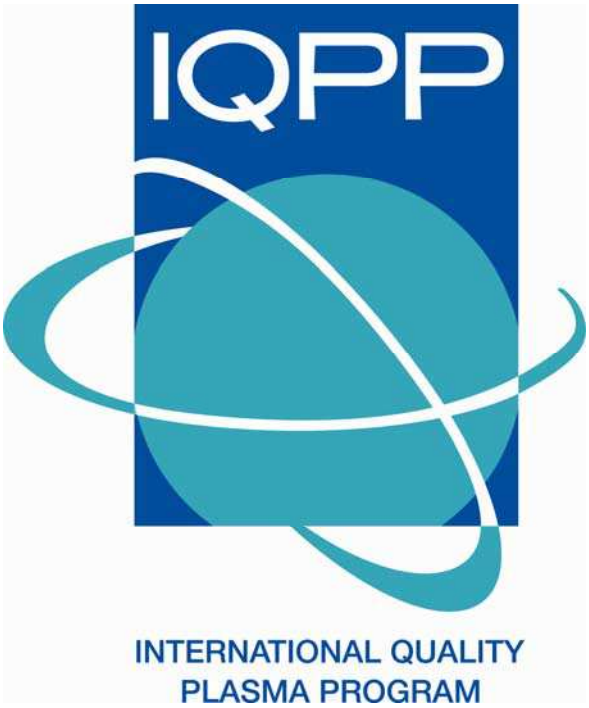

IQPP Plasma Center Audit Report Form and Checklist

Version 7.0
Effective April 1, 2015

PPTA
Plasma Protein Therapeutics Association

IQPP Plasma Center Audit Report Form
Version 7.0

Auditor _____

Plasma Center _____

Address _____

_____

Government Authority Identification _____

PPTA ID# _____

Telephone _____ Fax _____

Manager _____

Medically Qualified Person _____

Person Responsible for Quality Assurance _____

Date of audit _____ Start Time _____

(approx.) End Time _____

Other regulatory and government-agency approvals _____

_____

_____

Auditor notes unrelated to standards _____

_____

_____

Auditor Recommendation: [ ] For Certification/Recertification

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

Section(s) Page(s) _____

[ ] Significant 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 plasma center without prior written consent of such plasma center; 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 plasma center's IQPP certification file.

As a consultant appointed by PPTA to perform this plasma center'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 plasma center and/or PPTA.

As a consultant for the purposes of performing the IQPP audit of said plasma center, 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 Plasma Center Audit Checklist
Version 7.0

A – Qualified Donors, Donor Record File (DRF) Review & Donor Privacy				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	For Applicant Donors, does the plasma center conduct screening including a physical examination completed by a Physician or Physician Substitute in accordance with all applicable regulatory and IQPP screening and testing criteria?			Major
2.	Does the plasma center reclassify an Applicant Donor to a Qualified Donor based on the successful passing of the following within the minimum time interval between donations and no later than six months after the previous screening? a. Physical examination. b. NDDR check. c. Two donor screenings. d. Tested non-reactive for two sets of testing for HIV, HBV and HCV (based on all applicable regulatory and IQPP requirements) from donations and/or sample only collection.			Critical
3.	Is the classification of a person as a Qualified Donor administered by plasma centers operated under the same SOPs and utilizing the same database(s) to make such determinations?			Major
4.	Does the plasma center have a system in place to control Applicant Donor units and ensure they are not shipped for use in manufacturing of therapeutic products?			Major
5.	If a Qualified Donor does not return for donation within six months of their previous donation, is the donor re-classified as an Applicant Donor?			Critical
Auditor Comments on Section A:				

B – Community-Based Donor Population				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the plasma center have a system to identify potential donors who are outside the Donor Recruitment Area?			Minor
2.	Does the plasma center have a current (no more than one (1) year old) list of unacceptable addresses available for donor screening?			Minor
3.	Does the plasma center update this list every time it becomes aware of an unacceptable address?			Minor
4.	Does the list cover all areas from where donors are recruited/accepted?			Minor
5.	Does the plasma center verify the donor's address against the unacceptable address list (initially and annually)?			Minor
6.	Does the plasma center reject donors when the donor's address is a known hotel, mission, homeless shelter or transient camp?			Major
7.	Does the plasma center require new donors to provide valid photo identification issued by an employer, educational institution or government authority?			Major
NOTE: The following question does not apply to college/university students, locally-stationed members of the military or donors intentionally transported for the collection of source material for specialty donors.				
8.	Does the plasma center reject donors with permanent residences outside the plasma center's defined Donor Recruitment Area?			Minor
Auditor Comments on Section B:				

C – National Donor Deferral Registry or centralized donor deferral registry usage				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the plasma center check all Applicant Donors or donors being processed as Applicant Donors against the National Donor Deferral Registry?			Critical
2.	Is the response (verification code) provided by the NDDR system recorded and traceable to the donor?			Major
3.	Where applicable, are donors that are intentionally collected for anti-HIV, HBsAg, or anti-HCV positive units under a government-approved collection program checked against the NDDR and added to it if necessary?			Major
NOTE: The following questions do not apply to companies using an integrated system shared by their centers and the NDDR Data Entry Site/Laboratory.				
4.	Is there a position responsible for providing donor information to the NDDR Data Entry Site within three (3) business days of receiving positive test results?			Major
5.	Is donor information input into the NDDR within three (3) business days of notification of donor information?			Major
Auditor Comments on Section C:				

