![PSCI - Pharmaceutical Supply Chain Initiative - Building responsible supply chains]

PSCI Shared Audits

What have we learned about our suppliers and how it impacts our Capability Building efforts

Shelly Shope

Elanco Animal Health

Capability Committee Co-Lead

Speaker Bio

- Shelly Shope

- HSE Sr Advisor, Elanco Animal Health
- PSCI Capability Committee Co-Lead

PSCI audit sharing program

- **Audit sharing program** allows suppliers to be assessed against the standards agreed by PSCI members and enables suppliers to share audits with multiple members via a web-based platform. This means fewer audits for each supplier and efficiency gains for our members.

- It **covers five areas** listed in PSCI Principles: Ethics, Labor & Human Rights, Health & Safety, Environment and Management Systems.

- It is **applicable to ALL suppliers** in the Pharma supply chain.

- It **works in tandem with our capability building program** to support continual improvement of our suppliers.

- To take part in a PSCI audit, please visit: https://pscinitiative.org/sharedAudits

ETHICS　　**HUMAN RIGHTS AND LABOR**　　**HEALTH AND SAFETY**　　**ENVIRONMENT**　　**MANAGEMENT SYSTEMS**

A: SERVICE PROVIDERS & GENERAL MANUFACTURERS

| Fleet | Professional Services | IT Equipment | Garment Suppliers |
| Catering | Tier 2 Suppliers | Advertising | Stationary |

B: COMPONENT & MATERIAL SUPPLIERS

| Raw Materials | Packaging Components | Devices |
| Waste Facilities | Energy Operators | |

C: CORE SUPPLIERS & CONTRACT MANUFACTURERS

Pilot plats	Pharma packaging operators
R&D labs	Formulation suppliers
AFI / Intermediate suppliers	Animal testing facilities

PSCI audit platform overview

Until July 2020	644 Registered suppliers	442 Uploaded audits	67% Audited within 3 years	66% Shared audits	2200+ Audit downloads

- Steady growth of audit uploads in the past three years (2017-65, 2018-122, 2019-122). With the presence of pandemic, suppliers are encouraged to take virtual audits and close corrective actions in 2020.

- Over 65% audits are from core suppliers, such as, API, finished formulations and chemical suppliers.

- Around half of the audits are from suppliers in China (21%), India (15%), and the US (11%).
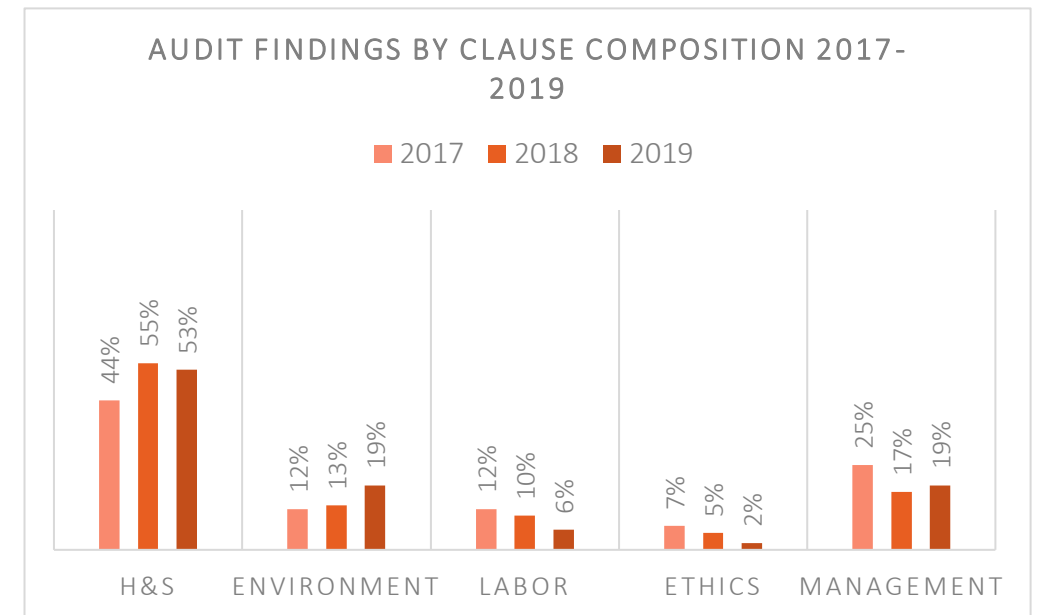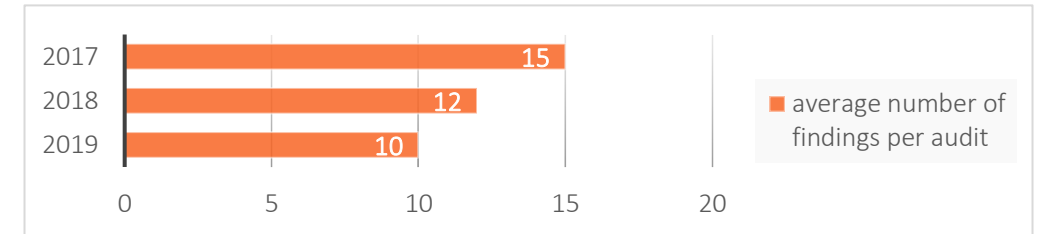
Audits distribution (until July 2020)

