QSEAL Audit Report Form and Checklist

Version 2.0
Implemented September 21, 2013

PPTA
Plasma Protein Therapeutics Association

QSEAL AUDIT REPORT
COVER SHEET

Auditor _____

Facility _____

Address _____

_____

Telephone _____ Fax _____

Facility Audit
Coordinator _____

Email _____

Government Authority ID _____
(e.g. EU registration #, FDA license #)

Date of Audit _____ Start Time _____

(approx.) End Time _____

Auditor Recommendation:

☐ For Certification

☐ Provisional for Certification,

Section(s) Page(s) _____

_____

_____

☐ Not for Certification, due to issues listed on report form,

Section(s)/Page(s) _____

_____

_____

PPTA Office Review _____ Date Reviewed _____

Auditor notes unrelated to QSEAL Standards:

PPTA Confidentiality Statement

Neither the Plasma Protein Therapeutics Association ("PPTA"), nor any PPTA employee, shall, either directly or indirectly, for its own benefit or the benefit of 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 any Quality Standards of Excellence, Assurance and Leadership ("QSEAL") audit, plasma collection facility, or manufacturing facility without prior written consent of the QSEAL-participating facility at issue; provided, however, that PPTA may, only to the extent reasonably necessary or appropriate to the performance of its duties as administrator of the QSEAL program: (i) maintain such confidential information as part of the facility's permanent QSEAL certification file, and (ii) disclose such confidential information to a person to whom disclosure is otherwise required by applicable law or regulation.

Auditor's Statement

As an auditor for PPTA QSEAL Certification, 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 facility without prior written consent of such facility; 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 QSEAL Certification or a person to whom disclosure is otherwise required by applicable law or regulation.

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

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

As a consultant for the purposes of performing the QSEAL audit of said facility, 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 _____

Facility Name/Location _____

_____

_____

QSEAL Audit Checklist

Purpose

The purpose of the audit is to provide independent, third-party assessment of a facility's adherence to the requirements of the QSEAL program. The auditor shall inspect all locations within the facility where operations pertaining to requirements for QSEAL certification are carried out. Where such operations are carried out by a third party, the manufacturer shall have responsibility for inspecting the facilities, and the auditor shall verify through the audit checklist that the manufacturer's inspections are completed.

Questions to be Addressed during the Audit

- Table 1, page 7 – Characterization of Plasma Used in Manufacturing
- Table 2, page 8 – Incoming Source Plasma from IQPP-certified and Non-IQPP-certified Centers
- Table 3, page 26 – Additional Questions for Use of Source Plasma from Non-IQPP-Certified Centers
- Table 4, page 29 – Intermediates
- Table 5, page 34 – Recovered Plasma Specification
- Table 6, page 38 – Integration Summary

Table 1 – Characterization of Plasma Used in Manufacturing			
Question	**Yes**	**No**	**Rating**
1. Does the facility use Source Plasma from centers that are NOT IQPP certified?	☐ YES ☐ Use Table 2 ☐ Use Table 3 ☐ Use Table 6	☐ NO	
1.1 Does the facility audit its supplier to assess compliance with the following standards:			
IQPP Viral Marker	☐ YES	☐ NO	
IQPP Qualified Donor	☐ YES	☐ NO	
1.2 Does the facility maintain a current list of active Source Plasma centers that are acceptable for use in the manufacturing process?	☐ YES	☐ NO	
2. Does the facility use Source Plasma from centers that ARE IQPP certified?	☐ YES ☐ Use Table 2 ☐ Use Table 6	☐ NO	
2.1 Is there a system to assure that the centers supplying Source Plasma to the facility are IQPP certified?	☐ YES	☐ NO	
2.2 Does the facility have in place a system to confirm that the centers' IQPP certification(s) were valid at the time that the plasma was collected?	☐ YES	☐ NO	
2.3 Does the facility maintain a current list of active Source Plasma centers that are acceptable for use in the manufacturing process?	☐ YES	☐ NO	
3. Does the facility receive intermediates from another company?	☐ YES ☐ Use Table 4	☐ NO	
4. Does the facility use Recovered Plasma?	☐ YES ☐ Use Table 5	☐ NO	
4.1 Does the facility have a system in place to assess compliance of its suppliers with the Recovered Plasma Specification?	☐ YES	☐ NO	
4.2 Does the facility maintain a current list of active Recovered Plasma centers that are acceptable for use in the manufacturing process?	☐ YES	☐ NO	

