

IQPP Plasma Center Audit Report Form and Checklist

Version 13.5



**INTERNATIONAL
QUALITY PLASMA
PROGRAM**

Implemented September 07, 2026

IQPP Plasma Center Audit Report Form Version 13.5

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 13.5

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
<u>Auditor Comments on Section A:</u>				

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 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 products.				
8.	Does the center reject donors with permanent residences outside the center's defined Donor Recruitment Area?			Minor
Auditor Comments on Section B: 				



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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? (In jurisdictions where the NDDR is not allowed by law, an in-house or locally administered deferral registry, or SOP to determine whether or not that donor is listed)			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

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.

Auditor Comments on Section C:



PLASMA PROTEIN
THERAPEUTICS
ASSOCIATION

D1 Donor Safety Standard – Cross Donation Management				
#	Audit Question	Yes	No	Ranking
1.	Does the center/company enter information into the CDCS in accordance with the Standard? <i>(The information may be entered either at the center or the corporate level.)</i>			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.	Does the center follow the Backup Process in accordance with the Standard?			Major
Auditor Comments on Section D1:				
D2 Donor Safety Standard – 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 D2:				

D3 – Donor Safety Standard – Donor Fluid Administration



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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
	NOTE: Refer to Appendix A for requirements specific to the US, Austria, Germany, Hungary, Czech Republic, and Egypt.			
<u>Auditor Comments on Section E:</u>				

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? (e.g., is area where the dumpster is located free of waste?)			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.	Does the entrance to the center control the flow of donors into the center?			Minor
7.	Is the center configured in a way that prevents public access to the unauthorized areas of the center?			Major
8.	Is adequate working lighting present in applicable parking areas and around the entrances and exits of the center?			Minor
9.	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
10.	Is signage, if present, professional in appearance and maintained in good order?			Minor
11.	Are all surfaces (walls, floor, ceiling, etc.) maintained in a clean and sanitary manner and kept in good repair?			Major
12.	Is interior lighting adequate and maintained in good operating order?			Minor
13.	Are there separate restroom facilities available for staff use?			Minor
14.	Are all restroom facilities maintained in a clean manner, adequately supplied, in good repair and are donor restrooms easily accessible to donors?			Minor
15.	Are the cleaning supplies in an appropriately sanitary state or condition?			Minor
16.	Do records indicate that storage areas are kept clean?			Minor



#	Audit Question	Yes	No	Ranking
17.	Are storage areas adequate in size to contain all supplies necessary for center operation?			Minor
18.	Are supplies stored in areas which are accessible only to authorized personnel?			Minor
19.	Is the infectious waste area accessible only to authorized personnel?			Major
20.	Are there procedures in place preventing donor access to manufacturing records, supplies, plasma units and corresponding samples?			Major
21.	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 – Quality Assurance				
#	Audit Question	Yes	No	Ranking
1.	Do Quality Assurance functions report independently within the center-level organizational structure, separate from operations?			Critical
<u>Auditor Comments on Section G:</u> 				
H– 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
<u>Auditor Comments on Section H:</u> 				



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I – 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 I:

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.