Numbers of audits

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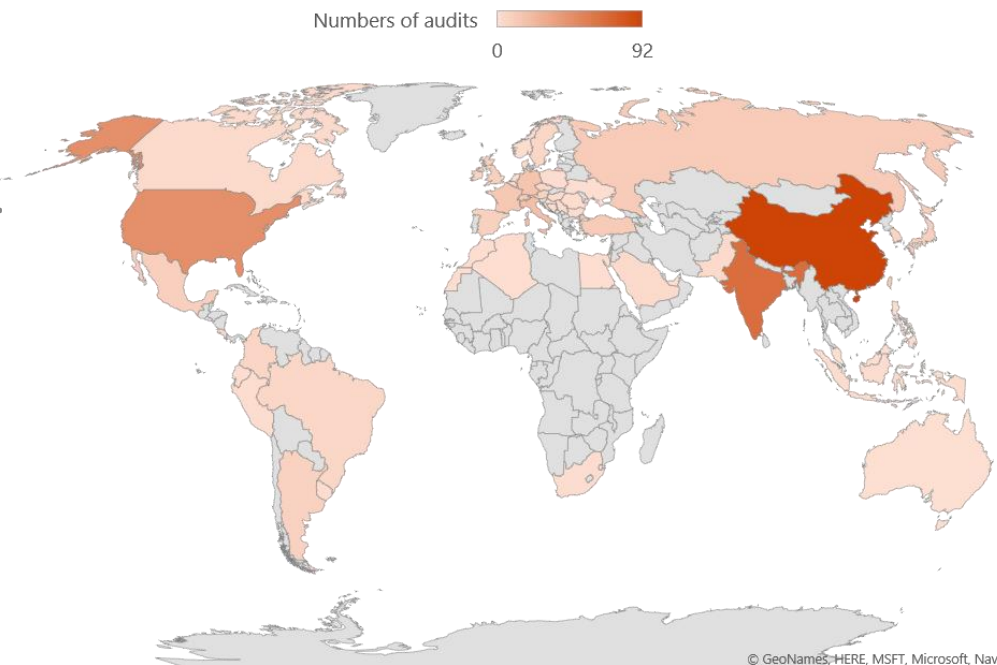
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Audit Findings Analysis (2017-2019)

- Average number of findings per audit tends to decrease over the years.

- H&S has always been the area with most findings, which occupies over 50% of the findings in 2019, followed by Management System and Environment.

- The presence of Environment findings has been growing over the past three years.

- Percentage of Labor and Ethics findings are going down annually, together consist of 8% of findings in 2019 - reasons behind this could include increased number of HSE audits, qualifications of auditors etc, or the emphasis on HSE focused audits vs Comprehensive audits (HSE + Ethics/Labor).