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Yes	No	Rating
5. Does the facility have a system in place to assure that it only uses plasma that was collected from facilities that were in compliance with the applicable national competent regulatory authority(ies) at the time of collection?	☐ YES	☐ NO	
6. Does the facility have a system in place to assure that it only uses intermediates that were manufactured in facilities that were in compliance with the applicable national competent regulatory authority(ies) at the time of manufacture?	☐ YES	☐ NO	
7. Does the facility engage in toll manufacturing?	☐ YES	☐ NO	

Table 2 – Incoming Source Plasma (from IQPP-certified and non-IQPP-certified Centers)

2.1 General

Question	Yes	No	Rating
1. Does the facility have a system in place to assess its suppliers of incoming plasma for compliance with requirements for Unique Donor Identification, Tracking and Traceability from the date of collection?	☐ YES	☐ NO	
2. Does the facility have in place a comprehensive system for tracking and tracing plasma, from the date on which it takes possession of the plasma through to the completion of the final product therapy?	☐ YES	☐ NO	

2.2 Receipt of and Holding Incoming Plasma

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
1. Does the facility have a policy/system that requires Source Plasma pooled for manufacture of plasma protein therapies to be exclusively from Qualified Donors as defined in the IQPP Qualified Donor Standard?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	
2. Does the facility have a system to physically or electronically segregate Source Plasma units that do come from Qualified Donors from those that do not comply? (e.g., Applicant Donor units, if such units are accepted from suppliers)	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
3. Does the facility have a system to segregate Source Plasma units from collection centers that do not comply with the Viral Marker Standard from those that do comply?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	
4. If Source Plasma Applicant Donor ("orphan") units are received, does the facility have a system whereby they are:				
a) quarantined until donor qualification records are received from the supplier,	☐ YES ☐ NO ☐ N/A	☐ A ☐ O ☐ SO ☐ N/A	☐ YES ☐ NO ☐ N/A	
b) destroyed, and/or	☐ YES ☐ NO ☐ N/A	☐ A ☐ O ☐ SO ☐ N/A	☐ YES ☐ NO ☐ N/A	
c) identified and segregated for use in research or production of non-therapeutic plasma products?	☐ YES ☐ NO ☐ N/A	☐ A ☐ O ☐ SO ☐ N/A	☐ YES ☐ NO ☐ N/A	
5. Can the facility certify that its plasma used in production was collected by, or received from, centers that had in place a comprehensive system for tracking and tracing plasma, from the date of collection to the date on which they transferred ownership of the plasma to the manufacturer?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	
a) Does this system include unique donor identification?	☐ YES ☐ NO			
6. Regardless of whether the plasma is held in the same facility as the manufacturing plant or in a separate facility, does the facility have a system in place to assess compliance with the Inventory Hold Standard?	☐ YES ☐ NO		☐ YES ☐ NO	
a) Does that system effectively control the release process?	☐ YES ☐ NO			

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
7. Does the facility have a system in place for receipt of Post Donation Information from Source Plasma collection centers?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	
8. Does the facility have a system in place to identify, retrieve, and remove Look Back units reported during Inventory Hold?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
a) Does that system effectively control these activities?			☐ YES ☐ NO	☐ A ☐ O ☐ SO
Comments:				

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

2.3 Testing Plasma

(Unless otherwise indicated, the questions below apply for both minipool and manufacturing pool testing.)

NAT Testing Standard - All incoming plasma is tested for HIV, HBV, HCV, HAV and Parvovirus B19 viral nucleic acid using a Nucleic Acid Amplification Technology test. Plasma reactive above the specified limits for HIV, HBV, HCV, HAV or Parvovirus B-19 nucleic acid is segregated and not pooled for production

General Questions (These questions apply whether or not testing is conducted directly by the manufacturer.)

