PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

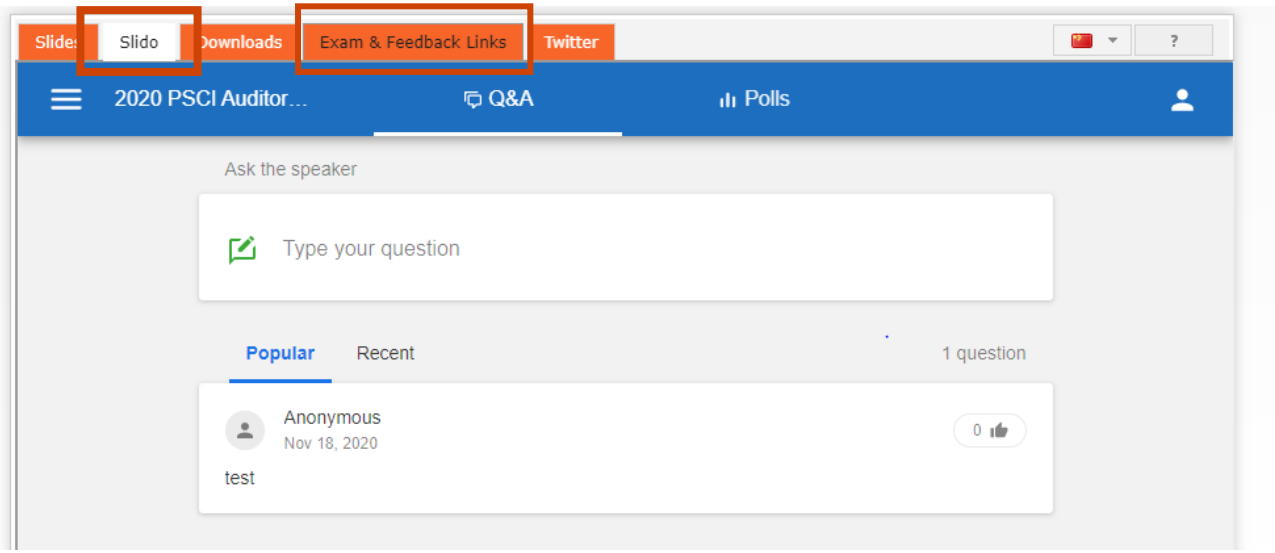
PSCI Auditor Training 2020

Day 1 PSCI Audit Update; Labor and Human Rights

24 Nov 2020

Practicalities

- Switch to audio feed only for better connection. Chinese attendees click at Live Stream (China)
- Break
- We'll be using Slido for Q&As, please click Slido tab to enter your questions or go to https://www.sli.do/ to pose questions with the code **#U662**
- Exam
- Certificates
- Feedback survey



Anti-Trust Statement

While some activities among competitors are both legal and beneficial to the industry, group activities of competitors are inherently suspect under the antitrust/anti-competition laws of the US, UK and other countries in which our companies do business. Agreements between or among competitors need not be formal to raise questions under antitrust laws, but may include any kind of understanding, formal or informal, secretive or public, under which each of the participants can reasonably expect that another will follow a particular course of action or conduct. Each of the participants in this meeting is responsible for seeing that topics which may give an appearance of an agreement that would violate the antitrust laws are not discussed. It is the responsibility of each participant in the first instance to avoid raising improper subjects for discussion, such as those identified below.

It is the sole purpose of this meeting to provide a forum for expression of various points of view on topics described in the agenda and participants should adhere to that agenda. Under no circumstances shall this meeting be used as a means for competing companies to reach any understanding, expressed or implied, which tends to restrict competition, or in any way to impair the ability of members to exercise independent business judgment regarding matters affecting competition.

Topics of discussion that should be specifically avoided are:

i. Price fixing;

ii. Product discounts, rebates, pricing policies, levels of production or sales and marketing terms customer and territorial allocation;

iii. Standards setting (when its purpose is to limit the availability and selection of products, limit competition, restrict entry into an industry, inhibit innovation or inhibit the ability of competitors to compete);

iv. Codes of ethics administered in a way that could inhibit or restrict competition;

v. Group boycotts;

vi. Validity of patents;

vii. On-going litigation;

viii. Specific R&D, sales or marketing activities or plans, or confidential product, product development, production or testing strategies or other proprietary knowledge or information.

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Welcome to the virtual PSCI Auditor Training 2020

Dr. Birgit Skuballa
Head of HSE Audits & Supplier Management
Bayer AG
PSCI Audit Committee Co-Chair

Why are we conducting this training?

- ✓ To ensure and support that all auditors meet the minimum qualifications and experience required to conduct PSCI Audits
- ✓ To further improve the overall quality of PSCI Audits
- ✓ To support suppliers in understanding and preparing for PSCI Audits


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

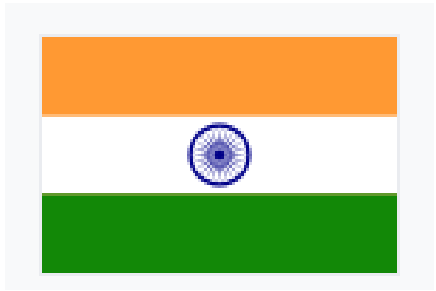
AUDITOR AND AUDIT REPORT INFORMATION

Report Number:
Report Owner:
Date of Audit:
Audit Firm Name:
Lead Auditor Name:
Names of further auditors:
Phone Number:
Company Name:
Site Name (if different):

The PSCI Auditor Training in 2020

- This virtual training has been designed especially for auditors from 3rd party audit firms, auditors from PSCI Members auditors and - new! - also their suppliers.
- The training has been organized by the PSCI Audit Committee and the PSCI secretariat (Carnstone) and will be provided by Senior Audit experts from PSCI member companies.
- The training will cover
  - the proper use of the PSCI SAQ/Audit Protocols, audit preparation, audit execution and writing of audit findings
  - Social auditing
  - Environment (including PiE (Pharmaceuticals in the Environment), AMR (Antimicrobial Resistance), Stormwater management)
  - Health & Safety (including General Safety, Process & Plant Safety, Occupational Safety & Industrial Hygiene, High-Risk Work & Red Flags for Dangerous Working)
  - Emergency Preparedness & Response

Special Focus on India



- This training is addressed to all auditors who conduct or plan to conduct PSCI Audits
- Besides that, this time we have put a focus on auditing in India, as many pharmaceutical companies as well as suppliers and contract manufacturers of the PSCI Members are in India.

Our Speakers

Manjit Singh
Centrient

Birgit Skuballa
Bayer

Dinesh Subhedar
Novartis

Daniel Rehm
Elanco

Kumarkrishna Bhattacharjee
Novartis

Jon Stanway
GlaxoSmithKline

Paul Barnett
GlaxoSmithKline

Pratap N. Padalkar
Gilead

Roberta Haski
Elanco

Training Agenda – Day 1 and 2

Day 1 - Tuesday, November 24, 2020

PSCI Audit Update; Labor and Human Rights	
13:15 – 13:30	Registration
13:30 – 13:40	PSCI Welcome and Opening Address (10 mins) **Birgit Isabelle Skuballa**, Head HSE Audit & Supplier Management, Bayer **Maggie Zhang,** Partner Manager, Carnstone
13:40 – 14:55	PSCI Audit Update 2020 (1hr) The presentation will provide a comprehensive overview on the PSCI Audit program, including current updates regarding the PSCI self-assessment questionnaires and report templates, guidance tools for auditors as well as tip/hints for audit preparation (both for auditors and auditees) and conduct (onsite and remote).The presentation will also cover important post audit activities like audit report generation, including tips and support on how to write audit findings and to classify them. **Birgit Isabelle Skuballa**, Head HSE Audit & Supplier Management, Bayer *Q&A (15 mins)*
14:55 – 15:05	BREAK (10 mins)
15:10 – 16:25	Corporate Responsibility with a Social Compliance Audits (1hr) The presentation will give a brief overview of what social compliance audit is and the needs of social compliance audits. It will also illustrate the types, key procedures, and common issues of social compliance. Two case studies will be shared at the end of the presentation. **Dinesh Subhedar** Group Third Party Risk Management -Labour Rights (India and West Asia), Novartis (NBS Human Resources) *Q&A (15 mins)*
16:25 -16:45	Exam (20 mins)
16:45 – 17:00	Closing Comments / end of day 1

Day 2 - Wednesday, November 25, 2020

Environmental Protection; PiE and AMR	
13:15 – 13:30	Registration
13:30 – 14:45	Environmental protection (40 mins) A presentation about the growing environmental issues of pharmaceuticals in the environment and insights of audit findings. **Manjit Singh**, Associate Director- Corporate Sustainability, Centrient Pharmaceuticals Stormwater management and Zero Liquid Discharge key points (20 mins) Stormwater management best practice and key points to look out in zero liquid discharge ETPs. **Daniel Rehm,** HSE Advisor, External Manufacturing EMEA & API, Elanco *Q&A (15 mins)*
14:45 – 14:55	BREAK (10 mins)
15:00 – 16:15	Introduction to PiE and AMR (30 mins) An introduction to the issues of pharmaceuticals in the environment and the possible occurrence antimicrobial resistance caused by manufacturing discharges of antibiotics. There will also be an introduction to the AMR Industry Alliance's Common Antibiotic Manufacturing Framework and discharge limits that will help manufacturing sites control their antibiotic environmental emissions. **Dr Paul Barnett**, Director, Environment Health & Safety, GlaxoSmithKline Assessing Antibiotic Manufacturing Sites Capability in Controlling their Antibiotic Emissions (30 mins) An introduction to the methodology of conducting a mass balance to assess a manufacturing sites antibiotic wastewater discharges and what elements of the PSCI audit protocol are relevant to assessing compliance with the Common Antibiotic Manufacturing Framework **Jonathan Stanway**, Downstream & Pilot Plant Manager, Biotechnology & Environmental Shared Service, Pharma Supply Chain, GlaxoSmithKline *Q&A (15 mins)*
16:15 -16:35	Exam (20 mins)
16:35 – 16:45	Closing Comments / end of day 2

Training Agenda – Day 3 and 4

DAY 3 – Wednesday, December 02, 2020

Process Safety; Emergency Preparedness & Response	
13:15 – 13:30	**Registration**
13:30 – 14:45	**Process safety risk – Identifying reactive hazards and powder processing hazard in pharmaceutical industry (1hr)** The presentation will help audiences to understand reactive hazards and powder processing hazard in pharmaceutical industry. It will also review PSCI questionnaires and typical observations related to process safety. **Kumarkrishna Bhattacharjee**, Head HS&E Supplier Assurance and Risk India Region, Novartis *Q&A (15 mins)*
14:45 – 14:55	**BREAK (10 mins)**
15:00 – 16:15	**Emergency preparedness & response (1hr)** Presentation on emergency response, fire protection basics, hazard information and an introduction to sprinkler protection. **Daniel Rehm**, HSE Advisor, External Manufacturing EMEA & API, Elanco *Q&A (15 mins)*
16:15 -16:35	**Exam (20 mins)**
16:35 – 16:45	**Closing Comments / end of day 3**

DAY 4 – Thursday, December 03, 2020

General Safety; Occupational Health and Industrial Hygiene; High Risk Work and Red Flags for Dangerous Working	
13:15 – 13:30	**Registration**
13:30 – 14:15	**Plant General Safety (30 mins)** The presentation will discuss general plant safety topics such as personal protective equipment (PPE), safety training, chemical storage & handling, emergency response, accident/incident investigation, hazard communication (HAZCOM), process hazard analysis (PHA), safety equipment (fire extinguishers, water sprinklers), etc. It will focus more on six (6) life-critical safety topics – lock out tag out (LOTO), confined space entry (CSE), hot work (HW), machine guarding (MG), respiratory protection (RP), and fall protection (FP). **Pratap Padalkar**, Associate Director, Chemical Development & Manufacturing, Gilead *Q&A (15 mins)*
14:15 – 15:00	**Occupational health and industrial hygiene in plants (30 mins)** The presentation will discuss chemical exposure, noise exposure, radiation/bio safety, occupational exposure limits (OELs), safety data sheets (SDSs), respirator types, medical clearance, fit-testing, laboratory safety and engineering controls, emergency preparedness, etc. **Pratap Padalkar**, Associate Director, Chemical Development & Manufacturing, Gilead *Q&A (15 mins)*
15:00 -15:10	**BREAK (10 mins)**
15:15 – 16:15	**High risk work and red flags for dangerous working (45mins)** High risk work, including confined spaces, hot work, working at heights, lockout/tagout and electrical work accounts for the majority of serious workplace accidents and injuries (in some cases fatalities) at a site. In many cases, these incidents can be prevented. Therefore, the session will give an overview of areas to focus on during a site assessment and commonly observed gaps in these programs. **Roberta Haski,** HSE Leader, External Manufacturing & Commercial, Asia Pacific, Japan, ANZ *Q&A (15 mins)*
16:15 – 16:35	**Exam (20 mins)**
16:35 – 16:45	**Closing comments / end of day 4**

Exams and PSCI Certificate of Participation

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

Certificate of Participation

VIRTUAL PSCI AUDITOR TRAINING

November 24 – 25 and December 02 – 03, 2020

Topics trained: Update on PSCI Audits, Labor & Human Rights, Environmental Protection, PIF and AMR, Process Safety, Emergency Preparedness & Response, General Safety, Occupational Health & Industrial Hygiene, High Risk Work and Red Flags for Dangerous Working

Trainee **Example**

Signed by

Dr Birgit Isabelle Skuballa | Audit Committee Lead| PSCI

THANK YOU AND ENJOY THE PSCI AUDITOR TRAINING 2020!

