

# Updated PSCI Audit/SAQ Templates and Audit Guidance

PSCI Audit Committee Sub team 'SAQ / Audit & Audit Guidance'

Gavin Loveday (Astra Zeneca), Birgit Skuballa (Bayer) & Noemi Molnar (Roche)

15<sup>th</sup> (Members) & 16<sup>th</sup> (Audit firms) February 2022

# Speaker and Team



Gavin Loveday
AstraZeneca
Sub Team Lead
SAQ/Audit & Audit Guidance



Noemi Molnar Roche



Birgit Skuballa Bayer

The team also wants to recognise significant (ongoing) support from the Carnstone team, in particular from:

Quqing Huang and Maggie Zhang

# Agenda

This webinar will cover the following topics:

# Updates to the SAQ/Audit templates

**Updates to the Audit Guidance document** 

Latest news from the Audit Committee, including a plan to move the SAQ online

Q&A

### Reminder: Importance of audits to the PSCI

- 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: Management Systems, Ethics, Human Rights/Labor, Health & Safety, Environmental Protection.
- The PSCI Shared 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.

# **Background: Updates to the SAQ/Audit templates**

- In preparation for moving the PSCI Self Assessment Questionnaire (SAQ) templates Online, a review / 'light' refresh was organized and lead by the SAQ / Audit & Audit Guidance Subteam.
- PSCI Topic Teams provided input to their relevant individual sections (Process Safety, PiE, AMR, Labour, Ethics etc.), whilst general sections (Facility Background Information, Management systems etc.) were reviewed / updated by the SAQ /Audit & Audit Guidance sub team.
- The review also considered best practices / improvements from other audit programmes, as well as input from PSCI Members, Audit Committee members, Audit Firms and Auditees.
- Proposed changes to the template included:
  - Simplification of the Categorisation of Suppliers (Category A, B or C)
  - Rewording/ reworking of a number of questions
  - Removal of some redundant questions/sub-parts
  - Addition of a limited number of new questions
  - Additional Auditor Guidance comments for multiple questions

# **Background: Updates to the SAQ/Audit templates**

- The Final draft version of the proposed new (Excel) SAQ was posted in October 2021 for a wider review by PSCI Members, seeking specific feedback or proposals for significant additional changes for consideration, ahead of publication.
- Following some additional changes/updates (and functionality checks), the final updated Excel template versions (both Full and Abbreviated, Versions 8.0) went 'Live' on 1st January 2022.
- Work is underway to complete translations of the new Excel templates in to Chinese (complete), Japanese, Spanish and German.

Note: As discussed and informed previously, the Word versions of the SAQ have not been updated and will be removed completely from the end of March 2022.



NEW VERSIONS RELEASED: PSCI SAQ/AUDIT TEMPLATE & AUDIT GUIDANCE

### Updates to the SAQ/Audit templates - Key Changes (I)

- Rewording of "coverage" to 'What is the scope of this PSCI Audit?'
  - HSE & Labour/Human Rights & Ethics & Management Systems (i.e. 'Full' audit)
  - HSE & Management Systems Only
  - Labour/Human Rights & Ethics & Management Systems Only

Note: ALL sections of the SAQ should always be completed, even if not audited.

- Standardisation on Audit Finding Categorisation method
  - Where previously there was a choice of categorisation method, either Critical / Other or Critical / Major / Minor, the only available option now is **Critical / Major / Minor**
- Simplification / clarification of the Categorisation of Suppliers (Category A, B or C)
  - All Categorisation has been reviewed and further options added in each category (see next page)
    - Category 'A' suppliers (Service Providers & Suppliers of non-supply chain goods) will use the Abbreviated SAQ
    - Category 'B' supplier (Component & Material) & 'C' (Core Suppliers and Contract Manufacturers) will use the Full SAQ
- Throughout the SAQ, Auditor Guidance notes/questions have been added/updated to provide additional clarity for Auditors (these notes also provide useful reference for Auditees as to what Auditors will be looking at).