2.3. A Testing Before Assembling the First Homogeneous Plasma Pool

Question	Yes	No	Rating and Notes
1. Does the facility have a written, approved document requiring that, before assembling the first homogeneous plasma pool, plasma donations are tested for viral nucleic acid of HIV, HBV, and HCV using NAT technology?	☐ YES Document Number or Title: _____	☐ NO	
2. Does the facility have a written, approved document requiring that, before assembling the first homogeneous plasma pool, plasma donations are tested for viral nucleic acid of HAV and Parvovirus B19 using NAT technology?	☐ YES Document Number or Title: _____	☐ NO	
3. For Source Plasma, does the manufacturer ensure that all donations are tested for HIV, HBV and HCV using licensed or approved test kits and/or validated test assays in compliance with national and international requirements?	☐ YES	☐ NO	
4. For Recovered Plasma, does the manufacturer perform, or require the collector (or designated contract lab), to perform minipool or individual NAT testing on all donations for HIV, HBV and HCV using licensed or approved test kits and/or validated test assays in compliance with national and international requirements?	☐ YES	☐ NO	
5. Where testing is performed by the plasma collector, does the manufacturer require the collector to report test systems and results?	☐ YES Document Number or Title: _____	☐ NO	

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Yes	No	Rating and Notes
6. Where testing is performed by the manufacturer, does the manufacturer report reactive results for HIV, HBV and HCV to the collector?	☐ YES Document Number or Title:	☐ NO	
7. Is the method of reporting jointly agreed to by the collector and the manufacturer?	☐ YES	☐ NO	
8. Is minipool testing for HIV, HBV and HCV resolved to the individual donation?	☐ YES	☐ NO	

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
9. Does the facility have a written, approved system to identify and retrieve units that are rejected and/or that received a positive minipool or individual NAT test result for HIV, HBV, HCV and HAV?	☐ YES Document Number or Title: ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
10. Does the facility have a written, approved system to identify and retrieve units with a high titer that would lead to a plasma pool exceeding 10^4 IU/mL Parvovirus B19?	☐ YES Document Number or Title: ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
11. Does the facility have a written, approved system whereby those units (see questions 9 and 10) are: ☐ destroyed, or ☐ segregated from units that have not been tested or that have received negative test results.	☐ YES Document Number or Title: ☐ NO		☐ YES ☐ NO	

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
12. If a first homogeneous plasma pool NAT test is confirmed positive for HIV, HBV, HCV or HAV, is the pool, or material derived from it, used in further manufacturing?	☐ YES Document Number or Title: ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
Comments:				

2.3. B First Homogeneous Plasma Pool Testing

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
1. Does the facility have a system in place to ensure that first homogeneous plasma pools do not exceed 10^4 IU/mL Parvovirus B19 DNA, and that pools or materials derived from them that do exceed this limit are not used in further manufacturing?	☐ YES Document Number or Title: ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
2. Is NAT testing for HIV, HCV HBV and Parvovirus B19 performed at the first homogeneous plasma pool level using validated test assays in compliance with applicable national and international requirements?	☐ YES Document Number or Title: ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
3. If HAV NAT testing is not performed before the plasma enters the first homogeneous plasma pool, is first homogeneous plasma pool testing performed for HAV?	☐ YES Document Number or Title: _____ ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
4. Does the manufacturer have in place a system to ensure that any such pool (see question 15), or material derived from it, is destroyed or designated for manufacturing into reagent material?	☐ YES Document Number or Title: _____ ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
5. Is NAT testing performed using a contracted laboratory?	☐ YES -Use Table 2.3.1 ☐ NO			
6. Is NAT testing performed by a facility under direct control of the manufacturer?	☐ YES -Use Table 2.3.2 ☐ NO			
Comments:				

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Table 2.3.1 – For Testing Performed by a Contracted Laboratory		
2.3.1 a) List Manufacturing Pool Centers (*If multiple pooling centers are used: In responding to the questions below, indicate if the response varies depending on the pooling center.)*		
Center Name	**Ownership**	**Location**