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

PSCI Audit Update

Dr. Birgit Skuballa
Head of HSE Audits & Supplier Management
Bayer AG

BIO

Dr. Birgit Isabelle Skuballa

- **Current position** and responsibilities: Bayer AG, Corporate HSE, global Head of HSE Audits & Supplier Management
- **Location:** based in Leverkusen, Germany
- **Background:** PhD in Organic Chemistry (University of Karlsruhe, Germany); post-doc at Nagoya University (Japan); ISO14001/OHSAS18001/17025 Lead Auditor; SA8000 Auditor, global Bayer HSE Audit Team Lead
- **Experience**: 25+ years within Pharma/Chemical Industry (Schering AG / Bayer) in the areas of API and pharmaceutical production, GMP/Quality Audit , HSE Management Systems, Responsible Care, HSE Data Management, global internal HSE Audits, Supplier Audits (PSCI, HSE, Social), Due Diligence
- **Roles in PSCI**: former PSCI Board Member, currently PSCI Audit Committee Co-Chair
- **Contact information**: birgit.skuballa@bayer.com

AGENDA

OVERVIEW ON PSCI AUDITS

PSCI SAQS AND AUDIT REPORT TEMPLATES

GENERAL PSCI AUDIT PROCESS

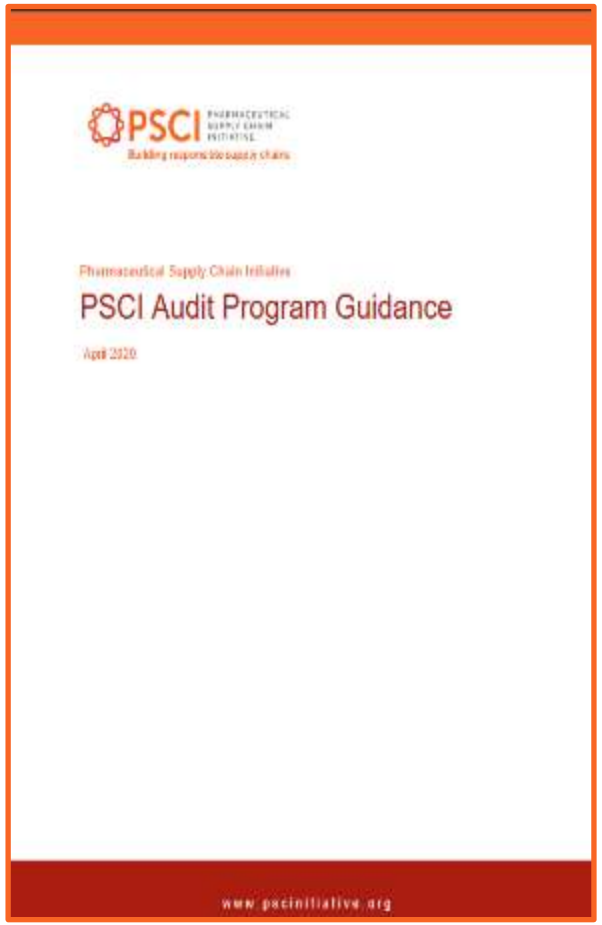
AUDIT REPORT WRITING

WHY DO WE AUDIT?

- PSCI Audits are designed to assess a supplier's performance against the PSCI Principles as well as against international standards and agreements, and local regulatory requirements in the areas of: Ethics, Labor, Health & Safety, Environmental Protection and Management Systems.
- The PSCI Audit Program provides a framework and methodology to ensure PSCI Audits are carried out in accordance with PSCI Standards, thereby delivering a credible, transparent and consistent audit approach.
- Our goal is to ensure that the PSCI auditing model and tools become the norm for our industry.
- We encourage members to use the PSCI tools and their suppliers to share the results.

THE PSCI AUDIT PROGRAM GUIDANCE

- Developed and regularly updated by the PSCI Audit Committee as an information source for PSCI members, 3rd Party Audit Firms, suppliers, and other interested stakeholders
- The PSCI Audit Program Guidance explains and specifies the requirements and procedures for a credible, transparent, and consistent audit approach, together with three other documents:
  - PSCI Principles
  - PSCI Implementation Guidance
  - PSCI SAQ /Audit Report templates (Full: Word & Excel; Abbreviated: Word & Excel)
- Provides foundation for the PSCI audit program:
  - Defined PSCI audit objectives and scope
  - A defined methodology for the audit process from initiation, through execution to reporting (including specifics for remote audits)
  - A defined methodology for responding to audit findings and corrective action tracking
  - A defined mechanism for sharing of audit reports
  - Clear requirements and defined minimum qualifications and experience for auditors conducting PSCI audits.



MAIN UPDATES IN THE PSCI AUDIT GUIDANCE

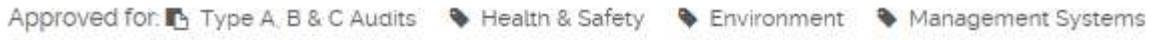
- Included revised SAQ/Audit Protocols
  - Auditor guidance notes embedded in the SAQ/Audit templates
- Revised audit findings classification
  - Now two methodologies (critical/others or critical/major/minor)
- Added new external reference (AMR Alliance) & reference to pre-audit information resources (OSHA, IPE)
- Updated qualification of social auditors
  - Equivalent training to SA8000 Training, including an example of BSCI training
- Provided more guidance and details on audit duration and audit process activities
  - Risk-based audit approach in case of time-constraints i.e. cover questions where there are additional auditor guidance notes in SAQ/ Audit templates
  - Audit duration for medium office: 1-2 days, same as large office
- Added language on option of suppliers to share PSCI SAQs/Audit Reports digitally and it being the preferred sharing method
- Addition/update of links to web pages & resources
- Improve language in whole document
- Addition of specifics on remote / partly remote audits

WHO CARRIES OUT PSCI AUDITS?

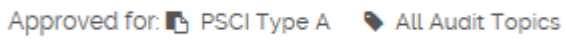
- In order to ensure the integrity of the audit process, PSCI Audits are carried out either by professional and independent 3rd party audit firms incl. qualified auditors or by PSCI member internal auditors.
- Note: PSCI Audits can be initiated by PSCI members or self-initiated by suppliers
- PSCI has currently approved fifteen professional, independent 3rd Party Audit firms to conduct PSCI Audits, see https://pscinitiative.org/auditCollaboration
- On the contact details of the 3rd Party Audit firm it is indicated for which supplier categories and which audit type the firm is approved , e.g.:
  - Audit Firm 1

  - Audit Firm 2

  - Audit Firm 3

SELECTION OF INDIVIDUAL AUDITORS

- All auditors who carry out PSCI Audits must be appropriately qualified and have applicable auditing and industry experience
- Details are defined in the PSCI Audit Program Guidance, Chapter 4
- 3rd party audit firms must ensure that only appropriately qualified auditors are proposed to PSCI Members or Suppliers (in case of self paid audits)
- PSCI Member Auditors are qualified equivalently
- A PSCI Auditor evaluation tool is available for checking 3rs party auditors for Type C audits against PSCI requirements

Auditor's Information Template

Auditing for Core Suppliers, External Manufacturers, Component & Material Suppliers, Service Providers and Manufacturers

		Auditor's Information
Auditor Details	Name of Auditor	
	Location of Auditor	
Educational Qualification	Bachelor's Degree in chemistry, chemical engineering or similar(Yes/No and specify the	
	Master's Degree in chemistry, chemical engineering or simila(Yes/No and specify the	
Language Proficiency	Proficient in local language (specify languages)	
	Proficient in English (written and spoken)	
Trainings/ Certific	ISO-19011 training (Yes/No)	
	ISO-14001 lead auditor certification (Yes/No)	
	OHSAS-18001/ISO 45001 lead auditor certification (Yes/No)	
	Certified Professional Auditor (CPA) - Yes/No	
	Certified Safety Professional (CSP) - Yes/No	
	Any other equivalent certification (please specify)	
Professional experience	Total no. of years of Industrial Experience	
	No. of years of experience in Pharmaceutical Industry (if any)	
	No. of years of experience in Chemical Industry	
	No. of years of experience in other Industry (Please specify which Industry)	
	Total no. of years of HSE auditing experience	
	No. of years of experience in Auditing Pharma Companies (if any)	
	Total no. of HSE audits conducted in last 2	
Other requirements	Knowledgeable in local regulations related to Health, Safety & Environmental (please explain)	
	Knowledge of specific HSE topics like Industrial Hygiene, Process Safety Management, Dust Explosion Hazards, Hazardous Waste	

For HSE auditor | For social auditor

EXPECTATIONS OF PSCI AND PSCI MEMBERS

A Standard Framework Agreement with each of our current and future 3rd party audit firms is in place, which outlines the PSCI expectations on conducting PSCI Audits, covering the following aspects:

- Audit performed according to latest audit program and documentation is complete with all required data in English
- Audit documentation does not contain customer-supplier relationship, competitive sensitive information, or personally sensitive data
- Audit firm pre-screens and proposes appropriate auditors per criteria for Supplier type A, B & C as per PSCI audit guidance document.
- Audit firm ensures that Auditors are familiar with and trained on Key PSCI Audit documents/webinars
- Audit firm conducts internal quality assurance review of audit reports
- Audit firm has feedback mechanism on auditors and take measures to ensure appropriate auditor conduct
- Escalation mechanism in place between PSCI (via PSCI Secretariat) & audit firm for issues
- Reasoning and method for audit firm removal from qualified PSCI Audit List (e.g. due to violations of agreement or guidance document)

PSCI GUIDANCE TOOLS FOR AUDITORS

Collaborative auditing embeds the PSCI Principles in our supply chain. The PSCI has developed guidance tools tailored for our industry for assessing performance and risk. These include:

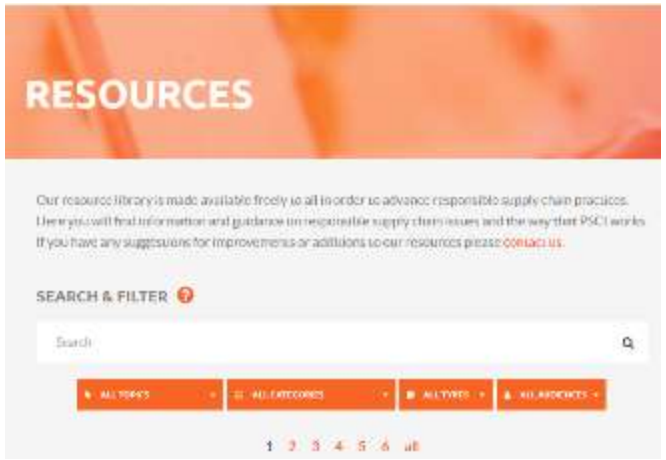
- PSCI Principles
- PSCI Implementation Guidance
- PSCI Audit Guidance
- PSCI Introductory Training for Auditors - webinar
- Full PSCI SAQ & Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers - word
- Full PSCI SAQ & Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers - excel
- Abbreviated PSCI SAQ & Audit Report Template for Service Providers & General Manufacturers (word and excel)
- PSCI SAQ & Audit Report Template Update - 20th February 2019 - webinar
- Introduction presentation for PSCI audit opening meeting
- Pre-Audit Document Request List
- Corrective Action Plan – excel and word
- Data Sharing Agreement
- PSCI Audit Sharing Platform Supplier User Guide
- PSCI Auditor Evaluation Tool

Chinese and Japanese translations available

Also Chinese Version available

FREE PSCI RESOURCES

Recent PSCI Resources recommended for both auditors and suppliers:



- Modern Slavery Webinar
- Ethics Webinar - Anti-Bribery and Corruption & GDPR
- Webinar on Antimicrobial Resistance
- Webinar on Emergency Preparedness and Response
- Webinar on Water Stress Management
- Webinar on Evaluating Supplier Ethics and Compliance Practices and Programs
- PIE/AMR Deep Dive Seminar Slide deck
- PiE/AMR Webinar (Wastewater treatment technologies) - Recording and slides
- Consolidated PEC:PNEC Calculator Tool for assessing API discharges
- Predicted-No-Effect-Concentration (PNEC) resource links
- Best Management Practices for Leak and Spill Control
- Process safety (hazardous reactions) Webinar - Recording and Slides
- PSCI Webinar: Managing active pharmaceutical ingredients (API) in manufacturing effluent

AGENDA

OVERVIEW ON PSCI AUDITS

PSCI SAQS AND AUDIT REPORT TEMPLATES

GENERAL PSCI AUDIT PROCESS

AUDIT REPORT WRITING

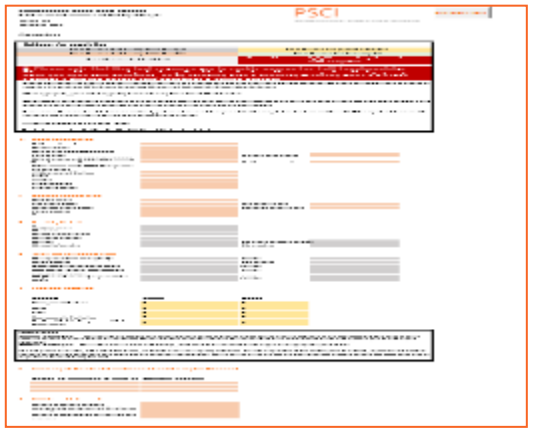
PSCI SUPPLIER CATEGORIES

For auditing purposes, suppliers are categorized according to their activities:

- "A" - service providers
- "B" - component & material suppliers
- "C" - core suppliers & contract manufacturers

PSCI SAQS & AUDIT REPORT PROTOCOLS

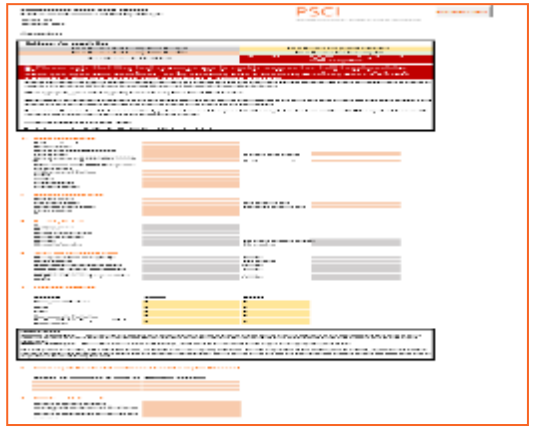
USE FOR "A" SUPPLIERS!!



Abbreviated PSCI Self Assessment Questionnaire (SAQ) & Audit Report Template for Service Providers & General Manufacturers

https://pscinitiative.org/resource?resource=31

USE FOR "B" and "C" SUPPLIERS!!

