Plasma Protein Therapeutics Association

# Preparing for a QSEAL Certification Audit

## Overview

**Purpose of this document**

This document is intended as a guide to help plasma fractionation companies (referred to herein as Company) prepare for an efficient and effective QSEAL certification audit.

**Intended audience**

All Company personnel involved in preparing for a QSEAL audit will find this document useful. These include:

- the Company Contact for the facility to be inspected,
- the host(s) of the audit,
- on-site Company personnel who manage operations responsible for implementing the PPTA Voluntary Standards,
- other Company corporate personnel who manage functions upon which the manufacturing facility depends as part of its adherence to the PPTA Voluntary Standards, and
- quality assurance personnel.

**Related documents**

Related documents for the QSEAL audit are:

- QSEAL Program Description
- QSEAL Audit Checklist

**In this document**

In this document we discuss the following topics:

# The Audit Approach and Agenda

**Purpose of the audit**

The purpose of the QSEAL certification audit is to verify that the Company has policies, specifications, procedures, and records in place for adherence to the Voluntary Standards established by PPTA. These standards are:

- Qualified Donor Standard
- Viral Marker Standard
- NAT Testing Standard
- Inventory Hold Standard
- Parvovirus B19 Standard
- Intermediates Standard

**Regulatory Compliance**

Upon receipt of the company's application for QSEAL Certification, the company must be fully operational.

Government actions resulting in the unscheduled voluntary or involuntary discontinuation of manufacturing and/or product release will result in withdrawal of QSEAL Certification. The facility, and company, are not eligible to be certified or recertified until government approval is obtained.

Manufacturing operations under increased regulatory control, such as FDA Consent Decree, may not affect QSEAL eligibility but will require QSEAL reaudit.

**Auditor's approach to the audit**

Procedures for adherence to PPTA's Voluntary Standards often cross the Company's departmental and/or corporate lines. The QSEAL Auditors will take a systematic approach to the audit by examining four control points within the Company's operations relative to the Voluntary Standards, and seeking documents/records to support implementation of the Standards, as follows:

| Control Points | Typical Documents/Records to be Reviewed |
|---|---|
| 1. Management commitment | policy statements, manufacturing specifications, procedures |

| | |
|---|---|
| 2. Supplier management | supplier contract clauses, supplier audit procedures and checklist questions |
| 3. Receipt of incoming material (plasma) | receiving procedures |
| 4. Release to pooling | criteria, procedures, and records, including batch review |
| 5. Software Control | Records of software testing relevant to QSEAL standards may be requested for review. |

**Company's approach to the audit**

PPTA and the QSEAL Auditors assume that each Company will be organized and staffed differently to meet the PPTA Voluntary Standards – ranging from centralized to decentralized within the Company and/or its Corporate structure. The Company should, therefore, be prepared to explain to the Auditor its system(s) for adherence to the Voluntary Standards.

**Agenda for audit**

The table below provides the agenda for the audit, the purpose of each agenda item, and suggested documents/records for examination during the audit.

| Item No. | Description (estimated time) | Purpose | Suggested Supporting Materials |
|---|---|---|---|
| 1. | Introductions (10 – 15 minutes) | Participants in the audit introduce themselves and their responsibilities. | |
| 2. | Company overview (60 minutes) | Company management provides auditor an overview of Company organization, facility layout, and management systems for assuring adherence to the Voluntary Standards. | • organization chart<br>• floor plans<br>• process flow diagrams<br>• introduction to relevant documents/records |

| | | | |
|---|---|---|---|
| 3. | The Voluntary Standards<br>(6 hours; may be longer if travel is required to perform inventory site visit) | Auditor discusses with the Company the checklist items for each of the Voluntary standards. Each standard will be examined at critical control points. | • policy/specifications<br>• contract clauses, memorandums of understanding<br>• supplier audit checklists & schedules<br>• procedures<br>• records<br>• computer system validation documentation relevant to QSEAL Standards<br>• site visit to inventory receiving/hold/storage facility<br>• batch review |
| 4. | Conclusion<br>(30 minutes) | Auditor will conduct an exit interview, presenting completed audit checklists and other findings to Company management. | |

# Helpful Hints for Preparation

**Hints**

Based on previous audits, the effectiveness and efficiency of the audit will be enhanced if the Company does the following before the audit:

- enlists any and all resources within the Company or Company corporate offices to help prepare for and/or participate in the audit.
- reviews their organization's systems for adherence to the Voluntary Standards using the QSEAL Checklist.
- prepares a systematic overview for the Auditor.
- reviews and brings to the audit relevant documents – including specifications, procedures, sample contract clauses, sample supplier audit checklists, and sample records.
- arranges for a light lunch during the audit.
- ensures the readiness of the inventory facility and arranges for transportation, if necessary.
- ensures that any government regulatory authority-required biohazard personal protective equipment (PPE) is available for all participants of the inventory facility visit.

# Audit Logistics

| | |
|---|---|
| **Scheduling the audit** | PPTA staff will coordinate potential audit dates with the Company Contact and the QSEAL Auditor. As outlined in the PPTA QSEAL Certification Program Description, the Auditor will confirm the exact date the audit will occur. |
| **Location for the audit** | A conference room large enough to accommodate all participants is the ideal setting for the first part of the audit. A visit to the plasma inventory hold area, and observation of inventory management and release (if appropriate) will follow the document review phase of the audit. |
| **Who should participate** | Each Company needs to decide the best people to participate in the QSEAL Audit. Recognizing the importance of the systems approach to the audit, we recommend that the Company have everyone present or available (possibly via teleconference) during the audit who is knowledgeable about technical details, SOPs, contracts, etc. related to the Voluntary Standards. These staff may all be located at the facility being audited or may include representatives of Corporate headquarters or related corporate units.<br><br>Each company should notify participants to allow sufficient time in advance to prepare for the audit. Participants should begin several days prior to the audit to assemble documents that will be reviewed during the audit. |
| **Length of audit** | The audit should take one day (approximately 6 hours) if the company has adequately prepared for the audit (document review and site visit) and relevant staff, materials or other resources are available. If travel is required to visit the plasma inventory hold facility, the audit may take longer |

| | |
|---|---|
| **Conclusion of audit** | When the Auditor has concluded his/her audit, he/she will conduct an exit interview, presenting completed audit checklists and other findings to the Company management. The Company management will sign and receive a copy of the checklist. The original checklist will be forwarded to PPTA for further processing as described in the PPTA QSEAL Certification Program Description. |
| **Questions?** | If you have any questions about this guidance or the QSEAL audit, please contact the PPTA QSEAL Certification Administrator. |