2.3.1 b) General *(Unless otherwise indicated, the questions below apply for both minipool and manufacturing pool testing.)*				
Question	**Documentation (policy, procedures, specifications, etc.)**	**Rating**	**Implementation (records, physical plant)**	**Rating**
1. Is there evidence that the manufacturer has verified that the minipool and/or first homogeneous plasma pool testing is compliant with the NAT Testing Standard?	☐ YES Document Number or Title: _____ ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
2. Are quality agreements and/or specifications in place between the manufacturer and provider(s) of NAT Testing to assure compliance with the requirements defined in the NAT Testing Standard?	☐ YES Document Number or Title: _____ ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

2.3.1 c) **At the Pooling Center** *(Unless otherwise indicated, the questions below apply for both minipool and manufacturing pool testing.)*				
Question	**Documentation (policy, procedures, specifications, etc.)**	**Rating**	**Implementation (records, physical plant)**	**Rating**
1. Does the facility have a system to ensure specimen identity is retained at all times?	☐ YES Document Number or Title: _____ ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
2. Are the specimens stored at appropriate temperatures?	☐ YES Document Number or Title: _____ ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
3. Does the facility have a system pertaining to an appropriate environment for pooling donation samples, which includes provisions for: o unidirectional flow; o segregation; o adequate space; and o organization of the space?	☐ YES Document Number or Title: _____ ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
4. For minipool testing: Does the pooling process assure that the identity of each individual donation in any pool is adequately documented?	☐ YES Document Number or Title: _____ ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
5. Are there systems in place to prevent, monitor and remedy cross contamination events?	☐ YES Document Number or Title: ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
Comments:				

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

2.3.1 d) NAT Testing Laboratory(ies)*

The NAT Testing Laboratory(ies) review must address the entire NAT test, including but not limited to preparation of reagents, isolation of nucleic acids from specimens, amplification of the target sequence, and detection of amplicons.

Name of Testing Laboratory	Location	Indicate if Minipool or Manufacturing Pool

** If multiple laboratories are used: In responding to the questions below, indicate if the response varies depending on the laboratory.*

(Unless otherwise indicated, the questions below apply for both minipool and manufacturing pool testing.)

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
1. Is NAT testing performed using validated assays?	☐ YES ☐ NO		☐ YES ☐ NO	
2. Are positive assay controls calibrated against dedicated International Standards (e.g., WHO, European Pharmacopoeia) when available or other well-characterized, commonly accepted reagents if not available?	☐ YES ☐ NO *If "no", explain:*		☐ YES ☐ NO *If "no", explain:*	
3. For minipool testing, is there a system to link each NAT result to its individual donation?	☐ YES ☐ NO		☐ YES ☐ NO	

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
4. Is there a reagent QC/monitoring program in place? If yes, does it include:	☐ YES ☐ NO		☐ YES ☐ NO	
a) Traceability	☐ YES ☐ NO		☐ YES ☐ NO	
b) Functional QC	☐ YES ☐ NO		☐ YES ☐ NO	
c) Specific reagent QC to address overall reagent quality?	☐ YES ☐ NO		☐ YES ☐ NO	
Comments:				

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Table 2.3.2 – For NAT Testing Performed by a Facility under Direct Control of the Manufacturer	
2.3.2 a) List Manufacturing Pool Centers *(If multiple pooling centers are used: In responding to the questions below, indicate if the response varies depending on the pooling center.)*	
Center	**Location**

2.3.2 b) General *(Unless otherwise indicated, the questions below apply for both minipool and manufacturing pool testing.)*				
Question	**Documentation (policy, procedures, specifications, etc.)**	**Rating**	**Implementation (records, physical plant)**	**Rating**
1. Does the facility have a system in place to assess compliance with the QSEAL NAT Testing Standard?	☐ YES Document Number or Title: _____ ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
2. Does the facility have a system to assure compliance with the NAT Testing Standard, specifically: A. Systems to ensure ○ That NAT specimen identity is retained at all times ○ That NAT specimens are stored at appropriate temperatures?	☐ YES Document Number or Title: _____ ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
B. Testing facilities are adequate to ensure ○ That NAT specimen identity is retained at all times ○ That NAT specimens are stored at appropriate temperatures?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
C. The written, approved training program includes NAT training as appropriate?	☐ YES Document Number or Title: ☐ NO		☐ YES ☐ NO	
3. Is compliance with the quality elements in the previous question verified through initial and regular quality assessments?	☐ YES Document Number or Title: ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
4. When minipool NAT testing is performed by the manufacturer, does the manufacturer have in place a written, approved specification to report reactive results for HIV, HBV and HCV to the collector?	☐ YES Document Number or Title: ☐ NO		☐ YES ☐ NO	

