date?			Major
4.	Do the written procedures include an articulated backup process in accordance with subclause 4.4 of the standard?			Major
5.	Do the written procedures include a process for transfer of required donor donation information to the CDCS?			Major
6.	Do the written procedures include a process to investigate situations when the data transfer fails?			Major
7.	Do the written procedures include an articulated process to determine whether an individual, found to be listed in the CDCS, is knowingly attempting to violate the donation frequency allowed by regulation?			Major
8.	Do the written procedures include an articulated process to apply a permanent deferral to a donor who is found i. to be knowingly attempting to donate more often than regulation allows, or ii. to have cross-donated?			Major
9.	Do the written procedures include an SOP requiring use of the CDCS (or, where the CDCS is not permissible by law, an alternative national or regional registry, if available, and, where no alternate deferral registry is available, an intra-company process) in accordance with the Standard?			Major
Auditor Comments on Section J:				

K – Standard for Recording Donor Adverse Events				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the company have a documented process for recording known Donor Adverse Events (“DAEs”) considered to be associated with any part of a Source Plasma donation program (this includes initial screening, donation, immunization for high titer collections, etc.) following company approved SOPs, and does this process conform to the Standard?			Major
2.	Does the process require centers to record, in the facility’s documentation system, DAEs as required by the Standard?			Major
Auditor Comments on Section K:				

L – Donor Fluid Administration Standard				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the company have written procedures that address the requirements in the standard?			Critical
Auditor Comments on Section L:				
General Overall Comments:				

Ranking Guidelines:

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

Scoring Guidelines:

A score of 51 points or more triggers a procedure in which a re-audit in less than one year may occur.