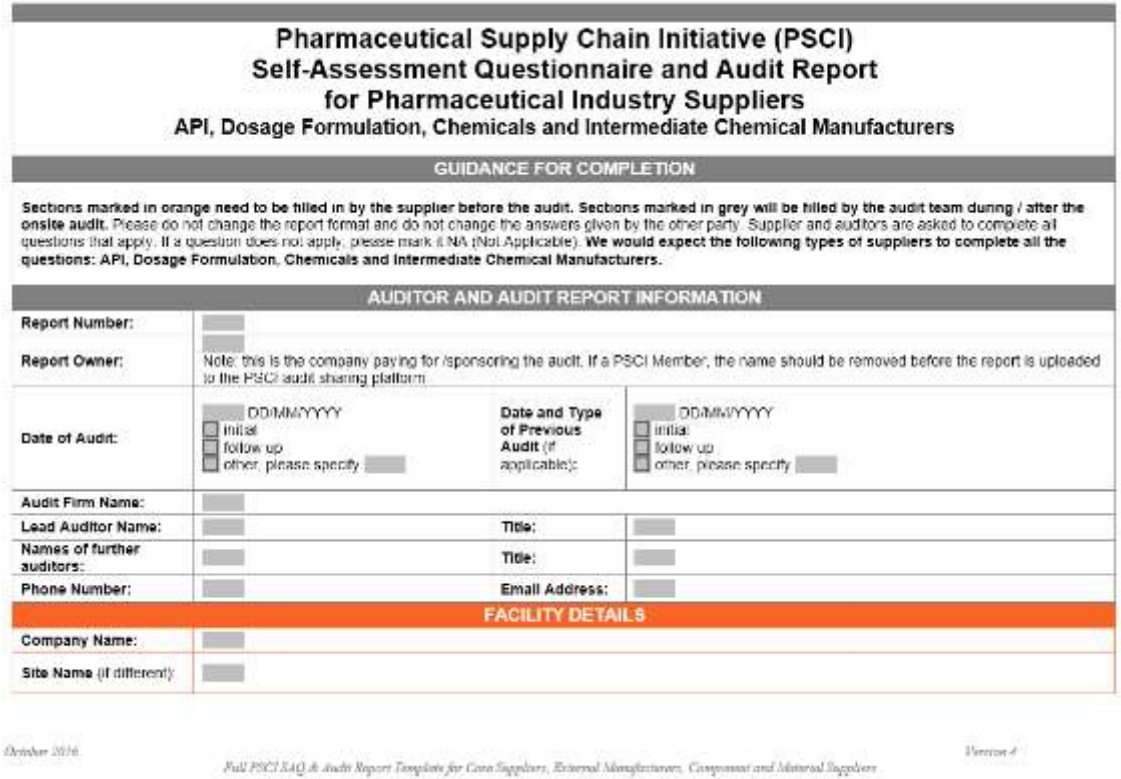


Full PSCI Self Assessment Questionnaire (SAQ) & Audit Report Template for Core Suppliers, External Manufacturers, Component and Material Suppliers

https://pscinitiative.org/resource?resource=32

PSCI SAQ/AUDIT TEMPLATES (WORD AND EXCEL)

!!Preferred Format!!



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

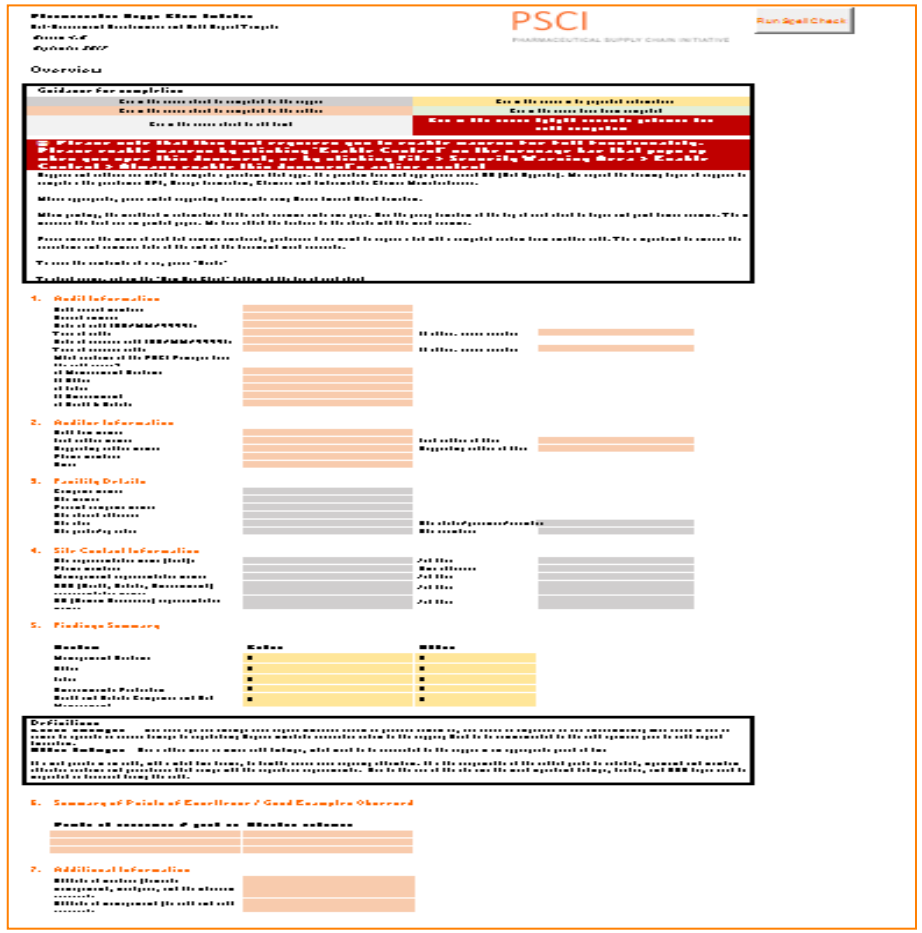
Report Number:			
Report Owner:	Note: this is the company paying for /sponsoring the audit. If a PSCI Member, the name should be removed before the report is uploaded to the PSCI audit sharing platform		
Date of Audit:	DD/MM/YYYY ☐ initial ☐ follow up ☐ other, please specify	**Date and Type of Previous 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



ONSITE, PARTLY REMOTE OR FULLY REMOTE AUDITS

New! By the end of October revised PSCI SAQ/Audit Report templates will be available also covering remote/partly remote audits. Auditors must indicate on the "overview and guidance" part of the audit report how the audit was conducted – onsite, partly remote or fully remote

Pharmaceutical Supply Chain Initiative
Self-Assessment Questionnaire and Audit Report Template

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

How this audit was carried out? | Fully Remote | If *Fully Remote* or *Partly Remote*, please specify the verification methods:

Fully Remote
Partly Remote
Onsite

ⓘ Please note that there are three ways to [illegible] (Fully Remote, Partly Remote, Onsite). Please select which way was used.
Fully Remote audit means the entire audit, including the verification of responses to questions within the SAQ *all* verified via remote methods, such as livestreaming video, telephone/video call, etc.
Partly Remote audit means *part* of the audit was conducted remotely and *part* of the audit was conducted on-site.
Onsite audit means the audit and the *all* verification of responses to questions on the SAQ were carried out via onsite visits.
Additionally, if this audit is either Fully Remote audit or Partly Remote audit, you'll be asked to fill in how you have collected and verfied information.

ⓘ Please note you will be asked to specifiy the verification methods for each topic area covered in the corresponding sheet as well.

WORD VERSIONS – Findings classifications

- **Findings classifications**, only the relevant executive summary should be filled in, depending on the findings classification methodology selected, i.e. either
  - Critical / Major / Minor (preferred)
  - Critical / Other

Note:

for details on audit finding classification see section "Audit Report Writing"

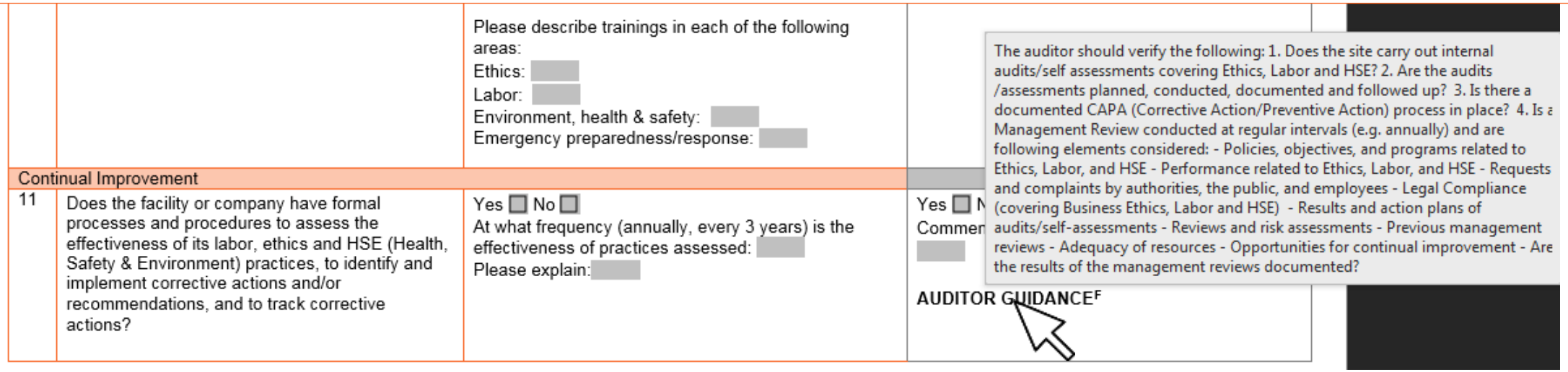
EXECUTIVE SUMMARY (FOR CRITICAL-OTHER)							
Overall findings		Please check applicable box(es) and indicate the number of findings					
		Critical	Number of Criticals	Other	Number of Others	No findings	Not reviewed
A	Management Systems	☐		☐		☐	☐
B	Ethics	☐		☐		☐	☐
C	Labor	☐		☐		☐	☐
D	Environmental Protection	☐		☐		☐	☐
E	Health & Safety Compliance and Risk Management	☐		☐		☐	☐

EXECUTIVE SUMMARY (FOR CRITICAL-MAJOR-MINOR)								
Overall findings		Please check applicable box(es) and indicate the number of findings						
		Critical	Number of Criticals	Major	Number of Major	Minor	Number of Minor	No findings	Not reviewed
A	Management Systems	☐		☐		☐		☐	☐
B	Ethics	☐		☐		☐		☐	☐
C	Labor	☐		☐		☐		☐	☐
D	Environmental Protection	☐		☐		☐		☐	☐
E	Health & Safety Compliance and Risk Management	☐		☐		☐		☐	☐

WORD VERSIONS – Auditor guidance (1)

Auditor guidance: the updated auditor guidance has been added to the tool using endnotes.

1) To view the guidance pop-up



To view the guidance for a question hover over the 'AUDITOR GUIDANCE' note against that question

WORD VERSIONS – Auditor guidance (2)

2) To view the full guidance text

Continual Improvement			
11	Does the facility or company have formal processes and procedures to assess the effectiveness of its labor, ethics and HSE (Health, Safety & Environment) practices, to identify and implement corrective actions and/or recommendations, and to track corrective actions?	Yes ☐ No ☐ At what frequency (annually, every 3 years) is the effectiveness of practices assessed: Please explain:	Yes ☐ No ☐ Comments AUDITOR GUIDANCE F

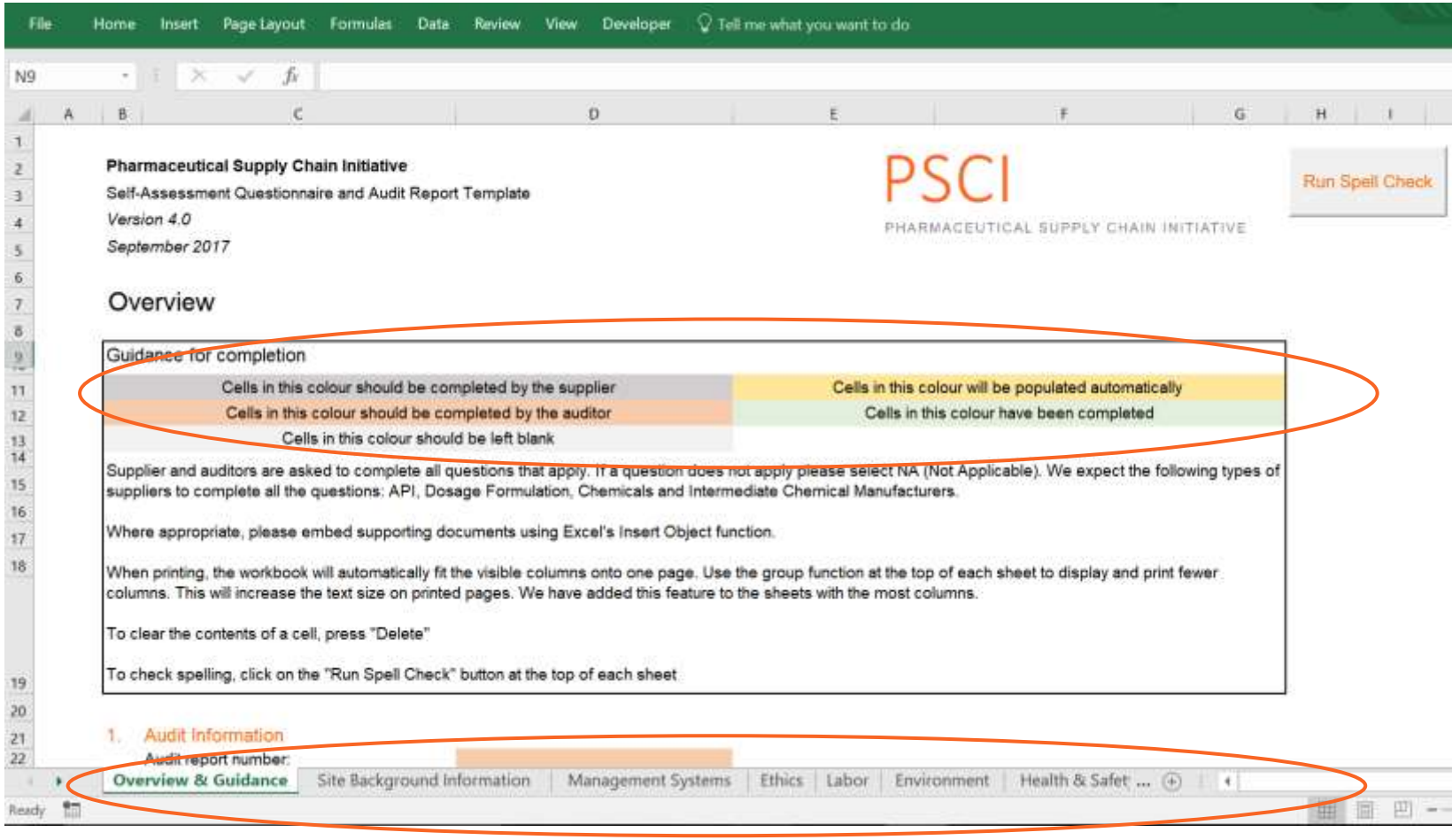
F The auditor should verify the following:

1. Does the site carry out internal audits/self assessments covering Ethics, Labor and HSE?
2. Are the audits /assessments planned, conducted, documented and followed up?
3. Is there a documented CAPA (Corrective Action/Preventive Action) process in place?
4. Is a Management Review conducted at regular intervals (e.g. annually) and are following elements considered:
   - Policies, objectives, and programs related to Ethics, Labor, and HSE
   - Performance related to Ethics, Labor, and HSE
   - Requests and complaints by authorities, the public, and employees
   - Legal Compliance (covering Business Ethics, Labor and HSE)

To access the full auditor guidance, double click the letter next to 'AUDITOR GUIDANCE'. This will take you directly to the end note in the auditor guidance section at the end of the document.