2.3.2 c) At the Pooling Center *(Unless otherwise indicated, the questions below apply for both minipool and manufacturing pool testing.)*

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
1. Are there systems to ensure specimen identity is retained at all times?	☐ YES Document Number or Title: ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
2. Are specimens stored at appropriate temperatures?	☐ YES Document Number or Title: _____ ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
3. Are the facilities adequate to ensure specimen identity is retained at all times and that they are kept at appropriate temperatures?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
4. Are there written, approved specifications and procedures pertaining to an appropriate environment for pooling donation samples, which include provisions for: o unidirectional flow; o segregation; o adequate space; and o organization of the space?	☐ YES Document Number or Title: _____ ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
5. Do the facilities provide an appropriate environment for pooling donation samples? This includes: o unidirectional flow; o segregation; o adequate space; and o organization of the space?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
6. For minipool centers only: Does the pooling process assure that the identity of each individual donation in any pool is adequately documented?	☐ YES Document Number or Title: _____ ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
7. Are there written, approved specifications in place to prevent, monitor and remedy cross contamination events?	☐ YES Document Number or Title: _____ ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
8. Are there written, approved specifications and procedures to ensure that pools for NAT testing will retain their identity and will be kept at appropriate temperatures?	☐ YES Document Number or Title: _____ ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
Comments:				

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

2.3.2 d) NAT Testing Laboratory(ies)*

The NAT Testing Laboratory(ies) review must address the entire NAT test, including but not limited to preparation of reagents, isolation of nucleic acids from specimens, amplification of the target sequence, and detection of amplicons.

Name of Testing Laboratory	Location	Indicate if Minipool or Manufacturing Pool

** If multiple laboratories are used: In responding to the questions below, indicate if the response varies depending on the laboratory.*

(Unless otherwise indicated, the questions below apply for both minipool and manufacturing pool testing.)

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
1. Is the laboratory design appropriate for the test system being used?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
2. Are the engineering controls and work practices appropriate for the test system being used?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
3. Is NAT testing performed using validated assays?	☐ YES ☐ NO		☐ YES ☐ NO	
4. Are positive assay controls calibrated against dedicated international standards (e.g., WHO, European Pharmacopoeia) when available or other well-characterized, commonly accepted reagents if not available?	☐ YES ☐ NO *If "no", explain:*	☐ A ☐ O ☐ SO	☐ YES ☐ NO *If "no", explain:*	☐ A ☐ O ☐ SO

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
5. Is there a written, approved procedure to link each NAT result to its individual donation?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
6. Is there a reagent QC/monitoring program in place? If yes, does it include:	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
a) Traceability	☐ YES ☐ NO			
b) Functional QC	☐ YES ☐ NO			
c) Specific reagent QC to address overall reagent quality?	☐ YES ☐ NO			
Comments:				

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Table 3 – Additional Questions for Use of Source Plasma from Non-IQPP Certified Centers				
3.1 – Inspections – Approvals and Standards				
Question	**Documentation (policy, procedures, specifications, etc.)**	**Rating**	**Implementation (records, physical plant)**	**Rating**
1. Does the facility have a system in place to assure that the Source Plasma suppliers comply with the following standards at the time of collection, which includes the facility conducting supplier audits to assess compliance [*I.e., audits no less frequently than every 36 months*]?				
a) IQPP Qualified Donor	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
b) IQPP Viral Marker	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
2. Does the facility have records of its audits of the centers from which it receives Source Plasma, showing that the plasma centers complied with the requirements of the following standards at the time of collection?				
a) IQPP Qualified Donor	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
b) IQPP Viral Marker	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
3. Are contracts between the facility and supplier(s) in place to assure compliance with the following standards?				
a) IQPP Qualified Donor	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
b) IQPP Viral Marker	☐ YES ☐ NO	☐ A ☐ O ☐ SO		