### Updates to the SAQ/Audit templates - Key Changes (II)

# **Previous** Examples for "A", "B" and "C" Suppliers



### **Updated** Examples for "A", "B" and "C" Suppliers

### Category A: Service Providers and Suppliers of non-supply chain goods.

Facility & Engineering Services Temporary Labor Agency Travel & Fleet services

IT Services or hardware supply Other Materials (e.g. Marketing, Lab Equipment, Garment)

Other Services (e.g. Marketing, Research, Catering)

### **Category B: Component & Material Suppliers**

Raw Materials Waste Facilities Waste Water Treatment Medical Devices
Packaging Materials Energy / Power Generators Construction Services
General Manufacture (e.g. Non Chemical) Secondary Packaging
Logistics / Warehouse (no open handling of chemical materials)

### **Category C: Core Suppliers & Contract Manufacturers**

Pilot Plants Contract Research Labs API (Active Pharmaceutical Ingredient)

Chemicals Biologics Primary Packaging Finished Formulations

Animal facilities (breeding, testing)

Logistics / Warehouse (open handling of chemical materials)

### Updates to the SAQ/Audit templates - Key Changes (III)

### Key changes to the **Facility Background Information** tab:

Rewording and additional clarifying question

Is the facility located in a region that has experienced any of the following natural disasters which have had a direct impact on the facility (check all that apply):

If the facility was impacted by any of the above, did it cause a business interruption and was the Business Continuity Plan activated?

If so, please provide details of each interruption:

Moved from Management systems tab:

Is the facility included in any management system certification schemes, such as ISO 14001:2015; ISO 45001:2018; ISO 50001:2018 etc.

If so, please provide details including dates of most recent assessment(s), expiry date(s) and validity of certification:

Is the company/facility a member of any organisation or initiative that promotes sustainability? If so, please provide details:

### Updates to the SAQ/Audit templates - Key Changes (IV)

### Key changes to the **Management Systems** tab:

■ New Questions 1, 2 & 13 (note: Question numbering refers to the latest Full Excel template)

1	Has the facility demonstrated commitment to the concepts described in the PSCI Principles (covering Management Systems, Ethics, Human Rights & Labor, Health and Safety and Environmental Protection)?
i.	Are relevant aspects of the Principles incorporated into annual business plans?
ii.	Is appropriate resource allocated and are accountabilities known, clearly defined and communicated?
iii.	Do the concepts of the Principles appear in documents and in communications to employees, contractors and suppliers?
2	Does the company have the required legal licences/permits for its operations, such as a valid business licence?
	If so, please provide details of licence/permit number(s), expiry date(s) and validity:
13	Does the company have an incident management and reporting system established, covering for example certain types of incidents, reporting lines, consequences and corrective actions required?
	Does the site apply a systematic root cause investigation process to ensure that true causes are identified?
	Please provide brief description:
	Are corrective actions identified for the incident(s) and are they tracked to implementation and closure?

Changed wording in main questions and/or changes in sub-parts in Q 3, 4, 5, 6 & 11

### Updates to the SAQ/Audit templates - Key Changes (V)

### Minor changes to the **Ethics** tab:

- Combined previous Q 12 & 13 (now Q 14)
- Changed wording in main questions and/or changes in sub-parts of Q 14 & 16

Key changes to Labour tab (now renamed Human Rights & Labour):

New Question 18

<mark>18</mark>

Does the facility or company have a publicly available policy or statement committing to respect for Human Rights, in accordance with internationally accepted standards i.e.

- OECD Guidelines
- UN Guiding Principles on Business and Human Rights
- Removed previous Q30 (Logistics Subcontractors)
- Changed wording in main questions and/or changes in sub-parts in Q 17, 19, 20, 22, 24, 26, 28 & 29

### Updates to the SAQ/Audit templates - Key Changes (VI)

- Key changes to the **Environment** tab:
- Additional sub-part questions for management of process wastewater

i. Pretreatment of process water Please describe method(s) (example – hydrolysis with caustic or heat pre-treatment): ii. On-site wastewater treatment: Please describe: Does the facility collect, store, and analyze samples of: Wastewater? Sludge? iii. Discharge to an offsite treatment facility: Please describe off-site treatment method (example – biological treatment followed by activated carbon filter): iv. Discharge to a settling/retention pond: Please describe: V. Discharge to surface water (e.g., river, lake, ocean): Please describe: vi. Collection and transfer to an off-site wastewater management facility/company: Please describe: Vii. Other, e.g. Zero liquid discharge, wastewater for irrigation, evaporation via cooling tower, incineration; deep well injection: Please describe:  Viii. Are risk assessments conducted and controls established to minimise discharge of APIs into the environment?.  Are API residues in wastewater quantified? Please describe method of quantification e.g. mass balance calculation, sampling with sufficiently sensitive methods etc.?		
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Changed wording in main question of Q 34, 39

### Updates to the SAQ/Audit templates - Key Changes (VII)

- Key changes to the Health & Safety tab:
- New Questions 51 & 60
- Does the site engage employees on Safety & Health issues through Unions, Worker Committees or any other worker voice mechanisms?
- Are there valid procedures for operations, tasks or use of equipment on site detailing the safety precautions required?