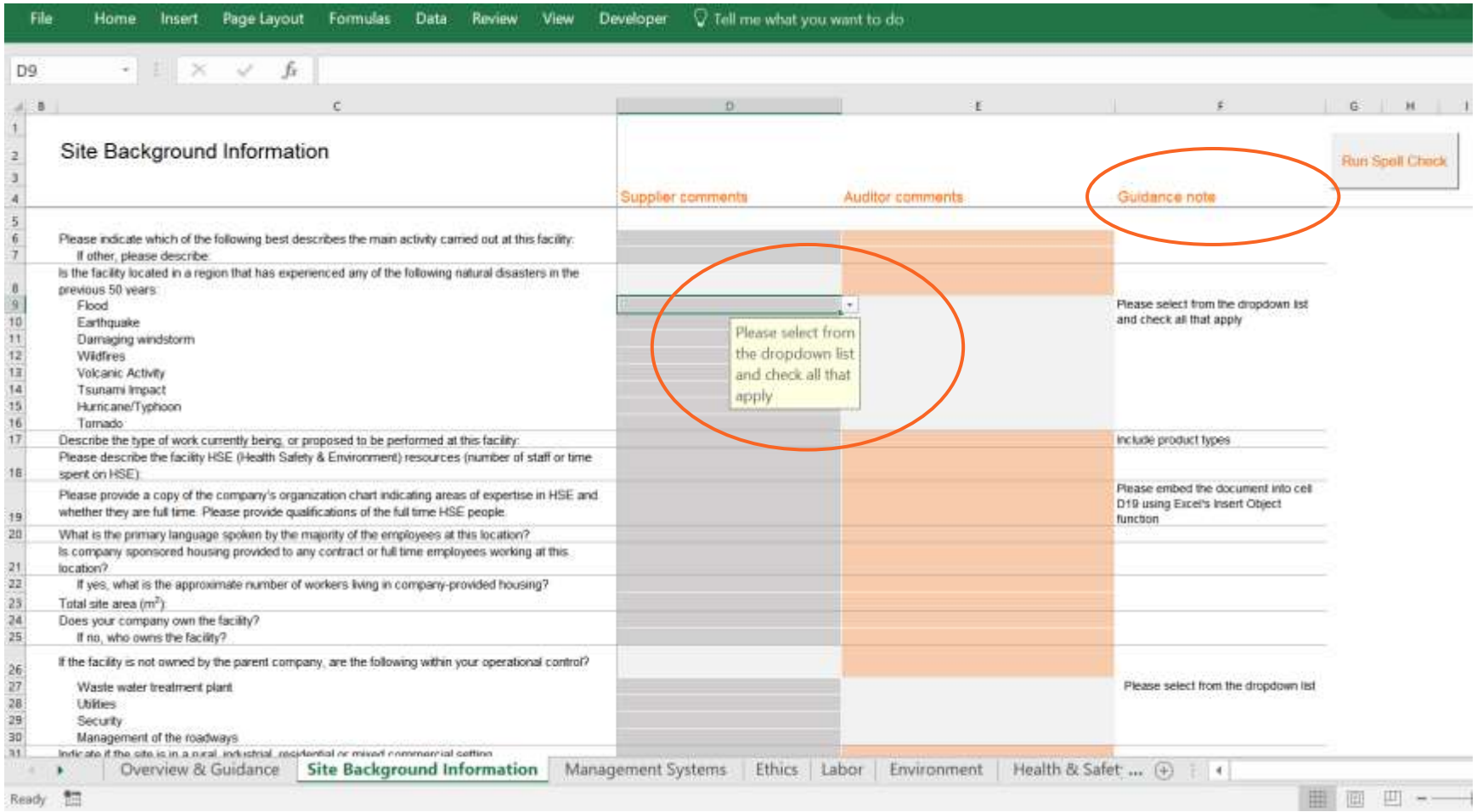
EXCEL TEMPLATE: KEY FEATURES (1)

- Preferred tool as we can drive overall evaluation of audit results better
- 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



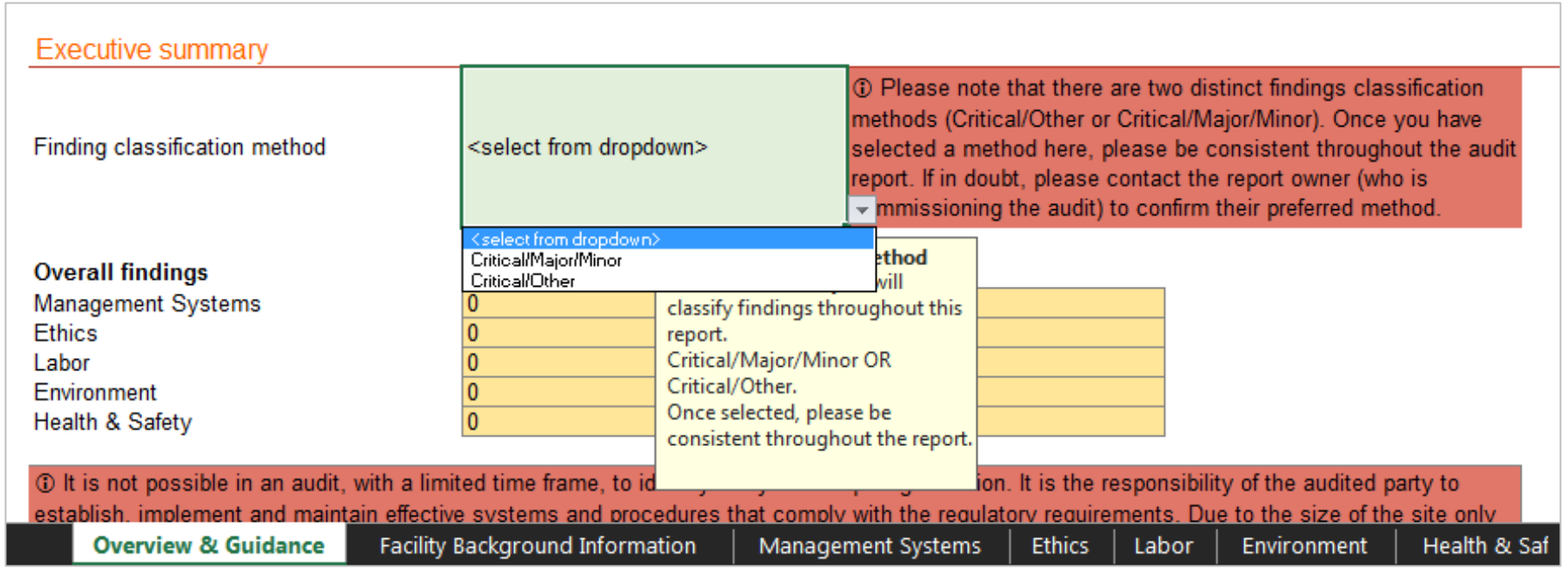
EXCEL TEMPLATE: KEY FEATURES (2)

- Detailed Auditor Guidance notes for questions covering higher risks
- Drop downs to standardise responses where appropriate



EXCEL VERSIONS – Findings classifications

- **Findings classifications**, in the excel version the classification method needs to be selected before starting the evaluation and must not be changed in the process. Select the findings classification required from the summary table on the 'Overview & Guidance' tab it will update automatically to:
  - Critical / Major / Minor (preferred!)
  - Critical / Other



EXCEL VERSIONS – Auditor guidance

- **Auditor guidance**, the additional auditor guidance that has been added is included in an 'Additional Auditor Guidance' column (K) in the excel tool.
- In case of time constraints, questions with auditor guidance notes should be preferably answered.

Pharmaceutical Supply Chain Initiative

Self-Assessment Questionnaire and Audit Report Template

Environment

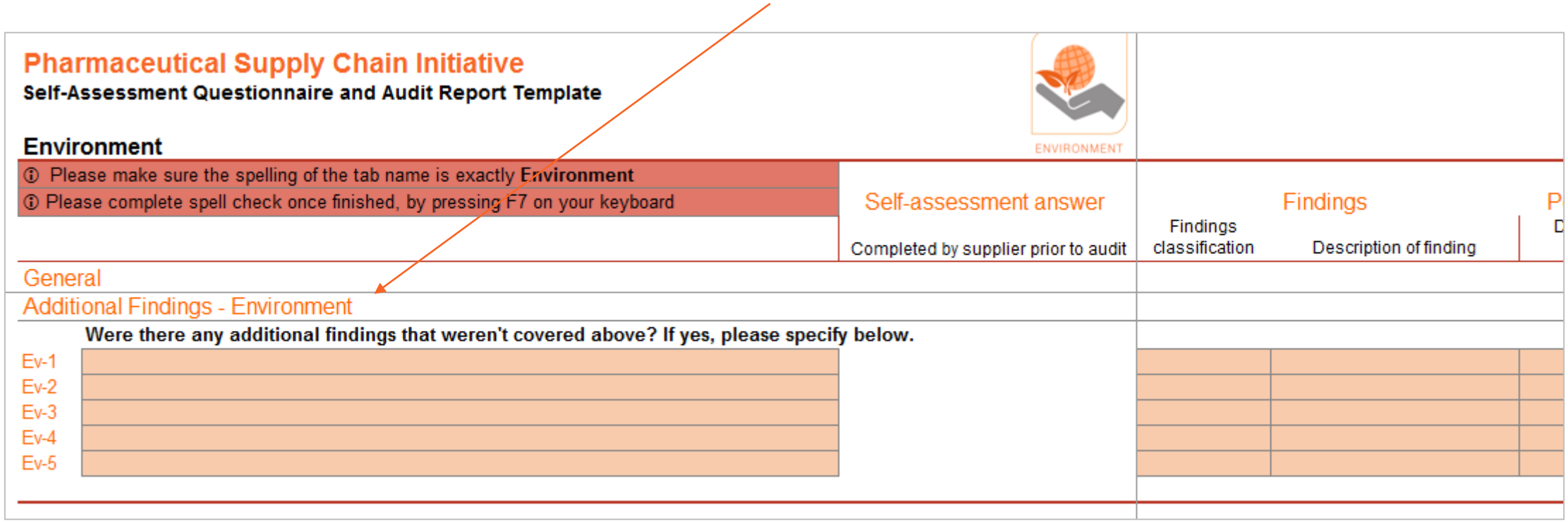
ENVIRONMENT

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

ⓘ Please make sure the spelling of the tab name is exactly **Environment** ⓘ Please complete spell check once finished, by pressing F7 on your keyboard		Self-assessment answer Completed by supplier prior to audit	Additional Auditor Guidance Where provided, it is mandatory to follow the guidance.
General			
31	**Does the facility have written environmental policy, procedures, and practices?**		
i.	Environmental policy?		
ii.	Environmental procedures?		
	Comments		
	If yes, please provide a copy of the policy and list of the procedure titles.		
32	**Does the facility have documented environmental objectives or goals for performance improvement, including metrics and targets?**		ⓘ Describe any formal or informal programs or procedures to reduce environmental impacts, noting any improvements made in recent (3) years. Does the supplier disclose environmental emissions and impacts to CDP?
	If yes, please describe goals, metrics, and/or targets and any improvements made in last 3 years		

EXCEL VERSIONS – Additional findings

- Space for additional findings, this is provided at the end of every section. This is aimed at including space for auditors to provide additional findings against a topic, like Environment that do not fit against a specific question.



Pharmaceutical Supply Chain Initiative

Self-Assessment Questionnaire and Audit Report Template

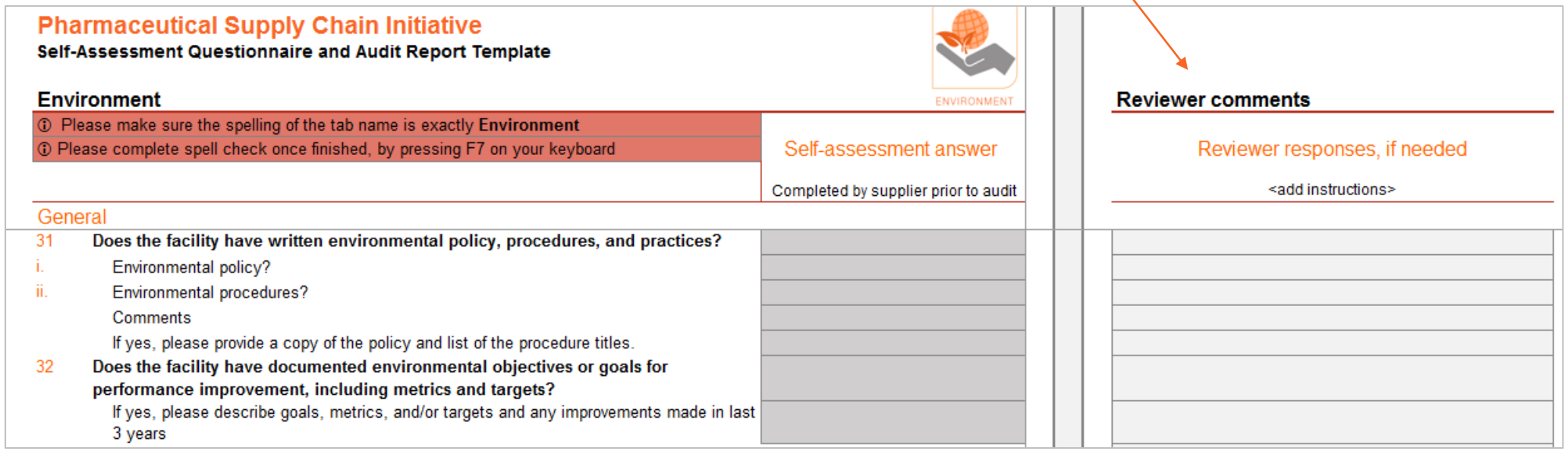
ENVIRONMENT

Environment

ⓘ Please make sure the spelling of the tab name is exactly **Environment** ⓘ Please complete spell check once finished, by pressing F7 on your keyboard	Self-assessment answer Completed by supplier prior to audit	Findings Findings classification	 Description of finding	P D
General				
Additional Findings - Environment				
Were there any additional findings that weren't covered above? If yes, please specify below.				
Ev-1				
Ev-2				
Ev-3				
Ev-4				
Ev-5				

EXCEL VERSIONS – Reviewer comments

- Reviewer comments, we've included an additional column (O) at the very right of each form for reviewer responses. This is intended to be a column where a reviewer can comment against questions if they have comments.



