PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

The Pharmaceutical Supply Chain Initiative (PSCI):

AUDIT PROGRAMME WEBINAR

Audit Programme Webinar| October 2017

AGENDA

Welcome

Supplier Self-initiated Audit Launch

Excel Audit Report Template Launch

Questions

SPEAKERS

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

BIRGIT SKUBALLA
Bayer
PSCI Vice Chair

KELLY KAPPLER
Johnson & Johnson
PSCI Audit Committee Co-Chair

ANNABEL BUCHAN
Carnstone
PSCI Secretariat

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PSCI AUDIT SHARING PROGRAMME

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- Less duplication
- Cost and resource savings
- Continuous improvement
- Greater visibility
- Better identification
- One industry voice

SUPPLIER SELF-INITIATED AUDIT: WHY?

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- 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:

SUPPLIER SELF-INITIATED AUDIT: HOW?

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

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

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)

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PSCI AUDIT TEMPLATES: OVERVIEW

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

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 by 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

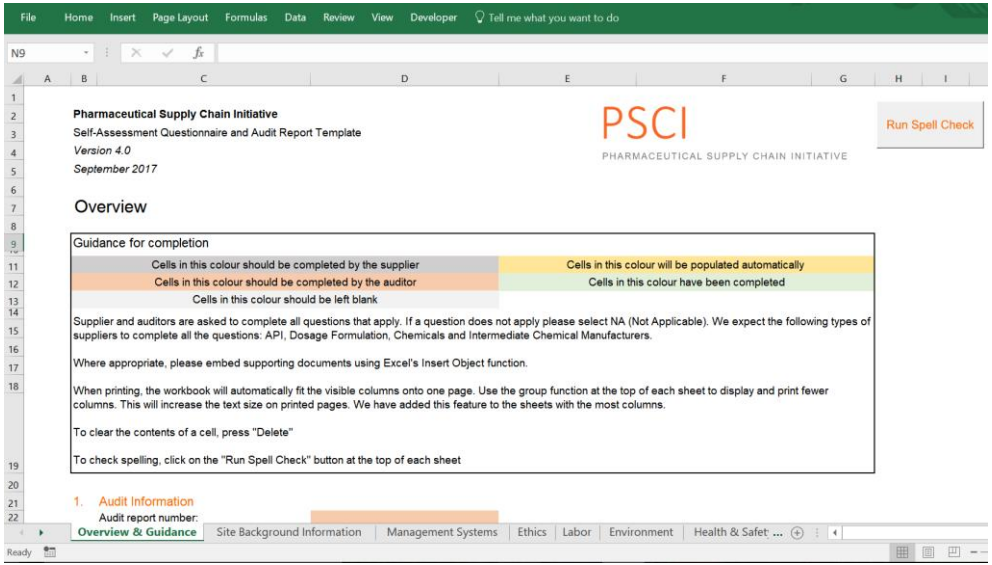
Report Number:			
Report Owner:	Note: this is the company paying for /sponsoring the audit. If a PSCI Member, the name should be removed before the report is uploaded to the PSCI audit sharing platform		
Date of Audit:	DD/MM/YYYY ☐ initial ☐ follow up ☐ other, please specify	**Date and Type of Previous Audit** (if applicable):	DD/MM/YYYY ☐ initial ☐ follow up ☐ other, please specify
Audit Firm Name:			
Lead Auditor Name:		**Title:**	
Names of further auditors:		**Title:**	
Phone Number:		**Email Address:**	

FACILITY DETAILS

Company Name:	
Site Name (if different):	

October 2016 *Version 4*

Full PSCI SAQ & Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers



EXCEL TEMPLATE: WHY?

