The Pharmaceutical Supply Chain Initiative (PSCI):

AUDIT PROGRAMME WEBINAR

Audit Programme Webinar | October 2017
Welcome

Supplier Self-initiated Audit Launch

Excel Audit Report Template Launch

Questions
SPARKS

BIRGIT SKUBALLA
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PSCI Secretariat

OCT 17
PSCI AUDIT PROGRAMME WEBINAR
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Excel Audit Report Template Launch

Questions
PSCI AUDIT SHARING PROGRAMME

- Less duplication
- Cost and resource savings
- Continuous improvement
- Greater visibility
- Better identification
- One industry voice
SUPPLIER SELF-INITIATED AUDIT: WHY?

- Supplier self-determination
- Supplier owns the audit
- Supplier can demonstrate proactivity and willingness to meet PSCI’s standards
- Supplier has total control over sharing, and by doing so, can avoid duplicate audits

The overall process is made up of the following steps:

1. Audit Initiation & Preparation
2. Audit Execution
3. Audit Report & Corrective Action Plan
4. Sharing & Follow-up
AUDIT INITIATION & PREPARATION

- **Supplier** selects a 3rd party audit firm from [PSCI approved list](#) (under *Who We Work With*)
- **Supplier** contacts audit firm and asks to be audited under PSCI protocol
- **Supplier** agrees audit scope with audit firm
- **Audit firm** provides appropriate PSCI audit report template
- **Supplier** fills out embedded self-assessment questionnaire (SAQ) and returns it to audit firm
- **Audit firm** introduces audit team and provides CVs for auditors
- **Supplier** reviews CVs against the PSCI criteria using the [PSCI Auditor Evaluation Tool](#) to check they meet PSCI’s standards
- **Supplier** confirms they are happy to proceed with the proposed team, or requests changes
- **Audit firm** plans audit with the supplier and agrees dates for the visit

*The full process and extra guidance is given in the [PSCI Audit Guidance](#)*
AUDIT EXECUTION

- **Audit firm** conducts the audit. This will typically include:
  - Opening meeting
  - A site tour
  - Employee interviews
  - Interview with management
  - Document review
  - Pre-closing meeting and preparation of draft Corrective Action Plan
  - Closing meeting and management sign-off on findings

* The full process and extra guidance is given in the [PSCI Audit Guidance](#)
AUDIT REPORT & CORRECTIVE ACTION PLAN

- **Audit firm** drafts PSCI Audit Report and Corrective Action Plan
- **Audit firm** runs a quality check of the draft
- **Audit firm** issues final PSCI Audit Report and Corrective Action Plan to supplier
- **Supplier** completes Corrective Action Plan

* The full process and extra guidance is given in the [PSCI Audit Guidance](#)
SUPPLIER SELF-INITIATED AUDIT: HOW

SHARING & FOLLOW UP

- **Supplier** decides to share the final PSCI Audit Report and CAP with PSCI
- **Supplier** redacts all audit documents
- **Supplier** uploads the documents to the PSCI Audit Sharing Platform and completes virtual DSA (preferred) OR sends documents and signed Word DSA by email to PSCI Secretariat.
- **PSCI** runs a final redaction check to make sure that no confidential information is disclosed, and a quality check
- **PSCI** releases document as per supplier sharing instructions (on DSA)
- **PSCI** captures the main findings of the audit and puts them into the system in a virtual CAP report
- **Suppliers** log into the platform and add responses to show the status of their corrective actions and provide evidence (e.g. descriptions, documents, photographs)
AGENDA

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Questions
# PSCI Audit Templates: Overview

**Pharmaceutical Supply Chain Initiative (PSCI) Self-Assessment Questionnaire and Audit Report for Pharmaceutical Industry Suppliers**

**API, Dosage Formulation, Chemicals and Intermediate Chemical Manufacturers**

### Guidance for Completion

Sections marked in orange need to be filled in by the supplier before the audit. Sections marked in grey will be filled by the audit team during/after the onsite audit. Please do not change the report format and do not change the answers given to the other party. Supplier and auditors are asked to complete all questions that apply. If a question does not apply, please mark it NA (Not Applicable). We would expect the following types of suppliers to complete all the questions: API, Dosage Formulation, Chemicals and Intermediate Chemical Manufacturers.

### Auditor and Audit Report Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Report Number:</td>
<td>(Insert)</td>
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<tr>
<td>Report Owner:</td>
<td>(Insert)</td>
</tr>
<tr>
<td>Note: this is the company paying for the audit. If a PSCI member, the name should be removed before the report is uploaded to the PSCI audit sharing platform.</td>
<td></td>
</tr>
<tr>
<td>Date of Audit:</td>
<td>(Insert)</td>
</tr>
<tr>
<td>Date and Type of Premises:</td>
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<tr>
<td>Audit (if applicable):</td>
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<td>Audit Firm Name:</td>
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<td>Lead Auditor Name:</td>
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<tr>
<td>Names of Further Auditors:</td>
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### Facility Details

<table>
<thead>
<tr>
<th>Field</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>Company Name:</td>
<td>(Insert)</td>
</tr>
<tr>
<td>Site Name (different):</td>
<td>(Insert)</td>
</tr>
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</table>

### Overview

**Pharmaceutical Supply Chain Initiative**

**Self-Assessment Questionnaire and Audit Report Template**

**Version 4.0**

**September 2017**

**Overview**

- **Guidance for completion**
  - Cells in this colour should be completed by the supplier.
  - Cells in this colour should be completed by the auditor.
  - Cells in this colour should be left blank.

**Supplier and auditors are asked to complete all questions that apply.** If a question does not apply please select NA (Not Applicable). We expect the following types of suppliers to complete all the questions: API, Dosage Formulation, Chemicals and Intermediate Chemical Manufacturers.

Where appropriate, please embed supporting documents using Excel’s Insert Object function.

When printing, the workbook will automatically fit the visible columns onto one page. Use the group function at the top of each sheet to display and print fewer columns. This will increase the text size on printed pages. We have added this feature to the sheets with the most columns.

To clear the contents of a cell, press “Delete”.

To check spelling, click on the “Run Spell Check” button at the top of each sheet.

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**October 2016**

Pharmaceutical Supply Chain Initiative (PSCI) Audit Report Template for Core Suppliers, Internal Liberators, Component and Material Suppliers

**Version 4.0**
EXCEL TEMPLATE: WHY?

- We needed a tool that
  - Allows us to extract data and analyse findings/trends
  - More user friendly
  - Can be updated easily
  - Allows better tracking of progress to resolve audit findings
  - Looks professional
EXCEL TEMPLATE: KEY FEATURES

- Separate tabs for the separate sections of PSCI Principles
- Extra tab for company specific questions (which can be removed before sharing)
- Colour coding to make obvious who should complete each section
- Integrated spell check function
- Green highlighting to track completed cells
- Guidance notes
- Drop downs to standardise responses where appropriate
One click automatic population of the Corrective Action Plan Report and summary findings table
If you have suggestions on how to improve this template, or have questions, please send them to info@pscinitiative.org

Our long term goal is to move to Excel only. For now, both formats can be used.

Start using the Excel templates today

Available for download from the PSCI website:
https://pscinitiative.org/auditCollaboration
Welcome
Supplier Self-initiated Audit Model
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Questions?
For more information about the PSCI please contact:

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