Pharmaceutical Supply Chain Initiative

Self-Assessment Questionnaire and Audit Report Template

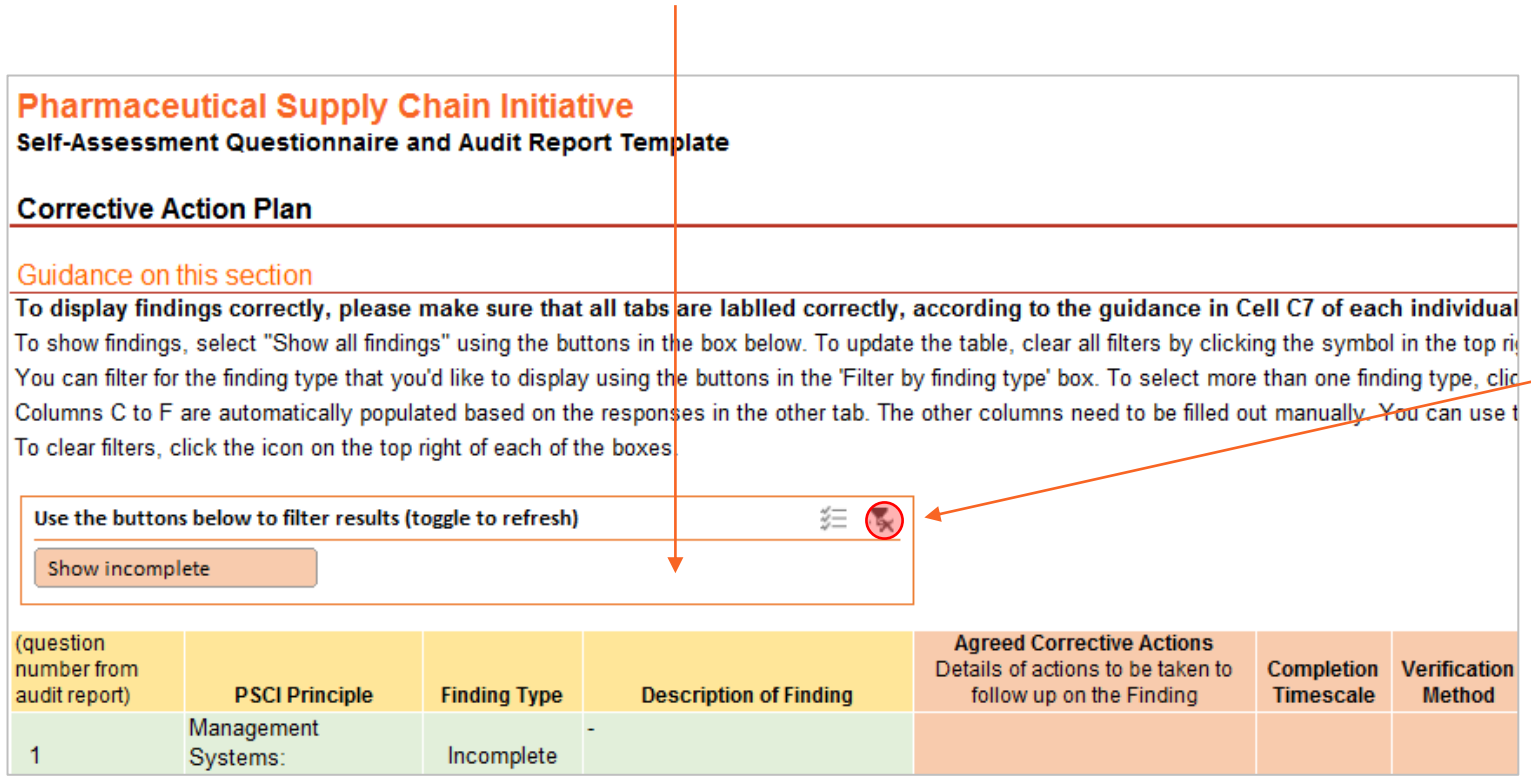
ENVIRONMENT

Environment

ⓘ Please make sure the spelling of the tab name is exactly **Environment**			
ⓘ Please complete spell check once finished, by pressing F7 on your keyboard		Self-assessment answer	Reviewer responses, if needed
		Completed by supplier prior to audit	<add instructions>
General			
31	**Does the facility have written environmental policy, procedures, and practices?**		
i.	Environmental policy?		
ii.	Environmental procedures?		
	Comments		
	If yes, please provide a copy of the policy and list of the procedure titles.		
32	**Does the facility have documented environmental objectives or goals for performance improvement, including metrics and targets?**		
	If yes, please describe goals, metrics, and/or targets and any improvements made in last 3 years		

EXCEL VERSIONS – CAP sheet updated

- CAP sheet updated, we've removed the Macro from the CAP sheet. The CAP sheet functionality is similar, but there are a few minor changes to how it works. Now findings can be filtered using the option menu at the top of the table.



Pharmaceutical Supply Chain Initiative

Self-Assessment Questionnaire and Audit Report Template

Corrective Action Plan

Guidance on this section

To display findings correctly, please make sure that all tabs are lablled correctly, according to the guidance in Cell C7 of each individual

To show findings, select "Show all findings" using the buttons in the box below. To update the table, clear all filters by clicking the symbol in the top ri

You can filter for the finding type that you'd like to display using the buttons in the 'Filter by finding type' box. To select more than one finding type, clic

Columns C to F are automatically populated based on the responses in the other tab. The other columns need to be filled out manually. You can use t

To clear filters, click the icon on the top right of each of the boxes.

Use the buttons below to filter results (toggle to refresh)

Show incomplete

(question number from audit report)	PSCI Principle	Finding Type	Description of Finding	Agreed Corrective Actions Details of actions to be taken to follow up on the Finding	Completion Timescale	Verification Method
1	Management Systems:	Incomplete	-			

EXCEL VERSIONS – Other points to consider

- Excel was unlocked in order to make using them simpler.

  Please take care NOT to:

  - Change any questions, similarly to the word version
  - If combining sheets keep to the original sheet names, *or the CAP sheet won't work correctly*

- Spell check was updated, we've removed the spell check Macro, as it was causing compatibility issues. Users now need to need to spell check using F7. This is clearly indicated at the top of each sheet where the spell check macro button used be

COMPLETING THE PSCI PROTOCOLS

TIPS/HINTS FOR AUDITORS

- Please do not change the report format and do not change the answers given by the supplier in the SAQ sections
- Auditors are generally asked to complete all questions that apply. If a question does not apply, please mark it NA (Not Applicable)
- If – e.g. in case of time constraints - some questions cannot be covered, this needs to be indicated as well.
- In case of time constraints a risk approach should be considered, and a focus should be set on the questions where auditor guidance notes are available
- Comments of the auditors should not be a simple copy and paste of the SAQ answer provided by the supplier or should not be a turn around of the audit question to an answer. Comments should reflect the auditor's actual observations during onsite audit.
- Please insert photographs when applicable and feasible, following the instructions as mentioned in the audit protocols

COMPLETING THE PSCI PROTOCOLS

TIPS/HINTS FOR SUPPLIERS

- Please do not change the report format
- Suppliers are asked to complete all questions that apply. If a question does not apply, please mark it NA (Not Applicable)
- Please add links or additional information where requested
- Provide explanations in case it is requested
- Check the auditor guidance notes in case you need further explanations in answering questions

COMMON ISSUES SEEN IN UPLOADED AUDIT REPORTS

- Outdated template: Some auditors fail to use the latest template available (Version 6.0 - January 2019. – see Word, Excel). Note that the templates will be updated by the end of October with a indication if the audit was conducted onsite, partly remote or fully remote.
- Audit Reports with incomplete sections indicated as Full Audits: Some audits were uploaded as 'full audit' when only the HSE sections or Ethics & Labour sections were evaluated. In such cases, the audit must be indicated as an HSE or Labour rights audit.
- Incomplete SAQ in supplier self-initiated audits: In some SSIAs, while all the sections are audited, some sections in the SAQ are left blank. We need to stress that the process of supplier completing SAQ before an audit needs to be strictly followed for SSIAs.
- For Chinese sites, some SAQs are filled only in Chinese . Sites and Auditors need to ensure that final SAQs reports are in English.
- Inconsistent use of audit classification methodology. In some reports, we see auditors first indicating the use of the critical/others classification, then use Critical/Major/Minor or Other-Major/Other-Minor in classifying findings. Some auditors fail to indicate the method at the beginning of the report. Auditors need to decide on one of the methodologies and then stick to it consistently.
- Inconsistent format in CAPR reporting:
  - Auditors should either use the CAP section in the PSCI audit template or upload a separate PSCI CAPR to summarise findings.
  - Agreed Corrective Actions, Completion Timescale and Verification Method are often left unfilled in the CAP section. Such information is mandatory as it's useful for later review.
  - In separate CAPRs, auditors generally used their own format, which doesn't include Agreed Corrective Actions, Completion Timescale and Verification Method as in the PSCI template.
- Signings by sites and auditors at the end of the report are often left blank.
- Audit property info containing auditor/sponsor info is often left unredacted. Property info can be found in 'File' > 'info' (word/Excel), or 'File' > 'Properties' (PDF).

AGENDA

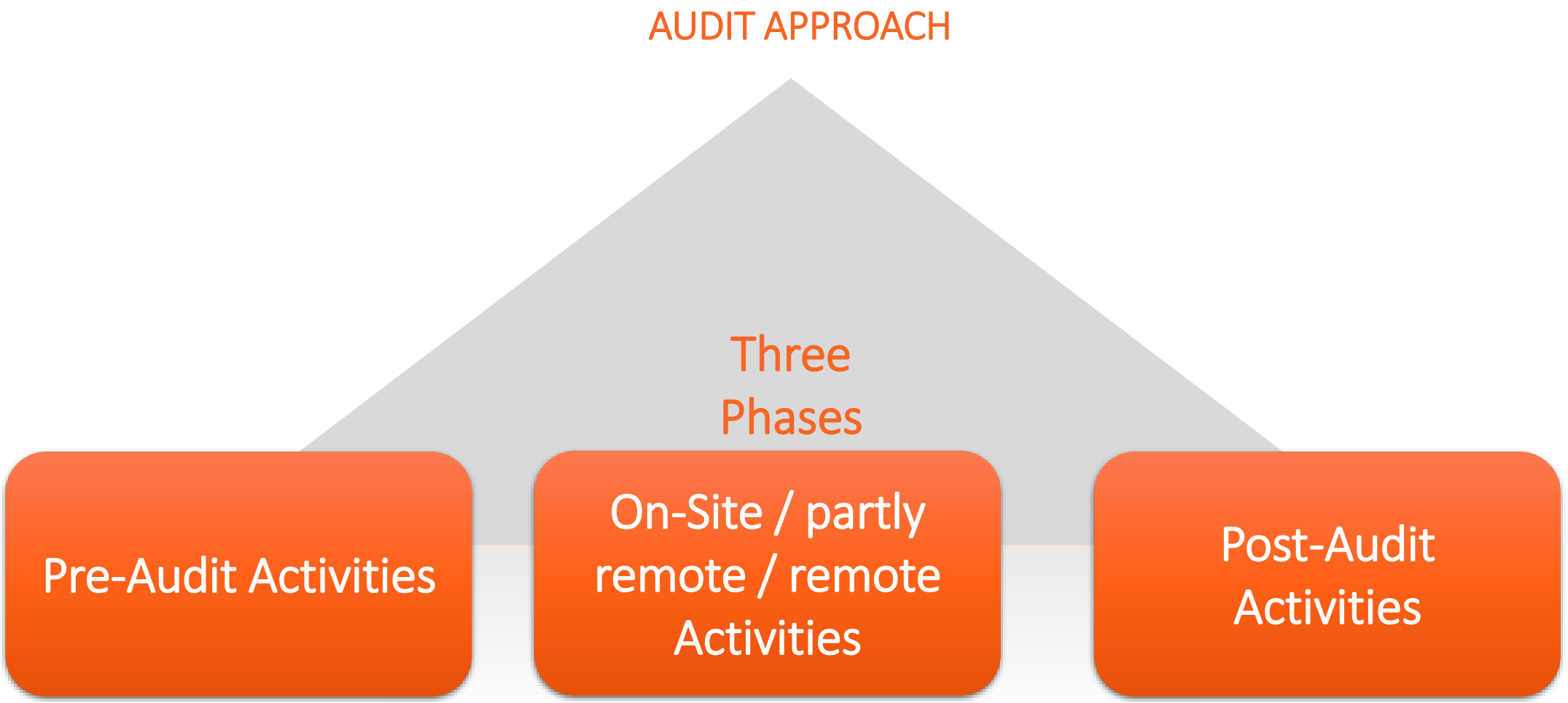
OVERVIEW ON PSCI AUDITS

PSCI SAQS AND AUDIT REPORT TEMPLATES

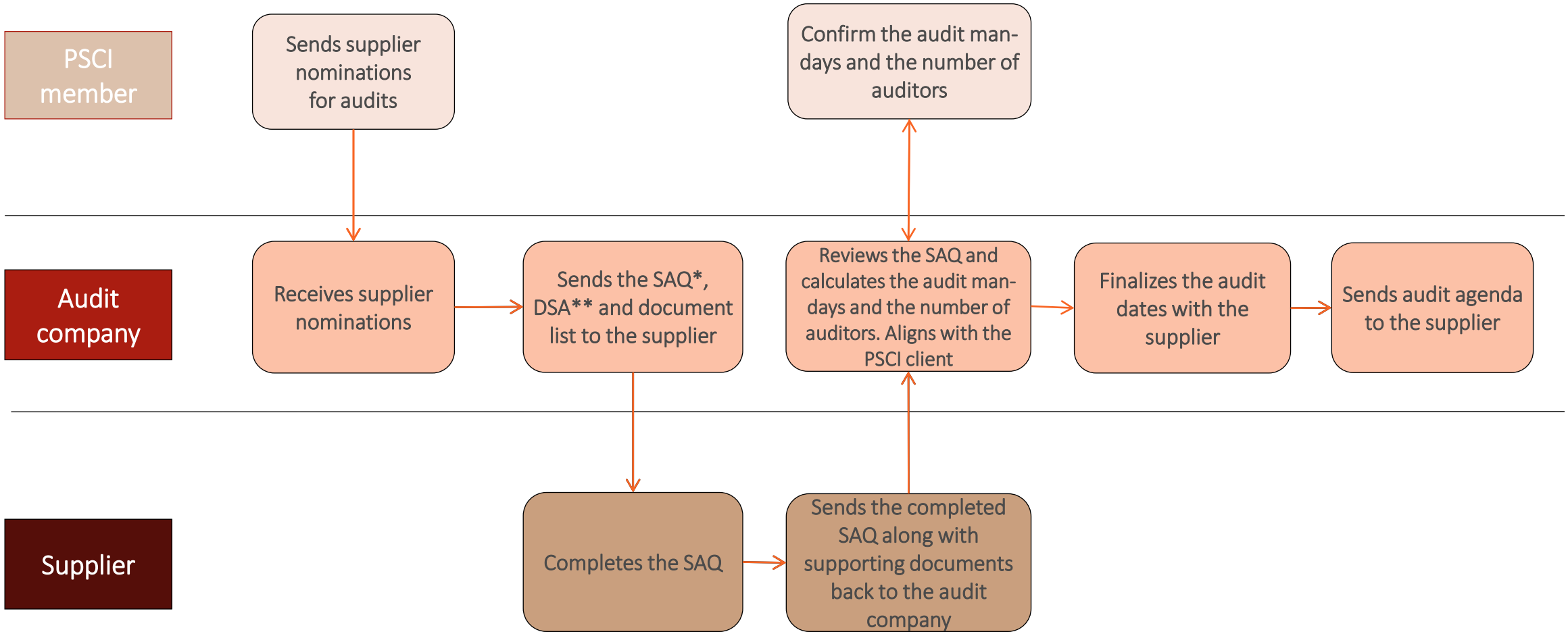
GENERAL PSCI AUDIT PROCESS

AUDIT REPORT WRITING

GENERAL PSCI AUDIT PROCESS



EXAMPLE PRE -AUDIT ACTIVITIES



*SAQ – Self assessment questionnaire **DSA – Data sharing agreement

AUDIT PREPARATION

TIPS/HINTS FOR AUDITORS

- Study the PSCI SAQ including the provided documents
- Ask for any additional information if needed from both the sponsor of the audit (if applicable) or the supplier
- Check with the client if there are any special topics that need to be considered
- Provide the supplier with an agenda and a tailored PSCI Pre-Audit Document checklist
- Check the website of the auditee
- Carry out some background research about the auditee,
  e.g. media reports about environmental issues (for China: IPE database, relevant databases or reports about fatalities, accidents, incidents, loss of primary containments, news about legal issues etc.
- Check if there are any special instructions upon arrival (be prepared to show identification if required, ask where to sign in, who to ask for upon arrival…)
- Check if any special personal protective equipment is required

