IQPP Plasma Center Audit Report Form and Checklist

Version 12.0

PPTA
Plasma Protein Therapeutics Association

IQPP Plasma Center Audit Report Form
Version 12.0

Auditor _____

Center Name_____

Address _____

City_____State_____Zip Code_____

Government Authority Identification_____

PPTA ID# _____

Telephone_____

Manager_____

Recipient's email address _____

Medically Qualified Person_____

Person Responsible for Q/A_____

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)_____

Recommendations for specific sections _____

[ ] 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_____

IQPP Plasma Center Audit Checklist
Version 12.0

A – Qualified Donors, Donor Record File (DRF) Review & Donor Privacy				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	For Applicant Donors, does the 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 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.	Does the 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
4.	If a Qualified Donor does not donate within six months of their previous donation, yielding test results that are acceptable for further manufacture, 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 center have a system to identify potential donors who reside outside the Donor Recruitment Area?			Minor
2.	Does the center have a current list of unacceptable addresses available for donor screening, or does it use an online search engine to verify that a donor's given address is not unacceptable?			Major
3.	If the center uses a list, does the center update this list every time it becomes aware of an unacceptable address, and is the list verified annually?			Major
4.	Does the list or online search engine, as applicable, cover all areas from where donors are recruited/accepted?			Minor
5.	Does the center verify that the donor's given address is acceptable (initially and at least annually)?			Minor
6.	Does the center reject donors when the donor's address is a known hotel, motel, mission, halfway- house, or shelter?			Major
7.	Does the center require new donors to provide valid photo identification issued by an employer, educational institution or government authority, and proof of Local Residence, in accordance with the requirements in the Standard??			Major

NOTE: The following question does not apply to:
• Local college/university students;
• Qualified Donors who have an established, approved local residence within a company's Blood Establishment Computer Software ("BECS") and available donation history, as long as the center has verified that:
  ○ the individual has an acceptable permanent residence at the location where they became a Qualified Donor, and
  ○ the individual is donating at centers within the same company using the same set of Standard Operating Procedures;
• Locally-stationed members of the military; or
• Donors intentionally transported for the collection of source material for specialty donors.				

8.	Does the center reject donors with permanent residences outside the 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 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.	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: Questions 4 and 5 below 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 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 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 center records reflect that the corporate training guide is being implemented and that the records are up to date?			Major
2.	Do all center employees, where applicable, have documented annual cGMP and Exposure Control Plan (Biosafety Practices and Procedures) training?			Major
3.	Is there documentation on file (such as a diploma, GED equivalent, college/university transcript or professional license) demonstrating that 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
4.	Does the center maintain job descriptions for every position in the donor center, and have existing personnel signed the job description associated with their position?			Minor

Auditor Comments on Section E:

F –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 center?			Minor
4.	Is the building and its immediate exterior surroundings kept free of litter and debris?			Minor
5.	Does the center have a policy stating that littering and loitering about the center are prohibited, and (where applicable) that smoking, while prohibited in the center, may be permitted about the center only in designated smoking areas, and is that policy 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 center?			Minor
8.	Is the center configured in a way that prevents public access to the unauthorized areas of the center?			Major
9.	Is adequate working lighting present in applicable parking areas and around the entrances and exits of the center?			Minor
10.	Is seating adequate to avoid the overflow of donors into aisles, doorways, the outdoors or other areas of the center outside of the designated waiting area (except during peak periods)?			Minor
11.	Is signage, if present, professional in appearance and maintained in good order?			Minor
12.	Are temporary signs such as posters and banners for promotional campaigns professional in appearance and maintained in good order?			Minor
13.	Are all surfaces (walls, floor, ceiling, etc.) maintained in a clean and sanitary manner and kept in good repair?			Major

14.	Is interior lighting adequate and maintained in good operating order?			Minor
15.	Are there separate restroom facilities available for staff use?			Minor
16.	Are all restroom facilities maintained in a clean manner, in good repair and are donor restrooms easily accessible to donors?			Minor
17.	Are adequate supplies for hand washing and sanitary purposes available in all restrooms and appropriate areas?			Minor
18.	Are the cleaning supplies in an appropriately sanitary state or condition?			Minor
19.	Do records indicate that storage areas are kept clean?			Minor
20.	Are storage areas adequate in size to contain all supplies necessary for center operation?			Minor
21.	Are supplies stored in areas which are accessible only to authorized personnel?			Minor
22.	Is the infectious waste area accessible only to authorized personnel?			Major
23.	Are there procedures in place preventing donor access to manufacturing records, supplies, plasma units and corresponding samples?			Major
24.	Does the 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 center follow company procedures regarding customer and/or donor complaints?			Major
Auditor Comments on Section G:				

H – Quality Assurance				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the center follow company procedures regarding stopping the release of plasma for shipment, if necessary?			Critical
2.	Does the 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 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 center?			Major
1B.	Has the corrective and preventive action (CAPA) plan been implemented?			Major
2.	Are the Viral Marker data in the Donor Record File 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 center/company enter into the CDCS information in accordance with the Standard? *(The information may be entered either at the center or the corporate level.)*			Major
2.	Does the center conduct donor checks in accordance with the requirements in the Standard?			Major
3.	Does the center keep objective evidence of the use of the System in accordance with the Standard?			Major
4.	If an individual is found to be listed in the CDCS, but not knowingly attempting to donate more often than regulation allows, is the donor informed about the health risks of exceeding the allowable limits and the reasons for the center's concerns for the individual's health and safety should cross donation occur?			Major
5.	If an individual is found to be knowingly attempting to donate more often than regulation allows, is the individual permanently deferred?			Major
6.	If an individual is found to have cross donated, is the individual permanently deferred?			Major
7.	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 physician or physician substitute classify all DAEs listed in the DAE Classifications list in Clause 4.2 which have an asterisk (*), utilizing the available information and best medical judgment?			Major
Auditor Comments on Section K:				

L – Standard for Donor Fluid Administration				
#	**Audit Question**	**Yes**	**No**	**Ranking**
1.	Does the facility administer a minimum of 250 mL of 0.9% sodium chloride solution (NaCl; saline) intravenously to donors as part of the automated plasmapheresis process, or alternate method, in accordance with the requirements of the standard?			Critical
2.	In accordance with the requirements of the standard, is there evidence showing when administration of intravenous NaCl 0.9% is not possible (including but not limited to examples of donors with limited venous access, donor reported complications with NaCl 0.9%, shortage of available NaCl 0.9% solution in the market), the facility a) administers either: • a minimum of 250 mL of an oral electrolyte solution that contains sodium, or • a combination of intravenous NaCl 0.9% and an oral electrolyte solution that contains sodium (where the total quantity administered is, at minimum, 250 mL); and b) takes measures to facilitate the successful consumption of the fluids by the donor within the center premises, in accordance with a method documented in the facility's SOPs?			Major
3.	Does the facility educate donors on the importance of fluid administration and maintaining appropriate hydration pre- and post- donation?			Major
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:

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.