



International Quality Plasma Program

Corporate Audit

Report Form and Checklist

Version 4.0

INTERNATIONAL QUALITY PLASMA PROGRAM (IQPP) CORPORATE AUDIT REPORT FORM

Auditor _____

Company _____

Address _____

Government Authority Identification _____

Telephone _____ Telefax _____

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 National Office 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.

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 _____

A – Qualified Donors, Donor Record File (DRF) Review & Donor Privacy				
#	Audit Question	Yes	No	Ranking
1.	Does the company have written procedures or, in the case of automated donor process, functional documentation (specifications/validation) that conform 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
<u>Auditor Comments on Section A:</u>				
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
<u>Auditor Comments on Section B:</u>				

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
<u>Auditor Comments on Section C:</u>				
D – Donor Education				
#	Audit Question	Yes	No	Ranking
1.	Does the company have written procedures in place that conform to the IQPP Education of Donors at Risk for Infectious Disease Standard?			Major
2.	Can the company show evidence of donor education material that is provided to the plasma centers to educate donors?			Minor
<u>Auditor Comments on Section D:</u>				

E – Personnel Education and Training				
#	Audit Question	Yes	No	Ranking
1.	Does the company have a written training guide with instructions or procedures to be performed by the trainee for each plasma center job function?			Major
2.	Does the company have an annual GMP training policy for all plasma center employees?			Major
3.	Is there documentation on file (such as a diploma, GED equivalent, college/university transcript or professional license) to assure that each plasma center employee is at least a high school graduate or appropriately grandfathered?			Minor
<u>Auditor Comments on Section E:</u>				
F – Professional Medical Facility Criteria				
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
<u>Auditor Comments on Section G:</u>				

H – Release Procedures				
#	Audit Question	Yes	No	Ranking
1.	Does QA/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
2.	Does the company have written procedures that outline and instruct QA/responsible person on 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
<u>Auditor Comments on Section H:</u>				
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
<u>Auditor Comments on Section I:</u>				

General Overall Comments:

Ranking Guidelines:

Critical Observations = 50 points each

Major Observations = 10 points each

Scoring Guidelines:

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