AUDIT PREPARATION

TIPS/HINTS FOR SUPPLIERS (AUDITEES)

- Understand that the upcoming PSCI Audit is a chance for continuous improvement
- Be clear on the scope of the audit and contact the auditor or the sponsor of the audit (PSCI Member) in case of any questions
- Complete the PSCI SAQ and provide it along with all requested information/links to the auditor
- Inform and brief relevant groups about important aspects of the upcoming audit
  - Site management
  - Workforce
  - Union or other worker representatives
  - Any labor providers (agencies) the site uses
- Ensure that correct key personnel and documentation as requested by the auditor is available on the day(s) of the audit
- Prepare a brief overview of your facility and processes
- Inform management and employees that auditors will randomly pick employees for individual and group interviews relating to their labor situation, and that employees have the right to refuse being interviewed without reason or consequence; employees should be informed about their right for data privacy in this context;
- Conduct a self-audit of your site/facility prior to the PSCI Audit – this will help to identify and correct any issue in advance

PSCI ONSITE AUDIT PROCESS

Opening meeting

- includes a short introduction round, reminder on scope of the audit and alignment of final agenda
- Involved parties: audit team, site/plant management, HR, works council rep., HSE, engineering, production management

Interviews

- Conducted in groups or with individuals
- Consideration of different shift pattern, worker types, gender etc

Pre-closing meeting:

- Internal discussion among the auditors
- Preparation of the preliminary CAP (Corrective Action Plan)

Site tour

- Production
- Other relevant infrastructure areas (e.g. wastewater, waste, utilities)
- If allowed, photos may be taken

Interviews

- With representatives of site leadership, HR, HSE, Engineering,

Document review

- Permits, licenses, policies, SOPs, records (see e.g. PSCI pre audit document list)

Discussions

- With technical experts and management (e.g. HSE, engineering, production)

Closing meeting

- Presentation of best practices and audit findings and preliminary CAP
- If possible, signing of preliminary CAP by both parties

OPENING MEETING

TIPS & HINTS FOR AUDITORS

- Be on time!
- Thank the management for hosting the audit
- Introduce yourself and audit team and ask the other participants to introduce themselves (facilitated by business cards & list of attendees)
- Provide a brief background about PSCI in case the company is unaware
- Explain the purpose and the benefits of the PSCI Audit
- Explain the audit plan (including areas to be inspected); be flexible if needed
- Ask the auditee to provide an overview of their facility and processes
- Ask if you may take photographs of selected areas (do not insist taking photographs if the auditee denies it)
- Ask for safety instructions and evacuation plan if not provided by the company.

PHYSICAL INSPECTION OF THE FACILITY

TIPS & HINTS FOR AUDITORS

- Good time management is key, especially during site tours
- Allow for sufficient time for the site tour, do NOT spend most of the time with document review in the office
- Ask for a site map for the tour to help you with the site orientation
- Keep in mind that gowning procedures in pharmaceutical finishing plants may require a significant amount of time
- Inspect main production areas, but be careful to reserve time for other areas (e.g. warehouses, waste storage/treatment, wastewater treatment units and other utilities are also important to visit)
- Try to inspect critical activities especially those with high risk potential e.g. construction activities, working in height, inspection & sampling, loading/unloading, material handling and transfer, waste packing and pick-up, confined space entry
- Observe the facility also from the outside

POINTS TO CONSIDER FOR REMOTE AUDITS

- More time needed for overall planning and aligning with auditee prior to audit
  - Detailed communication/agreements on logistics and technology is important
  - Use of technology the auditee is familiar with / prefers to use
  - Perform technology tests in advance
  - Consider what to do if technology fails
  - Documentation should be requested and evaluated prior to the audit and not during the discussion part
  - Data privacy topics to be clarified (additional non-disclosure agreements may be needed)
- Key personnel needs to be available during the whole audit
- Designate host to organize agenda and flow
- Keep attendees on track with the timing during the remote part
- Videos/Streaming:
  - Define specific processes to be checked rather than simulation of a full site tour
  - Clarify in advance what kind of streaming / photos are possible (consider data privacy, ex zones /hazardous areas or GMP areas)

BEHAVIOR DURING AN AUDIT

What an auditor should do:

- Look
- Listen
- Read
- Write down
- Ask questions
- Recommend
- Be friendly
- Be vigilant
- Don‘t criticize
- Reach agreements
- Be constructive
- Be objective

How an auditor should behave:

- Positive
- Helpful
- Accessible
- Patient

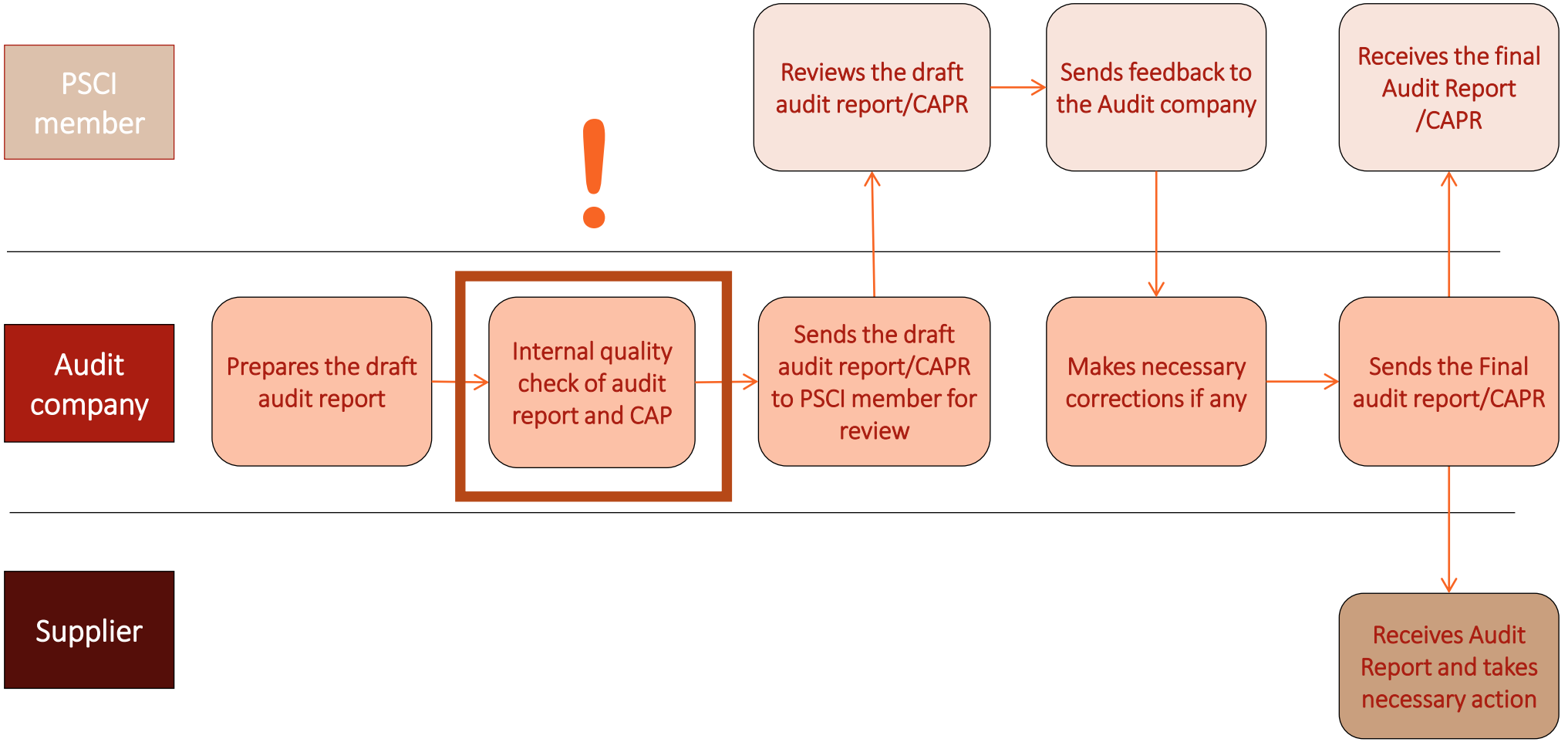
CLOSING MEETING (1)

- Thank the management for their time, patience and openness
- Re-confirm the purpose of the audit;
- Mention good working practices that have been observed during the audit;
- Explain that the audit was based on a sample examination of their site and that it is the site's responsibility to conduct a deeper investigation into their programs;
- Explain which findings and improvement potentials have been observed during the audit,
- Remind the supplier that they may challenge/discuss findings (or provide factual evidence that a finding was incorrect) in this meeting, but any issues they have agreed to will not be changed later;
- Besides listing the findings, ensure that any agreements or disagreements are clearly recorded on the Preliminary Corrective Action Plan;

CLOSING MEETING (2)

- If possible: Obtain the signature of the site management on this Preliminary Corrective Action Plan Report;
- Explain the next steps; Drafting of PSCI Audit Report and PSCI Corrective Action Plan, quality control of the audit report, finalization of the PSCI Audit Report and Corrective Action Plan Report and distribution to supplier and to the respective PSCI member;
- Encourage the management of the site to allow for sharing of the PSCI Audit Report and Corrective Action Plan Report with other PSCI member companies
  (either by signing the PSCI Data Sharing Agreement or by sharing online via the PSCI audit sharing platform)

EXAMPLE POST AUDIT ACTIVITIES



AGENDA

OVERVIEW ON PSCI AUDITS

PSCI SAQS AND AUDIT REPORT TEMPLATES

GENERAL PSCI AUDIT PROCESS

AUDIT REPORT WRITING

AUDIT REPORT WRITING

Note: Audit Report writing already starts during the audit!

- Ensure that notes are accurate (all are potentially “discoverable”)
- Document all evidence reviewed (even if it is not a finding)
- Take photos of documents & situations, if allowed
- Document where a photo was taken
- Note title/job description/area of interviewees
  (but never give names in the audit report)
- Note specific ID # for an SOP, other documents, equipment etc.
- If possible, give # reviewed of total # available

WRITING AUDIT FINDINGS (1)

TIPS & HINTS FOR AUDITORS

- Use full sentences and keep them short, to the point
- Report facts, not opinions
- Define all acronyms when used the first time
- Do not make legal conclusions (e.g., “not compliant…”)
- Limit the use of adjectives (e.g. “always,” “every,” “any,” “none”)
- Do not exaggerate or overstate
- Use everyday language, avoid technical jargon
- Consider language like “was not available,” “no evidence of,” versus “there was no…”
- Use “active voice”

OK: wastewater operator performs weekly wastewater sampling at the outfall point for criteria A, B, & C. The results are shared monthly with the local authority as per permit.
Not OK: sampling was performed of the wastewater

WRITING AUDIT FINDINGS (2)

Following basic questions should be considered while writing a finding:

- Who? is involved in the finding
- What? is the subject of the finding
- When? did the finding take place
- Where? was the location of the finding
- How? did the finding come about and provide if possible, examples
- How often? does the finding happen: a single event/case or a systematic error

And: Challenge significance of each finding by asking "So what?"

WHAT´S WRONG WITH THESE AUDIT FINDINGS?

FINDINGS	MISTAKES
The audit team was told that there have been a number of spills of hazardous materials by the maintenance staff. The audit team recommends that these individuals be disciplined and retrained.	
It seemed that the emergency exits in the warehouse were not always signed.	
Bob Myer reported that work permits were not always issued when staff enters confined spaces. This violates the site´s confined space entry program.	
The emergency response plan was found deficient and should be improved. This is a serious concern.	

WHAT´S WRONG WITH THESE AUDIT FINDINGS?

FINDINGS	MISTAKES
The audit team was told that there have been a number of spills of hazardous materials by the maintenance staff. The audit team recommends that these individuals be disciplined and retrained.	Be precise and avoid including hearsay. Don´t put recommendations into findings. Don´t recommend disciplinary measures
It seemed that the emergency exits in the warehouse were not always signed.	
Bob Myer reported that work permits were not always issued when staff enters confined spaces. This violates the site´s confined space entry program.	
The emergency response plan was found deficient and should be improved. This is a serious concern.	

WHAT´S WRONG WITH THESE AUDIT FINDINGS?

FINDINGS	MISTAKES
The audit team was told that there have been a number of spills of hazardous materials by the maintenance staff. The audit team recommends that these individuals be disciplined and retrained.	Be precise and avoid including hearsay. Don´t put recommendations into findings. Don´t recommend disciplinary measures
It seemed that emergency exits in the warehouse were not always signed.	Avoid including terms like “seems” and “not always”.
Bob Myer reported that work permits were not always issued when staff enters confined spaces. This violates the site´s confined space entry program.	
The emergency response plan was found deficient and should be improved. This is a serious concern.	

WHAT´S WRONG WITH THESE AUDIT FINDINGS?

FINDINGS	MISTAKES
The audit team was told that there have been a number of spills of hazardous materials by the maintenance staff. The audit team recommends that these individuals be disciplined and retrained.	Be precise and avoid including hearsay. Don´t put recommendations into findings. Don´t recommend disciplinary measures
It seemed that the emergency exits in the warehouse were not always signed.	Avoid including terms like “seems” and “not always”.
Bob Myer reported that work permits were not always issued when staff enter confined spaces. This violates the site´s confined space entry program.	Hearsay (no real factual evidence) Do not mention names of employees Avoid terms like “not always” “violates”– avoid extreme language
The emergency response plan was found deficient and should be improved. This is a serious concern.	

WHAT´S WRONG WITH THESE AUDIT FINDINGS?