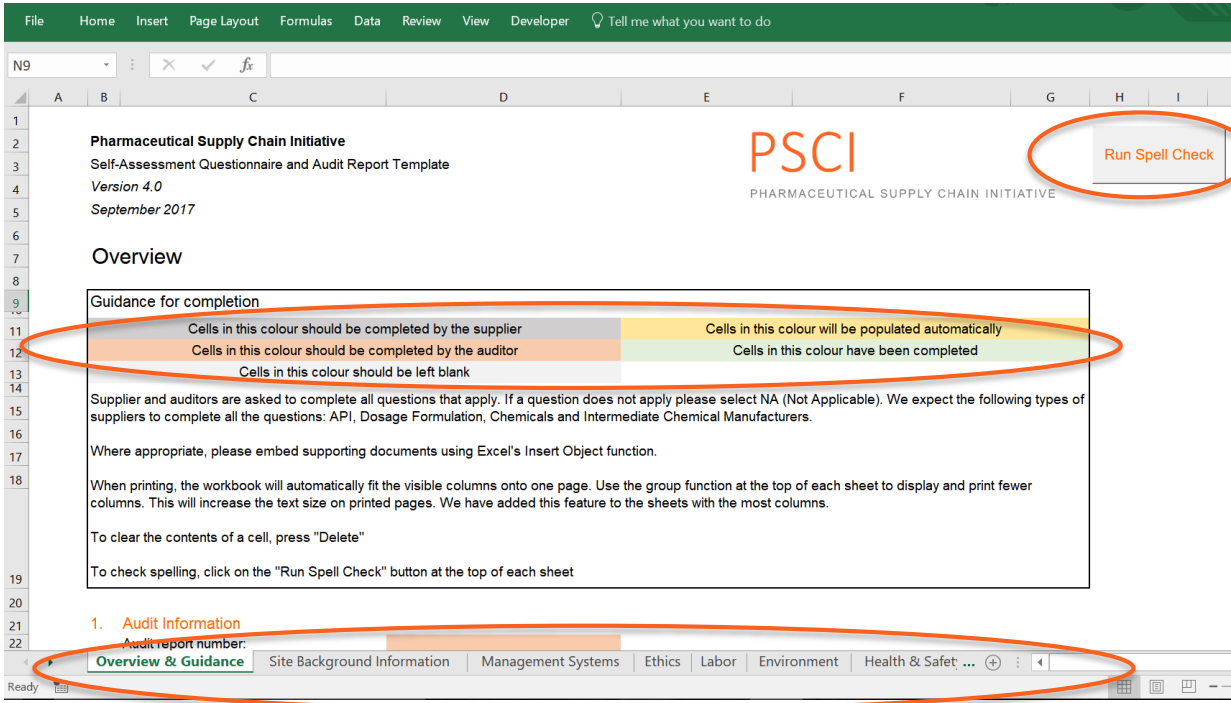
PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- 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

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

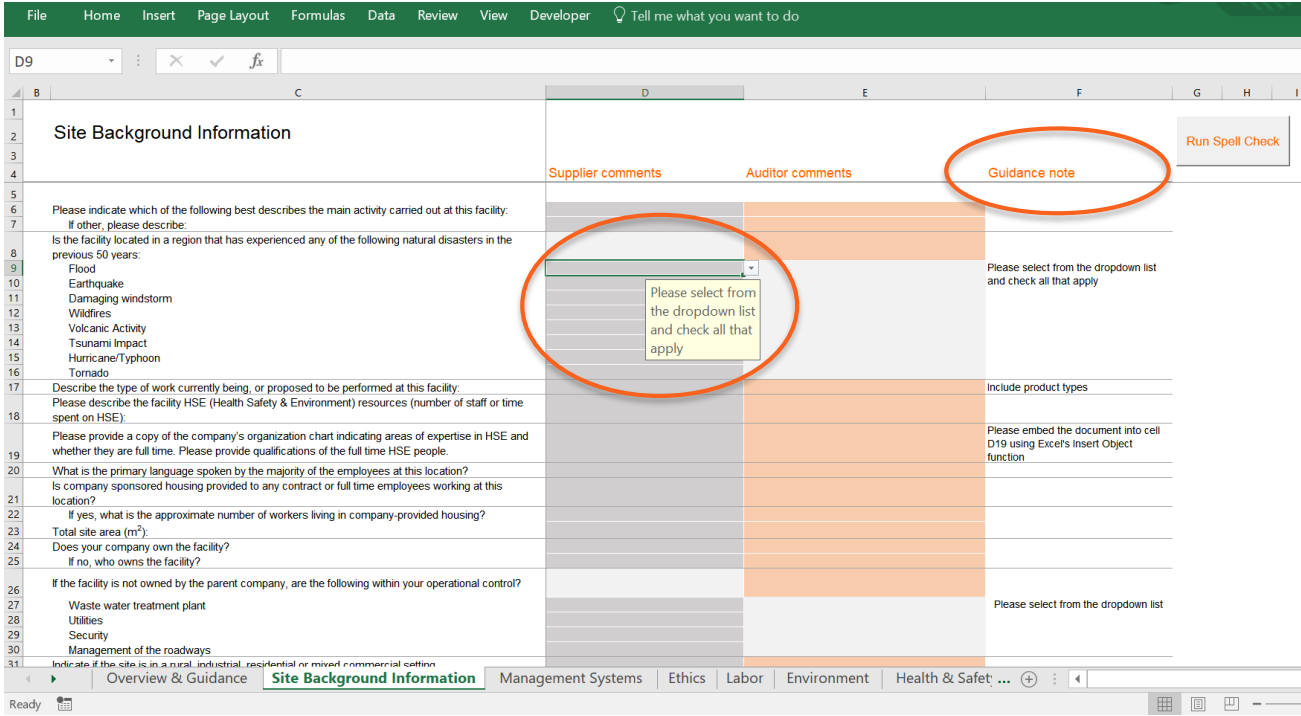
- Separate tabs for the separate sections of PSCI Principles
- Extra tab for company specific questions (which can be removed before sharing)
- Colour coding to make obvious who should complete each section
- Integrated spell check function
- Green highlighting to track completed cells