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
4. Does the facility have a system to ensure that Source Plasma units are pooled for manufacture of plasma derivatives only if they were collected from Qualified Donors?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
Comments:				

3.2 – Viral Marker Standard – Source Plasma units will be collected from collection centers that meet the Viral Marker standard as defined by the IQPP Viral Marker Standard.				
Question	**Documentation (policy, procedures, specifications, etc.)**	**Rating**	**Implementation (records, physical plant)**	**Rating**
1. Does the facility have a policy/specification that requires Source Plasma units to be collected from collection centers that meet the Viral Marker Standard as defined by PPTA?	☐ YES Document Number or Title: _____ ☐ NO	☐ A ☐ O ☐ SO		
2. Does the facility have a system in place to assure that the Source Plasma suppliers comply with the Viral Marker Standard, including:				
2.1 Specifications and/or procedures for Source Plasma collection center viral marker requirements are in the contract between the facility and plasma supplier?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
2.2 The current PPTA Source's viral marker standard is used to evaluate viral marker data?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
2.3 Viral marker data are reviewed at least every six months?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
2.4 There is an alert system in place by which the facility monitors a collection center?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
2.5 Viral marker data of suppliers are periodically reviewed and accepted or rejected by the company – and in an appropriate timeframe?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
3. If a center has rates that are above Alert Limits established through the Viral Marker Standard, does the facility have a mechanism requiring that that center implement a CAPA?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
4. Does the facility have a system to ensure that only Source Plasma units from collection centers that meet the Viral Marker Standard are pooled for manufacture of plasma derivatives?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
Comments:				

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Table 4 – Intermediates: To further assure the consistency, quality and traceability of intermediate products being incorporated into final therapeutics. Note: This standard does not apply to toll manufacturing.				
Question	**Documentation (policy, procedures, specifications, etc.)**	**Rating**	**Implementation (records, physical plant)**	**Rating**
1. Can the facility verify that there is a contract between each supplier and each supplier of the intermediates?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
2. Does the contract stipulate quality requirements for the intermediates?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
3. Are the quality requirements verified through initial and subsequent regular quality assessments?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
4. Can the facility certify that its intermediates acquired from another company were manufactured using a comprehensive system for tracking and tracing plasma?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
5. Does the facility have in place a comprehensive system for tracking and tracing the intermediates, from the date on which it takes possession through to the completion of the final product therapy?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
6. Does the facility have a system in place to verify that the plasma used in the manufacture of the intermediates was collected and subsequently pooled in accordance with the requirements of the applicable regulatory environment?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
7. Does the facility have documentation verifying that the pools of plasma used to manufacture these intermediates met QSEAL requirements valid at the time of pooling? This includes compliance with the following:				
a) Qualified Donor Standard	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
b) Inventory Hold Standard	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
c) Viral Marker Standard	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
d) If applicable, the Recovered Plasma Specification	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
e) NAT Testing Standard	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
8. Documentation of Starting Material: Does the manufacturer of the plasma pool(s) provide adequate documentation of the starting material (e.g., Certificate of Analysis or equivalent documentation) to meet the requirements of 7 above?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
9. Can the current owner of the intermediate verify, by way of the regular quality assessment of the supplier that includes an audit report, that the previous manufacturing processes used to produce the intermediate are able to consistently provide intermediates fulfilling the mutually agreed upon specifications?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
10. Transfer of Ownership				
a) Does the facility have a record listing and linking the following data items:				
o Each previous owner of each intermediate?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
o The previous processes of the intermediate?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
b) Does the facility have the following documents for intermediates available, and does the information contained demonstrate that the intermediates were manufactured in compliance with the requirements for QSEAL certification before they were in possession of the current owner:				