 Changed wording in main questions and/or changes in sub-parts in Questions 68-77 (Occupational Health and Industrial Hygiene section)

### Updates to the SAQ/Audit templates - Key Changes (VIII)

New Questions 78-83 (Occupational Health and Industrial Hygiene section)

<mark>78</mark>	Are safety showers and eye-wash equipment installed and easily accessible, especially from work stations involving hazardous chemicals handling?
<mark>79</mark>	Does the company ensure that medical care for the employees is provided in case of emergency?
<mark>80</mark>	Does the site provide well-stocked and maintained first aid boxes in relevant areas (e.g. manufacturing, offices, warehouses etc.)
<mark>81</mark>	Does the company have any further medical facilities (e.g. doctors room) on site?
<mark>82</mark>	Does the company have trained First Aid Responders and/or Medical Professionals?
	Please describe:
83	Has the facility developed and implemented a plan to protect First Aid Responders and Medical Professionals from exposure to body fluids?
	Please explain:
	Does the program include:
i.	Training?
ii.	Exposure response kits regularly checked?
iii.	The offer of Hepatitis B vaccinations?

• Changed wording in main questions and/or changes in sub-parts of Q 54, 58, 61, 63, 84, 85, 86, 95 & 100

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## **Updates to the SAQ/Audit templates - Summary**

- The updates made in the PSCI SAQ templates serve as a baseline to build an Online SAQ (project ongoing, under initial testing)
- Thanks to the input from multiple parties and the work of a small, dedicated team over a period of 9+ months, agreed changes were made to the Excel template at the end of 2021 and include:
  - Simplification of the Categorisation of Suppliers (Category A, B or C)
  - Rewording/ reworking of a number of questions
  - Removal of some redundant questions/sub-parts
  - Addition of a limited number of new questions
  - Additional Auditor Guidance comments for multiple questions
- The updated Excel template versions (both Full and Abbreviated, V8.0)
   went 'Live' on 1<sup>st</sup> January 2022.
  - The existing Word versions of the templates (Full, Abbreviated, CAPR) have not been updated and will be removed completely from the end of March 2022.



# **Updated SAQ/Audit templates - Next steps**

- The simplification of the Supplier Categorisation has led to a reduction in the number of questions for the Abbreviated SAQ (Category 'A' Suppliers) down from 71 to 59. This results in:
  - reduced audit time and better time management opportunities
  - notably shorter SAQ, mainly from the streamlining of Environment and Health & Safety areas
  - less time and effort from the supplier to fill out → higher engagement as the audit scope feels more fitting
- The questions in the Full SAQ (Category 'B' and 'C') increased slightly from 98 to 106. This results in:
  - some additional questions on Occupational Health and Industrial Hygiene section
  - increased scrutiny to keep our audit protocol up-to-date on high standards of the mentioned area

### Recommended next steps for PSCI Members

- Start using the updated SAQ for new audits in 2022.
- Continue to use PSCI recommendations on how to classify audit findings

# Recommended next steps for 3<sup>rd</sup> party Audit Firms and Auditors

- Engage your PSCI client in a conversation to use the updated SAQ if not yet done.
- Share this webinar with auditors to update them on the changes.

# Agenda

This webinar will cover the following topics:

**Updates to the SAQ/Audit templates** 

### Updates to the Audit Guidance document.

Latest news from the Audit Committee, including a plan to move the SAQ online

Q&A

### **Updates to the Audit Guidance document**

- The audit guidance document provides a detailed overview on
  - how to carry out a PSCI audit
  - the processes and the roles/ responsibilities at each stage of the process.
- The Audit Guidance was reviewed and updated in December 2021 to align with the changes to the SAQs.
  - Updated to reflect changes to Supplier Categorisation, classification of findings only as critical/major/minor (and added link to <u>finding classification guidance document</u>) and remove reference to the now withdrawn OHSAS 18001

Note: References to the Word versions of the SAQ templates have been retained, until access is removed at end 1Q22. A further update will be made at this point to remove these references.