2017   15
2018   12
2019   10

average number of findings per audit

AUDIT FINDINGS BY CLAUSE COMPOSITION 2017-2019

■ 2017   ■ 2018   ■ 2019

	H&S	ENVIRONMENT	LABOR	ETHICS	MANAGEMENT
2017	44%	12%	12%	7%	25%
2018	55%	13%	10%	5%	17%
2019	53%	19%	6%	2%	19%

Audit Findings Analysis (2018-2019)

- Over 70% of the findings are found in **API, Chemical and Finished Formulations suppliers**, half of them are from **China and India** (2018-2019).

- Topics/subclauses with most findings:
  - #1 -H&S:
  - #2 - Environment:
  - #3 - Management System:
  - #4 - Labor:
  - #5 - Ethics:

- Around 1% of total findings are critical findings every year.
  - Many suppliers & members opt not to share audits while they are closing critical findings – which may explain why it is low

- 2018 Audit process expanded to add formal "Major/Minor" categories

- **Critical findings are found in H&S, Environment and Labor in the past two years**, but not in Ethics and Management System.

Critical = immediate attention required

Finding classification	2017	2018	2019
Critical*	1%	1%	1%
Major	4%	16%	14%
Minor	2%	22%	44%
Other	92%	61%	42%

Top Critical & Major Findings…if you have these issues also please <u>proactively focus</u> on them

- **Health & Safety:**

  - #1: **Exposure & PPE:**
    - Risk to employees not acceptable and/or No risk assessment to pharmaceutical dust
    - PPE is inadequate, insufficient or employee/contractors not trained

  - #2: **Safe to Work programs** have significant gaps:
    - Significant gaps in grounding/bonding/electrical classification; no Arc flash assessment
    - Confined space permit not evident or exists but not completed based on permit review
    - No Lockout/tagout program and no Contractor Safety approval process or training
    - Machinery on walkthrough are missing guards with no SOP to work on them
    - Hot work permits show evidence of not following policy on check-backs etc
    - Pallet racks show visible danger to personnel from falling hazards

  - #3: **Process Safety**
    - HAZOP not done or recommendations not implemented with no plan
    - Significantly missing process safety information on basis for safety of reaction
    - No combustible dust hazard assessment with high energy unit ops and dust collectors
    - Inerting practices & procedures inadequate on inerting (charging tanks, drums, vessels and milling)

  - #4: **Emergency Response**
    - Emergency equipment and alarms not functional/not maintained
    - Missing emergency equipment in high hazard areas, no smoke detectors or other fire protection alarm
    - Drills don't cover all employees and not learning recorded or acted on

For major learning - call into the <u>free</u> India/China Safety, PSM, and IH webinar series on 19 October 2020

Top Critical & Major Findings…if you have these issues also please proactively focus on them

- Environmental:
  - #1: **Spill Control / Leaks**
    - No secondary containment for hazardous chemicals or haz waste or overfill on underground tanks
    - Spill kits not available or no spill procedure
    - Visible evidence of past or current leaks on ground
    - Release valves not connected to a collection system for treatment before discharge
  - #2: **Wastewater**
    - Site has not measured its compliance parameters or exceeds a parameter or has missed required frequency of monitoring
    - Site has not assessed its API discharge impact to the environment
    - Site has sludge which is not properly stored to protect spill, exposure, or discharge
  - #3: **Hazardous Waste**
    - lack hazardous waste disposal record;
    - empty solvent drums disposed without cleaning
    - quantity of hazardous waste generation is higher than consent quantities by agency
    - Full chemical barrels stored on soft soil in scrap yard without weather or spill protection
    - Waste burned on site without license and/or Non-authorized vendors used to handle hazardous waste
  - #4: **Permits**
    - Missing permit for a plant within the site
    - Permit applied for but not received and operation started

> For major learning - call into the <u>free</u> India/China Environmental webinar series on 24 September 2020

Top Critical & Major Findings...if you have these issues also please proactively focus on them