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
o Temperature records of storage and shipping?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
o Shipping documentation?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
o Release certificate and CoA in which the QA/QC department approves release of the intermediate?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
11. For any intermediate for which a claim for a viral removal / inactivation step was made:				
a) Does the facility assure that the claim is valid; and	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
b) Does the facility have a system in place to assure that critical deviations in the supplier's manufacturing process which could have affected viral clearance are reported by the supplier?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
12. Temperature and Storage				
a) Are there agreed specifications between the supplier and the buyer for temperature of storage and shipping of the intermediates?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
b) Are there records provided by the supplier whereby:				
o The supplier certifies that these temperature requirements have been met in all previous transactions?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
o The buyer has verified the temperature requirements for the most recent transaction?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
13. Does the current owner either:				
a) specify in the contract with the supplier that samples of the first homogeneous plasma pool(s) must be provided, OR	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
b) accept certification of pool testing?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
14. Does the current owner verify that samples of the first homogeneous plasma pool(s) accompanied the product at every transfer of ownership, and that their inclusion is specified within the contract, unless pool testing certification was accepted by the buyer?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
15. Lookback				
a) Does the current owner have a written procedure to address lookback after the product is transferred to another owner?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
b) Does that procedure require that the current owner inform the next owner of the intermediate about a Notifiable Event as soon as possible but not to exceed five (5) working days after it becomes aware of the Event?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
c) Does the current owner require confirmation of receipt of the notification from the next owner?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
d) Can the current owner provide backup information to support a risk assessment?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
16. In the contract for purchase of the intermediates:				
a) Does the current owner require that the supplier inform it of a Notifiable Event as soon as possible but not to exceed five (5) working days after it becomes aware of the Event?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
b) Is there a requirement for the supplier to provide backup information, if requested, to support a risk assessment?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
c) Does the current owner ensure that this reporting requirement is followed throughout the entire chain of manufacturers / owners of intermediates up to the final therapeutic product?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
17. Are materials sold for reagent use only? If no, go to next question. If yes:	☐ YES ☐ NO			
a) Are the materials labeled as such?	☐ YES ☐ NO			
b) Does all documentation reference that the materials are deemed for reagent use only and that they will not be used for manufacture of therapeutic products?	☐ YES ☐ NO			
18. Have there been no more than three (3) transactions (no more than four owners) from the first homogeneous plasma pool to the final therapeutic product?	☐ YES ☐ NO			
o Does the facility have a system limiting the number of transactions?	☐ YES ☐ NO			
CASE STUDY: Review of records for 3 batches from individual donations through intermediate manufacture. The batches selected should be representative of the types of material utilized in manufacturing (e.g., Source, recovered, Intermediate).		☐ A ☐ O ☐ SO		
Batch records reviewed during the CASE STUDY:				

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Table 5 – Recovered Plasma Specification				
5.1 – General				
Question	**Documentation (policy, procedures, specifications, etc.)**	**Rating**	**Implementation (records, physical plant)**	**Rating**
1. Does the manufacturer have a process to evaluate and approve Recovered Plasma suppliers?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
2. Does the manufacturer have a contractual supply agreement and quality agreement with the Recovered Plasma collector?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
3. Does the manufacturer have records of its audits of the centers from which it receives Recovered plasma, showing that the collection centers complied with the applicable requirements of the following standards at the time of collection: o NAT Testing Standard (if the collector or its agent conducted the NAT testing) o Recovered Plasma Specification?	☐ YES ☐ NO	☐ A ☐ O ☐ SO		
4. Does the manufacturer verify that the collector is inspected, authorized and/or licensed by its national health authorities?	☐ YES ☐ NO			
5. Does the manufacturer verify that the collector has a system in place that allows for the unique identification of each donor for the purpose of traceability?	☐ YES ☐ NO		☐ YES ☐ NO	
6. Does the manufacturer verify that the collector has processes in place for performing look back procedures (e.g. for unacceptable test results and post donation information)?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
7. Does the manufacturer verify that the collector has processes for assessing the donor's medical history and general health at the time of donation, including but not limited to, vital signs, high-risk behavior and medical history questions?	☐ YES ☐ NO		☐ YES ☐ NO	
8. Does the manufacturer verify that the collection center maintains donor history, collection and testing records as required by national regulations?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
9. Does the manufacturer verify that soft-goods used in the collection process are approved for the intended use by national regulations?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
10. Does the manufacturer verify that the collection center has an adequate policy to prevent plasma derived through autologous donations from being shipped as Recovered Plasma?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
11. Does the manufacturer verify that directed donations shipped as Recovered Plasma met the same requirements of an allogeneic donation?	☐ YES ☐ NO		☐ YES ☐ NO	
12. Does the manufacturer verify that the collection center's labeling complies with national regulations?	☐ YES ☐ NO		☐ YES ☐ NO	
13. Does the manufacturer verify that the container label for the Recovered Plasma includes, at minimum, the following information: a) unique identification number to ensure complete traceability for each unit back to the donor and individual donation, b) name and/or identification code of the collector, c) the appropriate product name, d) volume*, e) storage condition*, f) test results*, g) collection and/or expiration date(s)*, h) anticoagulant used*? * Starred (*) information above, in some regions, can be provided in documentation (e.g., electronic records, shipping documents, supplier agreements) other than the container label.	☐ YES ☐ NO		☐ YES ☐ NO	
14. Does the manufacturer require and verify that freezing/storage and transportation are in compliance with applicable national and/or international regulations?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
15. Are systems for freezing, storage and transportation validated?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
Comments:				