FINDINGS	MISTAKES
The audit team was told that there have been a number of spills of hazardous materials by the maintenance staff. The audit team recommends that these individuals be disciplined and retrained.	Be precise and avoid including hearsay. Don´t put recommendations into findings. Don´t recommend disciplinary measures
It seemed that the emergency exits in the warehouse were not always signed.	Avoid including terms like “seems” and “not always”.
Bob Myer reported that work permits were not always issued when staff enter confined spaces. This violates the site´s confined space entry program.	Hearsay (no real factual evidence) Do not mention names of employees Avoid terms like “not always” “violates”– avoid extreme language
The emergency response plan was found deficient and should be improved. This is a serious concern.	“Deficient” in what? Be precise. “serious” – avoid extreme wording

CLASSIFICATION OF AUDIT FINDINGS (1)

- **Critical Findings:** Are very high-risk findings that require immediate action to protect human life, the health of employees or the environment; May result in loss of license to operate or serious damage to reputation; Require immediate corrective action by the supplier; Need to be communicated to the audit sponsor prior to audit report finalization.
- **Other Findings:** Are all other major or minor audit findings, which need to be corrected by the supplier in an appropriate period of time.
  - **Major Findings:** Findings that may pose major impacts to workers, the community, or the environment. Findings that may pose major regulatory non-compliances or illustrate systemic program gaps.
  - **Minor Findings:** Findings that may pose minor impacts to workers, the community, the environment. Findings that may pose minor regulatory non-compliances.
- **Non-Finding remarks:** Are where the auditor wishes to raise an important comment, but this comment would not constitute any type of finding.
- **NOTE:** When writing the audit report, please choose **one** of the two classification methodologies (i.e. either critical/other OR critical/major/minor and consistently stay with it within the report.

EXAMPLES: CLASSIFICATION OF AUDIT FINDINGS

Critical

- Evidence of child labor
- Falsified record in wages, contracts or other documents
- Wage below legal minimum wage
- No permits or license to operate in place as mandated by authorities
- Systematic and regular breaches of legal requirements, laws and HSE Standards
- Finding that requires an immediate stoppage of work due to life threatening situation
- Intentional shut-down or bypassing of important safety installations

Major

- No formal Ethics Policy or Company Code of Conduct in place covering anti bribery & corruption and other important company business practices
- No reliable records of working hours (standard hours & overtime hours)
- No management system in place for HSE compliance and/or risk mitigation
- Significant gaps in risk assessments
- Deficiencies in important HSE Programs (e.g., permit-to work, lock out-tag out, preventive maintenance, HSE training)
- Significant deficiencies in Emergency Response Planning, fire detection/suppression, Management of Change in HSE
- No testing of API content in effluent OR No PEC/PNEC consideration OR clearly excessive limits set OR No/ineffective contingency plan for ETP
- No documented HSE objectives/targets
- No/inadequate Business Continuity Plan
- Unsafe behaviors observed during site tour (e.g. not following SOPs, not wearing required PPE, unsafe forklift usage, cell phone usage in ex-areas)

Minor

- Single cases/smaller deficiencies not indicating a systematic error e.g.
  - Missing of one sign but all other signs are in place
  - A few safety data sheets not available in local language

THANK YOU!

CONTACT

pscinitiative.org

info@pscinitiative.org

Annabel Buchan:
+44 (0) 7794 557524

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Carnstone Partners Ltd
Durham House
Durham House Street
London
WC2N 6HG

info@pscinitiative.org

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BREAK

Conference resumes at 15:05. Please come back in 10 minutes.

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Drive "*Corporate Social Responsibility*" *along with "Social Audits" …*

Dinesh Subhedar

Group Third Party Risk Management -Labour Rights (India and West Asia)
Novartis, Mumbai, India

24th November, 2020

AGENDA

Why “social audit” in emerging world?

How social audit is conducted?

Which are the issues treated as Non Conformities

Case studies..

Social audit in modern era and during pandemic..

Q&A

Dinesh SUBHEDAR, Novartis – Mumbai

Dinesh Subhedar working with Novartis, Mumbai India as Third Party Risk Management – Labor and Human Rights group auditor for India and West Asian countries.

Dinesh has completed his management degree in Corporate Governance and Law from Pune university, India.

Dinesh has more than 18+ years and more than 5000 hours of social audits experience in the field of Manufacturing, public sector undertakings, information technology, chemical, petrochemicals and pharmaceuticals industry.

Why “social audit” in emerging world?

- **Corporate social responsibility (CSR) is taking on an ever more important role towards “Sustainability Development”.**

Enhance the organization’s image and gain a clear competitive advantage by demonstrating a responsible approach to social and ethical issues to deliver the value

It is especially important for business to apply an active and positive influence on the trust of your stakeholders such as customers, investors, procurement, regulators, suppliers & society.

Purpose of "*social audit*"...

Re-defines the inspiring purpose

Re-creates a Vision that is aspirational

Re-develops a strategy that creates a sustainable value

Re-builds a Winning Culture !

Social Compliance Audits. Nurturing Values...

Difference between "*social audit V/s other audits*"...

Financial Audit	Operational Audit	Social Audit
Directed towards recording, processing, summarising and reporting of financial data[3].	Establishing standards of operation, measuring performance against standards, examining and analysing deviations, taking corrective actions and reappraising standards based on experience are the main focus[4].	Social audit provides an assessment of the impact of a department's non-financial objectives through systematic and regular monitoring on the basis of the views of its stakeholders.

Principles of "*social audits*"...

- Aim to reflect on voices of all those stakeholders including families and individuals..

Multi Perspective..

- Aims to report on all aspects of Organizations work & performance..

Flexible, Comprehensive & Participatory

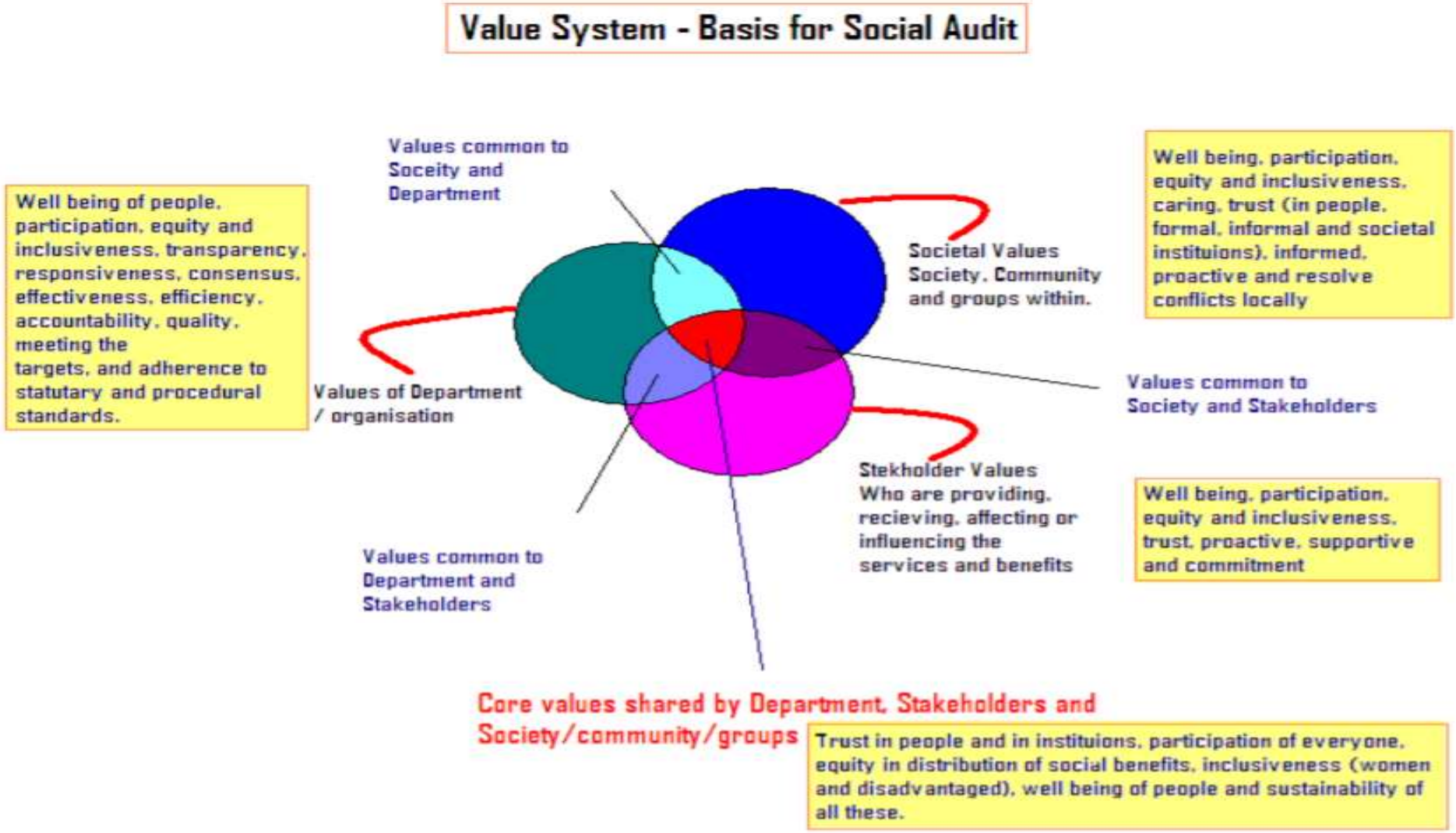
- Aims to produce social accounts on regular basis and provides comparison of its own improvement..

Regular & Comparative

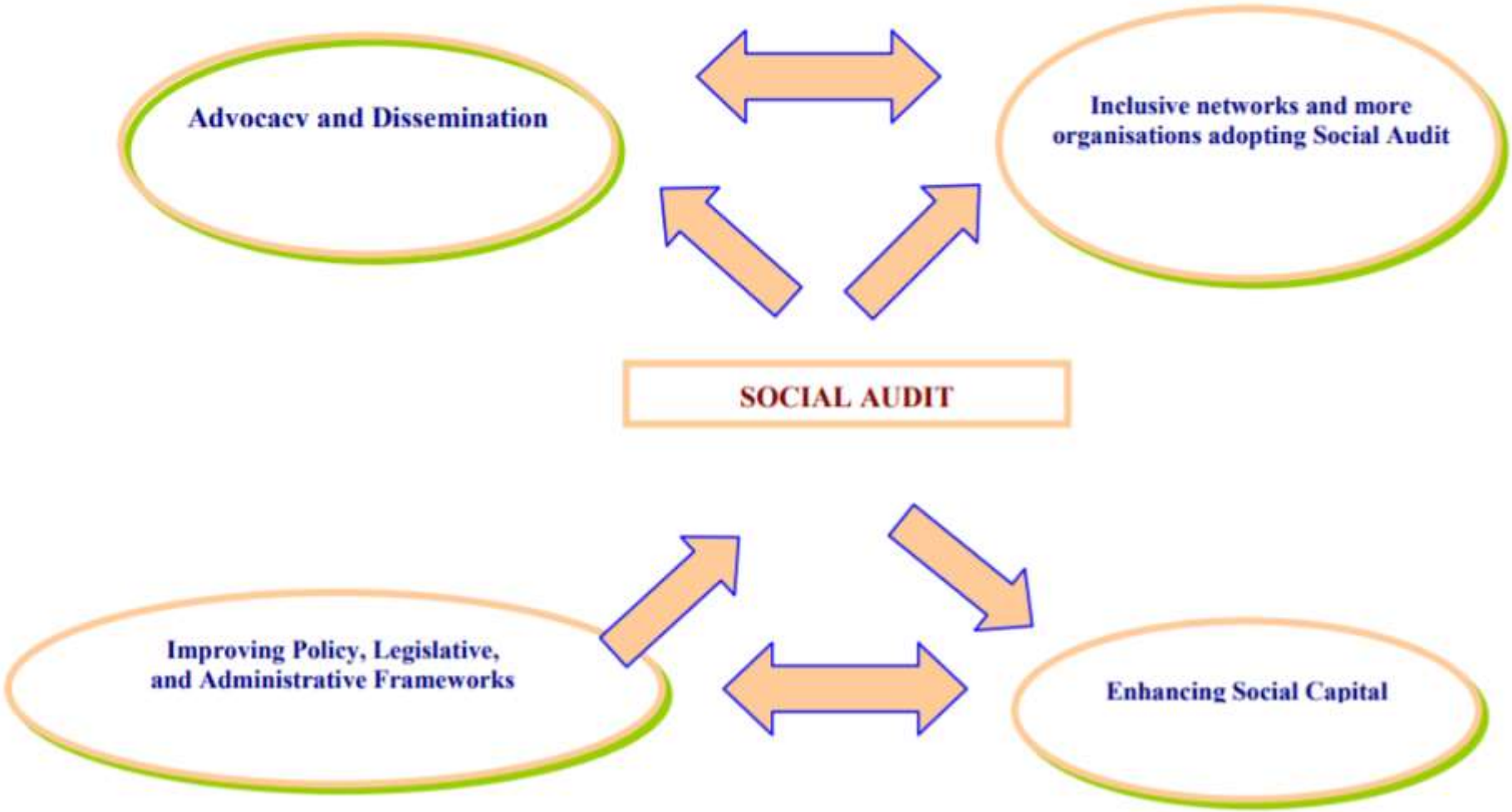
- Impartial assessment and audits by experts and brining accountability and transparency within society...

Verified & Disclosed...

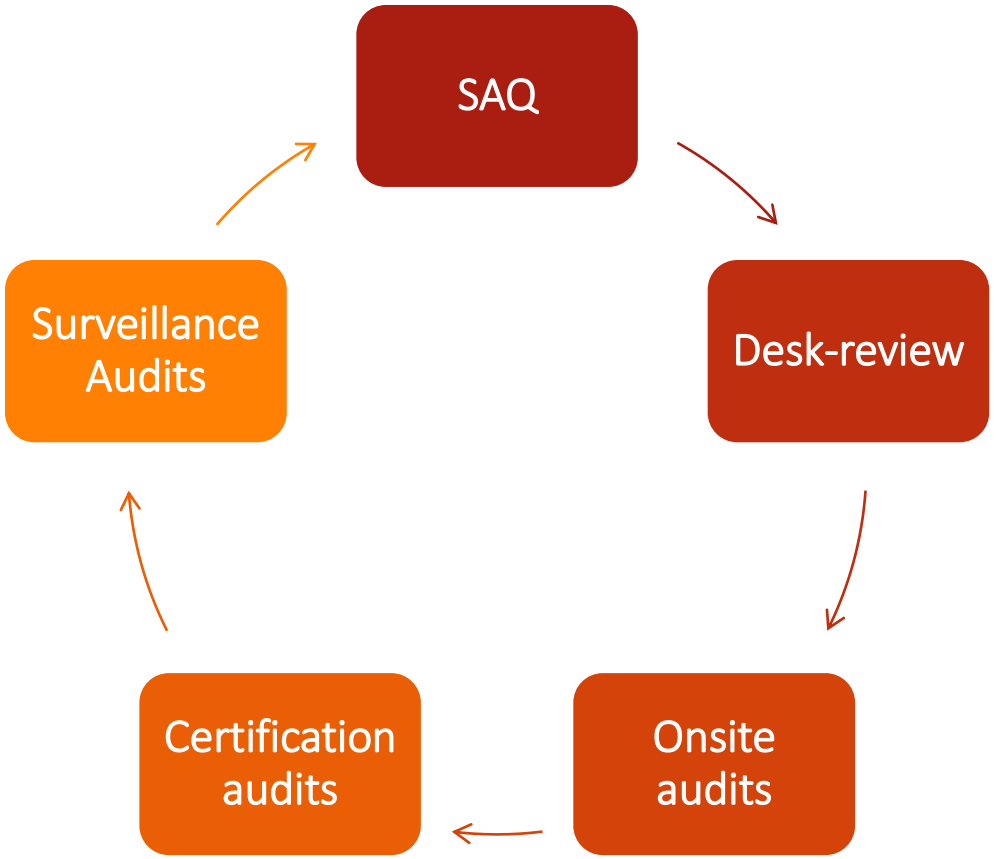
Value system "*social audits*"...