D – Donor Education				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the plasma center have an electronic, paper or video-based education system (or materials) to help donors address risk behavior?			Major
2.	Is the donor's comprehension of the information assessed initially in order to assure their understanding of risk behavior?			Major
3.	Does the plasma center provide materials (e.g., electronic, paper or video-based) to educate the donors, on their initial visit, on general well-being practices for plasma donation as directed by the corporate office?			Minor
Auditor Comments on Section D:				

E – Personnel Education and Training				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Do the plasma center records reflect that the corporate training guide is being implemented and that the records are up to date?			Major
2.	Do all plasma center employees have documented annual GMP training?			Major
3.	Is there documentation on file (such as a diploma, GED equivalent, college/university transcript or professional license) demonstrating 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				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Is the building structurally sound and showing no evidence of loss of exterior integrity?			Major
2.	Are windows and doors maintained in good repair?			Minor
3.	If windows are open, is adequate screening in place to prevent insects, debris, etc. from entering the plasma center?			Minor
4.	Is the building and its immediate exterior surroundings kept free of litter and debris?			Minor
5.	Does the plasma center follow company policies regarding littering, loitering and smoking in and about the plasma center and are they effectively implemented and enforced?			Minor
6.	Is the area in which the dumpster is located free of waste?			Minor
7.	Does the entrance to the center control the flow of donors into the plasma center?			Minor
8.	Is the plasma center configured in a way that prevents public access to the unauthorized areas of the building?			Major
9.	Do entrances, exits and applicable parking areas have adequate lighting?			Minor
10.	Is seating adequate to avoid the overflow of donors into aisles, doorways, the outdoors or other areas of the plasma center outside of the designated waiting area (except during peak periods)?			Minor
11.	Are all areas of the plasma center configured to provide for safe and proper operation?			Major
12.	Is signage, if present, professional in appearance and maintained in good order?			Minor
13.	Are temporary signs such as posters and banners for promotional campaigns professional in appearance and maintained in good order?			Minor
14.	Are all surfaces (walls, floor, ceiling, etc) maintained in a clean and sanitary manner and kept in good repair?			Minor
15.	Is interior lighting adequate and maintained in good operating order?			Minor
16.	Are there separate restrooms facilities available for staff use?			Minor
17.	Are donor restroom facilities maintained in a clean manner, in good repair and easily accessible to donors?			Minor
18.	Are adequate supplies for hand washing and sanitary purposes available in all restroom facilities and appropriate areas?			Minor
19.	Are the cleaning supplies in an appropriately sanitary state or condition?			Minor

20.	Do records indicate that storage areas are kept clean and at their appropriate temperature levels?			Minor
21.	Are storage areas adequate in size to contain all supplies necessary for plasma center operation?			Minor
22.	Are supplies stored in areas of the facility which are accessible only to authorized personnel?			Minor
23.	Is the infectious waste storage area accessible only to authorized personnel?			Major
24.	Are there procedures in place preventing donor access to manufacturing records, supplies, plasma units and corresponding samples?			Major
25.	Does the plasma center maintain Donor Record Files and information in a confidential manner to ensure access by authorized personnel only?			Major

Auditor Comments on Section F:

G – Complaints				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the plasma center follow company procedures regarding customer and/or donor complaints?			Major

Auditor Comments on Section G:

H – Release Procedures				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the plasma center follow company procedures regarding stopping the release of plasma for shipment, if necessary?			Critical
2.	Does the plasma center follow company procedures regarding the specific checks that must be verified as acceptable before plasma units are released?			Critical
3.	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.	Has the plasma center been placed on the Viral Marker Alert List since the previous IQPP audit? If yes, answer question 1A – 1B below.			N/a
1A.	Is a copy of the corrective and preventive action (CAPA) plan response available at the plasma center?			Major
1B.	Has the corrective and preventive action (CAPA) plan been implemented?			Major
2.	Are the data in the Donor Record File consistent with the Viral Marker data reported?			Major
3.	Are the reactive data at the center consistent with the viral marker data reported?			Major

Auditor Comments on Section I:

J – Cross Donation Management Standard				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the plasma center enter into the CDCS information in accordance with the Standard?			Major
2.	Does the plasma center conduct donor checks in accordance with the requirements in the Standard?			Major
3.	Does the plasma center keep records of its donor checks in accordance with the Standard?			Major
4.	If a donor is found to be donating in more than one center, and not exceeding the maximum allowable limits for donating, is the donor 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?			Major
5.	If a donor is found to be cross-donating, is the donor permanently deferred?			Major
6.	Does the center follow the Backup 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 center follow the company's approved process for recording known DAEs considered to be associated with any part of a Source Plasma donation program?			Major
2.	Does a licensed center physician or physician substitute classify all DAEs in accordance with the DAE Classifications list in the Standard, utilizing the available information and his/her best medical judgment?			Major
3.	Does the center's oversight program include monitoring of asterisked records to confirm compliance with the definitions in the standard?			Major

Auditor Comments on Section K:

List any GMP concerns:

General Overall Comments:

Ranking Guidelines:

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

Scoring Guidelines:

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.