5.2 – Collector Unit Testing				
Question	**Documentation (policy, procedures, specifications, etc.)**	**Rating**	**Implementation (records, physical plant)**	**Rating**
1. Does the manufacturer have requirements in its contracts with the collector, requiring that:				
a) the collector (or designated contract laboratory) perform serology tests (anti-HIV-1/2, anti-HCV and HBsAg) using licensed or approved test kits in compliance with national and international requirements?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
b) the collector report serology test systems (anti-HIV-1/2, anti-HCV and HBsAg), including device manufacturer and assay name) to the manufacturer as well as results and/or certification that all units are negative? o Is the form for reporting results jointly agreed to by the collector and the manufacturer?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
2. Are epidemiological data collected on those blood-borne infectious agents for which a potential transmission by blood products is well recognized and routine testing of blood and plasma donations is mandatory? These infectious agents currently include human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV).	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
3. Does the collector collect data for viral marker rates for each marker performed and report the viral marker rates to the manufacturer in a mutually agreed upon format?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
4. Does the manufacturer have a process for periodically evaluating these data, looking for collection centers that are above defined acceptable rates from the donor population within a geographic area?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
5. Does the manufacturer, in consultation with the collector, establish epidemiological in-process controls (rates, alert levels, corrective and preventive action plans) and monitor the collector's performance?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
6. Is there a system to ensure that only Recovered Plasma units from collection centers that meet the criteria defined by the manufacturer (in accordance with the requirements of the Recovered Plasma Specification) are pooled for manufacture of plasma derivatives?	☐ YES ☐ NO	☐ A ☐ O ☐ SO	☐ YES ☐ NO	☐ A ☐ O ☐ SO
Comments:				

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation

Table 6 – Integration Summary

Assess the integration of the Voluntary Standards into the manufacturing process by conducting a case study. Starting from finished product, verify adherence to the following requirements in the PPTA Voluntary Standards.

Question	Documentation (policy, procedures, specifications, etc.)	Rating	Implementation (records, physical plant)	Rating
1. Source Plasma must be held in inventory for a minimum of 60 days from the date of collection.			☐ YES ☐ NO	
2. Incoming Source Plasma will be tested for viral nucleic acid of the target viruses HIV, HBV, HCV, HAV and Parvovirus B-19 using Nucleic Acid Amplification Technology and found acceptable.			☐ YES ☐ NO	☐ A ☐ O ☐ SO
3. Source Plasma units will be collected from collection centers that meet the requirements of the IQPP Viral Marker standard.			☐ YES ☐ NO	
4. Source Plasma donations from only Qualified Donors will be pooled for manufacturing of plasma derivatives.			☐ YES ☐ NO	
5. Manufacturing using Recovered Plasma shall be in compliance with the Recovered Plasma Specification.			☐ YES ☐ NO	☐ A ☐ O ☐ SO

Comments:

Where no Rating is indicated, if "No" is the response for any given question, an observation will automatically occur. Rating (when applicable): A=Acceptable; O=Observation; SO=Serious Observation