- Human Rights/Labor:
  - overtime working for excessive hours without sufficient pay as per law
  - taking deposit for workers
  - records related to wages, benefits and working hours were not available
  - no policy regarding labor practice; no written form
  - no child labor policy or not keeping employee age proof records

- Ethics:
  - No refresher training for ethics training
  - No formal grievance process

For major learning - call into the <u>free</u> India/China Ethics and Human Rights/Labor webinar series on 15 October 2020

Top Critical & Major Findings...if you have these issues also please proactively focus on them

- Management System:
  - No BCP program or BCP not tested and outdated
  - No oversight of CAPAs including investigation of incidents
  - No Management of Change for HSE
  - No process to evaluate your own Suppliers for HSE
  - Ineffective self-auditing to ensure practice matches policy for HSE programs (based on other findings)

Sept 17th learning focus

Why do we find the Critical and Major issues?

What can PSCI do to promote a stronger HSE culture and HSE Management System?

Post a PSCI audit – do you seek to understand the root cause of the gap? Or just fix that one issue found?

PSCI Audit Resources: Under What we do…

Document ABBREVIATED PSCI SAQ & AUDIT REPORT TEMPLATE FOR SERVICE PROVIDERS & GENERAL MANUFACTURERS (EXCEL VERSION) >	**Document** ABBREVIATED PSCI SAQ & AUDIT REPORT TEMPLATE FOR SERVICE PROVIDERS & GENERAL MANUFACTURERS (WORD VERSION) >
Document AUDIT GUIDANCE FOR PSCI AUDITS >	**Document** CORRECTIVE ACTION PLAN TEMPLATE (WORD VERSION) >
Document AUDIT GUIDANCE FOR PSCI AUDITS >	**Document** CORRECTIVE ACTION PLAN TEMPLATE (WORD VERSION) >
Document DATA SHARING AGREEMENT >	**Document** FULL PSCI SAQ & AUDIT REPORT TEMPLATE FOR CORE SUPPLIERS, EXTERNAL MANUFACTURERS, COMPONENT AND MATERIAL SUPPLIERS (EXCEL VERSION) >
Document FULL PSCI SAQ & AUDIT REPORT TEMPLATE FOR CORE SUPPLIERS, EXTERNAL MANUFACTURERS, COMPONENT AND MATERIAL SUPPLIERS (WORD VERSION) >	**Document** PRE-AUDIT DOCUMENT REQUEST LIST >
Document PSCI AUDITOR EVALUATION TOOL >	**Document** PSCI SHARED AUDIT PROGRAM BROCHURE >

PSCI E-LEARNING TOOL

We have created the e-learning tool to help member companies and suppliers to understand the Principles. The tool is available freely to all.

☐ VISIT SITE
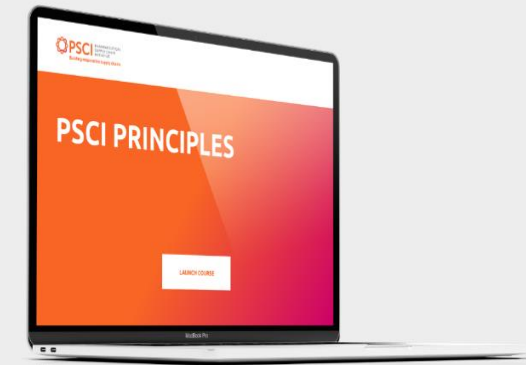
APPROVED AUDITORS

In order to ensure quality and integrity, *PSCI Audits* are carried out either by qualified internal auditors working at PSCI member companies or by professional and independent third party audit firms.

PSCI has approved twelve professional, independent third party audit firms to perform *PSCI Audits*:

Audit resources can be found on PSCI website: https://pscinitiative.org/sharedAudits

CONTACT

pscinitiative.org

info@pscinitiative.org

Annabel Buchan:
+44 (0) 7794 557524

PSCI

@PSCInitiative

For more information about the PSCI please contact:

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

info@pscinitiative.org

+44 (0) 7794 557 524

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.

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