Link - <u>PSCI audit guidance</u>



**PSCI** Audit

Report and

Action Plan

**PSCI** Audit

Execution

Pre Audit Activities

Announcement and

Sharing of

**PSCI** Audit

Report and

related

Documents

Follow up

on CAP

# Agenda

This webinar will cover the following topics:

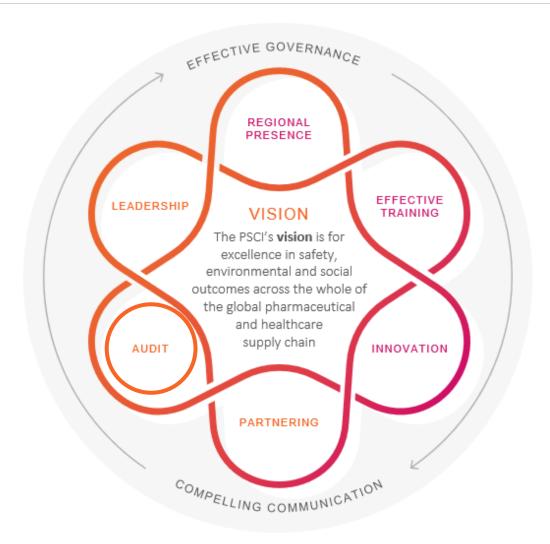
**Updates to the SAQ/Audit templates** 

**Updates to the Audit Guidance document** 

Latest news from the Audit Committee, including a plan to move the SAQ online

Q&A

# **Audit Committee Objectives**



2021-2023 STRATEGY
THREE OBJECTIVES FOR AUDIT

- Promote consistency, quality and innovation in all aspects of supplier evaluation and audit
- Exponential growth in the number of suppliers sharing information via the PSCI
- Create a community of excellent auditors

AUDIT COMMITTEE
SUB TEAMS







### How we work

### **AUDIT COMMITTEE CO-CHAIRS**



BIRGIT SKUBALLA
Baver

ROY AGOSTINI
Mallinckrodt

### SAQ/AUDIT AND AUDIT GUIDANCE

#### **GAVIN LOVEDAY**

AstraZeneca

- Light refresh of SAQ
- Move SAQ Online
- Review/rationalise pre-audit document checklist

### **AUDIT SHARING**

#### ANDREI KATSKO

#### KAREEN SAUNIER

Pfizer

Novartis

- Increase audit sharing by 20%
- Promote Supplier Self-initiated Audits (SSIA)
- Improve quality of shared audits and introduce qualitative metric around the satisfaction of users

### **AUDITOR TRAINING**

#### DANIEL REHM

**FLORIAN HILLER** 

Elanco Animal Health

Roche

- Virtual on-demand auditor training
- Execute on audit firm oversight
- Explore options for approved auditor model & roadmap

Supported by the Carnstone Secretariat team

# Latest news from the Audit Committee, including a plan to move the SAQ online

- Initial work completed to establish potential online workflows, provisional ways of working, functionality requirements etc. and address issues such as differing audit scopes (HSE, Labour & Ethics; HSE Only; Labour & Ethics only), finding classification; Supplier Categorisation versus mandatory questions; inconsistencies between the current SAQ and the platform; verification method by question not sheet etc.
- It was agreed that the 'build' stage should commence only once the changes/updates to the SAQ had been finalised.
- The updated SAQ has been provided to the developer and work commenced to build an online version on the Link.
- The team had an opportunity to view the work to date in mid-January 2022.
- Following completion of the 'build', extensive testing will be carried out by the team during 1Q22.
- A roll-out plan will then be agreed, along with appropriate communication and training, during 2Q22.
- Official launch of the online version is targeted to take place around the middle of 2022.

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the SAQ online

Q&A

### CONTACT



pscinitiative.org



info@pscinitiative.org



Annabel Buchan: +55 (11) 94486 6315



**PSCI** 



### For more information about the PSCI please contact:

#### **PSCI Secretariat**

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

info@pscinitiative.org

+55 (11) 94486 6315

#### About the Secretariat

Carnstone Partners Ltd is an independent management consultancy, specialising in corporate responsibility and sustainability, with a long track record in running industry groups.