EXCEL TEMPLATE: KEY FEATURES

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

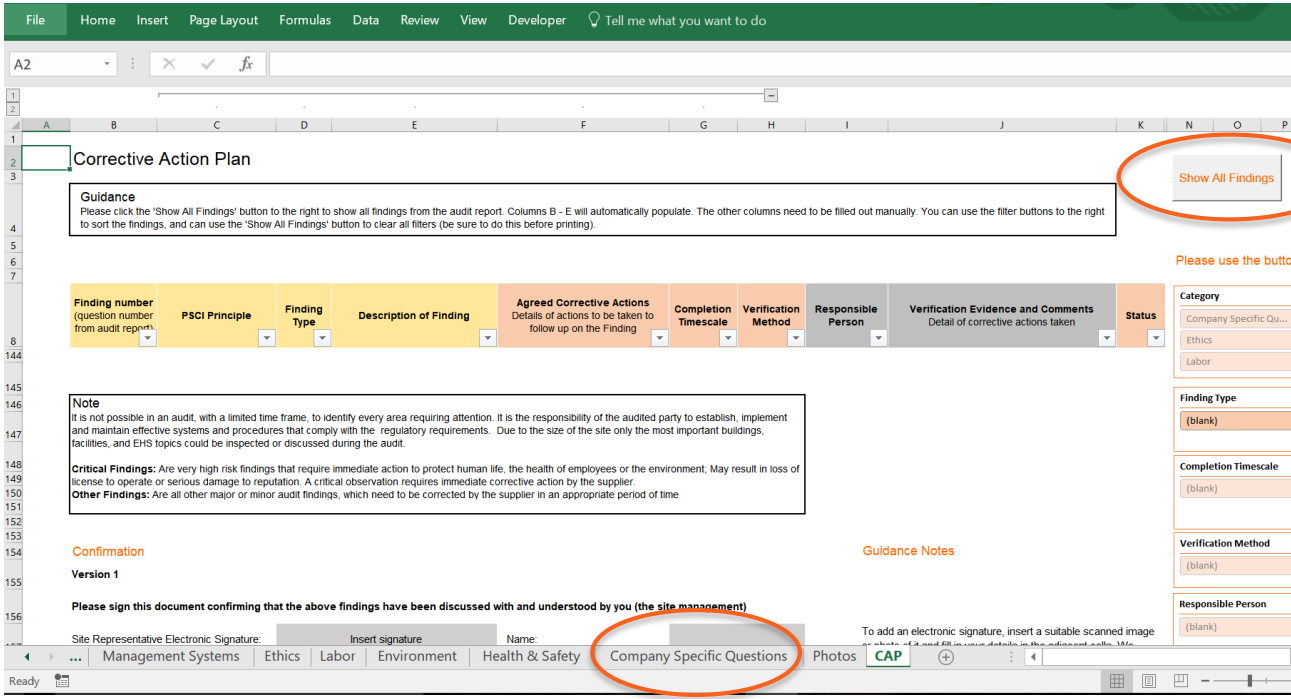
- Guidance notes
- Drop downs to standardise responses where appropriate



EXCEL TEMPLATE: KEY FEATURES

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- One click automatic population of the Corrective Action Plan Report and summary findings table



EXCEL TEMPLATE: SUMMARY

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

- 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

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Supplier Self-initiated Audit Model

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Questions?

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

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