"Social capital"...



How social audit is conducted?

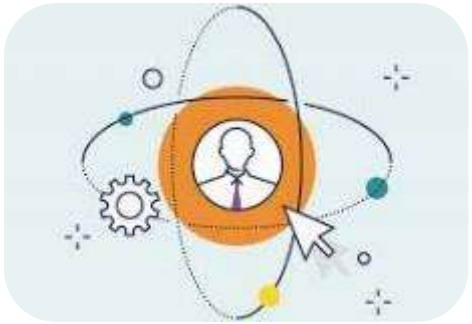


P D C A

- P – SAQ, Survey, Interview, Group Exercises
- D – Desk-review, On site audits
- C- Certification audits
- A – Surveillance audits

Steps in social audits..

Preparatory actions



Define audit scope and stakeholders

Social Accounting & Book keeping

Use of Social Accounts

Dissemination

Feedback of audit

How social audit is conducted?

Managing the audit program

- Establishing audit program objective
- Implementing audit program
- Monitoring audit program
- Review of audit program

Conducting an audit

- Feasibility
- Audit plan
- Document review
- Collecting and verifying
- Determining audit conclusions

Competence & evaluation of auditors:

- General
- Personal behavior and communication methods
- Knowledge and skills
- Feedback of auditors

Establishing auditor evaluation criteria:

- Selecting auditor evaluation method
- Conducting auditor evaluation
- Maintaining and improving auditor competence

How social audits are conducted?

Questionnaire, external agencies point / ratings

↓

Desk Review / Table Top Assessment

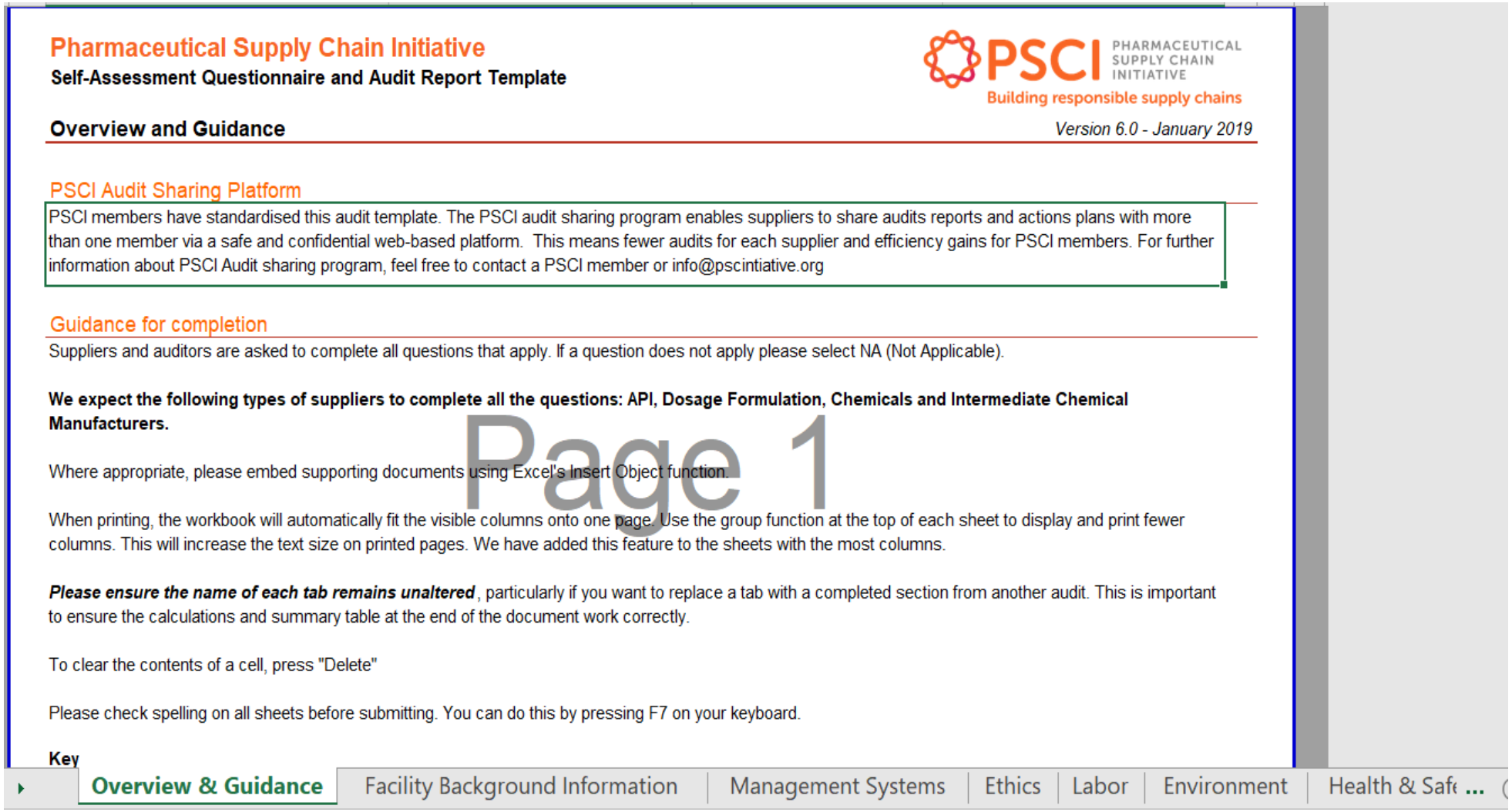
↓

Physical on site audit

↓

Virtual Audits

SAQ...expectations & challenges...



Pharmaceutical Supply Chain Initiative

Self-Assessment Questionnaire and Audit Report Template

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

Overview and Guidance

Version 6.0 - January 2019

PSCI Audit Sharing Platform

PSCI members have standardised this audit template. The PSCI audit sharing program enables suppliers to share audits reports and actions plans with more than one member via a safe and confidential web-based platform. This means fewer audits for each supplier and efficiency gains for PSCI members. For further information about PSCI Audit sharing program, feel free to contact a PSCI member or info@pscintiative.org

Guidance for completion

Suppliers 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.

Page 1

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.

Please ensure the name of each tab remains unaltered, particularly if you want to replace a tab with a completed section from another audit. This is important to ensure the calculations and summary table at the end of the document work correctly.

To clear the contents of a cell, press "Delete"

Please check spelling on all sheets before submitting. You can do this by pressing F7 on your keyboard.

Key

Overview & Guidance | Facility Background Information | Management Systems | Ethics | Labor | Environment | Health & Safe ...

- Completeness & Adequacy
- Check Hold Points
- Verification & Validation
- CAP

SAQ...expectations & challenges...

Topic	Question Summary
Facility Information	**Is the facility located in a region that has experienced any of the following natural disasters in the previous 50 years (check all that apply)**
	Total employee population onsite (including temporary, part-time and contract workers)
	Migrant or Foreign Workers
	Total employee population onsite (including temporary, part-time and contract workers) **(Male and Female).** Full time employees/workers directly employed by the company Part-time employees/workers directly employed by the company Indirect, contract or dispatch employees/workers Employees/workers under the age of 18 Migrant or Foreign Workers Student workers (include students, apprentices and interns)
Management System	**Does the facility have any ethics, labor, environment, health and safety, management system accreditations, certifications, or awards?**
	OHSAS 18001 ISO 14001 ISO 50001 SA8000 **If other, please specify: Please make a mention for TFS, SEDEX or any other similar type of assessments or audits including self certification efforts or organization.**
Legal and Customer Requirements	Are there any historical major regulatory actions? - strikes, lockouts etc.,
	Does the facility have processes in place to enforce responsible business practices, aligned with the PSCI Principles, with their suppliers, i.e. Labor, Ethics, Environment, Health & Safety? (if yes - please present and explain).
	Is there a purchasing policy that ensures only approved suppliers are used? (if yes - please explain in detail to auditors).
	Are suppliers measured against the responsible business practice expectations? (on site audit / assessment?).
Risk Management	**Does the facility and/or company have policies and/or practices in place to risk assess their programs and potential business impacts?**
	Reputation risks (community impacts, waste discharge, etc.) Legal risks (environmental permits, fair wage practices, etc.) other methods
	Does the facility or company have a process to manage all changes (e.g. raw materials, processes, personnel non-GMP, facilities, etc.)? Ethics (CoC) Labour (standing orders) Organizational changes (any changes in procedures).
	Does the supplier have Business Continuity Management program in place to minimize the impact of potential business disruptions, including natural disaster?
	Are notification procedures/processes in place to inform customers when a crisis event occurs and a business continuity plan activated?
	In case of strikes, lockouts etc.,

SAQ...expectations & challenges...

Documentation	**Does the facility or company maintain documentation for the following:** Audit findings Injury and Illness Logs Worker Benefits and Pay Information Inspections by Regulatory Agencies Worker Complaints Performance Assessments Training Records
Training and Competency	**Are workers made aware of policies and procedures, and are they trained accordingly?** Please explain how policies and procedures are communicated and implemented: Please describe training in each of the following areas: Ethics: Labor: Environment, health & safety: Emergency preparedness/response:
General	**Does the facility or company have a policy(ies) (or statement of commitment) regarding labor practices? [effectiveness]** If yes, does the policy cover: Prohibition of child labor Freedom of Association, Non Harassment Non-discrimination Grievance mechanism Whistle blower reporting and anti-retaliation policy Freely chosen employment Anti-Human Trafficking Labor Broker Recruitment Fees/Deposits Freedom of Movement Recruiting and termination Wages, Benefits, Working Hours, Overtime Maternity / paternity leave Leave due to short term sickness Leave due to long term sickness Accident/medical emergency at work Whistle blowing
Freely chosen Labour	Has the company performed a risk assessment to determine if there are areas of their business at risk for forced, bonded, or involuntary prison labor?
Migrant Workers	Does the facility or company employ contract and/or migrant workers?

SAQ...expectations & challenges...

Child Labor and Young Workers	Does the facility or company ensure that no child labor takes place in their operations?
Non-Discrimination and Fair Treatment	Does the facility or company ensure that there is no discrimination in hiring, compensation, access to training, promotion, termination or retirement based on race, caste, national origin, religion, age, disability, gender, marital status, sexual orientation, union membership or political affiliation and is a corresponding policy in place?
Wages, Benefits, and Working Hours	Is overtime voluntary at the facility or company (except for legally defined situations of urgency or emergencies that require the full workforce)?
Freedom of Association	Are there mechanisms in place to allow employees and management to collectively express concerns and issues?
Logistics Subcontractors	What is the company's process for managing human rights risks at third party logistics (3PL) providers?

Case study..

Physical infrastructure for social programs

Benchmarking & Governance processes

Employee agreements / NDA / Non compete

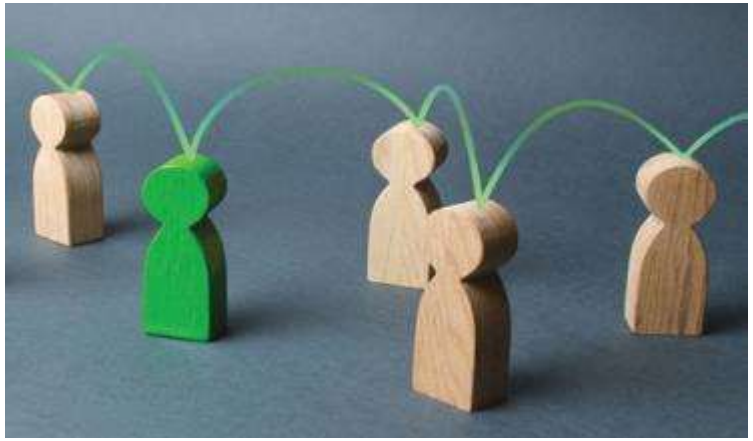
Illicit drug trafficking / contract labor issues

Supplier Improvement Programs

Issues may be treated as "Non Conformities"..

Identification of Stakeholders	How core values of an Organization are linked to Indicators?	Participation of stakeholders in improving objectives?	General Check list	How social indicators are being measured?
• Analysis matrix • Methods • Importance of stakeholders on projects • Degree of influence of stakeholders on projects.	• Value, Information areas and indicator • Society, department level values etc., • Identification of Indicators.	• Social objectives • Involvement level of stakeholders. • Existing practices • Activity V/s Impact analysis	• Policies / Goals • Legal support • Core Values • Planning • Monitoring mechanism • Intent of SL Teams • Budget	• Mechanism for measuring the indicators? • Relevance • Scope • Usability • Performance • Targets

Experience on Virtual Social Audits...July, 2020



- Execute tasks remotely
- Preparations
- Document review
- Interviews
- Dependencies

Questions and Answers...

Thank You...

CONTACT

pscinitiative.org

info@pscinitiative.org

Annabel Buchan:
+44 (0) 7794 557524

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Durham House
Durham House Street
London
WC2N 6HG

info@pscinitiative.org

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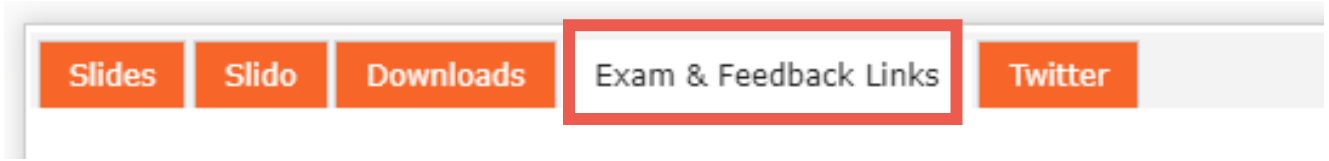
Exam (20 mins) & Feedback survey

Please **scan below QR Code** OR click at links under "**Exam & Feedback Links**" tab on Live Stream page to access exam & feedback survey.



Exam QR Code

Feedback survey QR Code

We recommend everyone to take the exam. Only auditors joining all the sessions and exams will receive certificates of participation.

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