

Audit Findings Analysis Report



Welcome from the Audit Committee

We are delighted to share our first public Audit Findings Report and the insights within.



Birgit Skuballa
Bayer

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Common and shared approaches to auditing is at the heart of the PSCI's mission and drives the core of our focus on audit quality. We are pleased that the PSCI auditing tools have become a recognized industry framework for a range of audits for suppliers in the pharmaceutical and healthcare sector, and that we continue to see growth

in the quantity of PSCI audits being conducted year-on-year. Our audits reflect the PSCI Principles and are carried out by approved audit firms or qualified PSCI Member internal auditors. Via our shared audit platform, members and suppliers can gain efficiencies on audits and we can track supplier maturity and improvement over time.

As part of our goal to promote consistency, quality, and innovation in all aspects of supplier evaluation and audit, we analyze PSCI audits conducted and uploaded on our shared platform on an annual basis. This report shows what we've found by analyzing 3,500 findings from 339 PSCI audits conducted during 2020-2022 and uploaded to the PSCI platform by the end of 2022. We are specifically interested in understanding how the findings are distributed across the five areas of the PSCI Principles*, our blueprint for responsible supply chain management and foundation of our tools. This analysis gives us visibility over how findings are changing over time and our impact on the industry.

In this report, you can see the results of a deep dive analysis into each area, focusing on 1,955 findings from 195 PSCI audits uploaded by the end of 2022. These findings reveal key risks, areas for improvement, and opportunities for PSCI members to support their suppliers to improve their practices. They also provide us with a high-level understanding of regional differences and levels of maturity, allowing us to provide regionally specific support on hot topics through our capability building work and begin to understand our own impact on the industry. We hope you enjoy reading these insights and findings.

The PSCI Principles



Ethics



Human Rights
& Labor



Health
& Safety



Environment



Management
Systems

*The PSCI Principles were updated in May 2023 after this analysis had been conducted in line with our previous Principles and sub-topics.

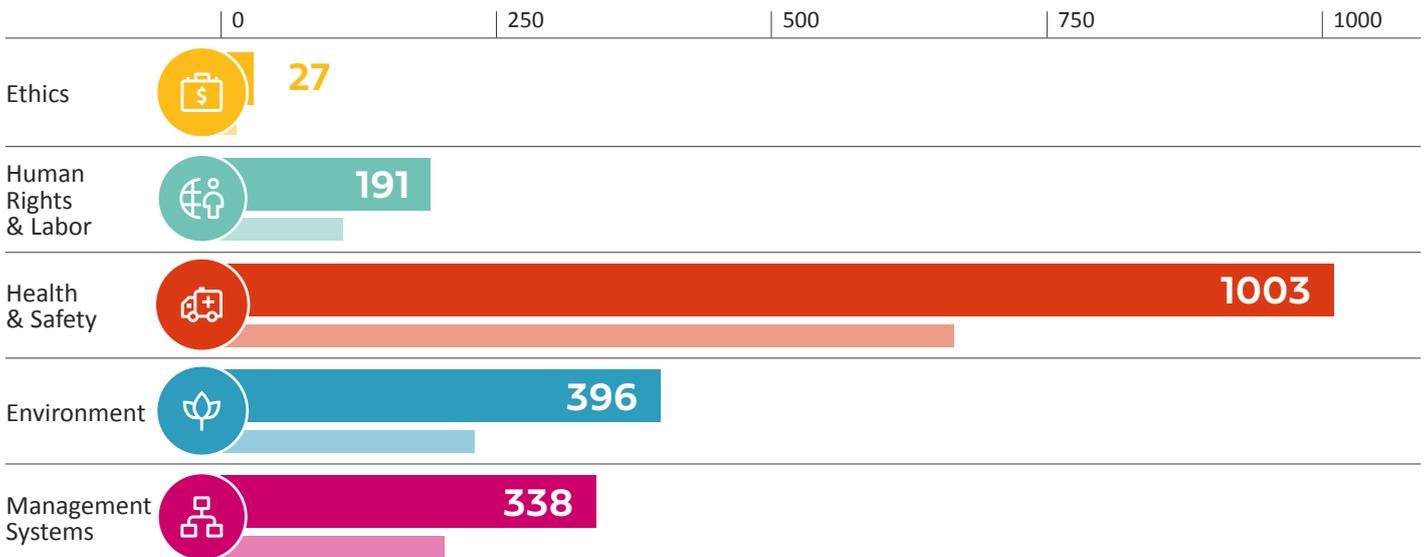
Audit Findings Analysis

Every year, we analyze the findings from audits on the PSCI platform under the relevant topic areas of the PSCI Principles. This gives us visibility over how audit findings are changing over time and our impact on the industry.

Health & Safety continues to be the area with most findings, reflecting the most common areas of concern for members (almost all audits include Health & Safety, but not all include other topics like Labor and Ethics).

2022 audit findings

Change in share of total 2022 (solid) vs 2021 (tint).



These include HSE, Labor and Ethics audits, HSE only audits, and Labor and Ethics only audits.

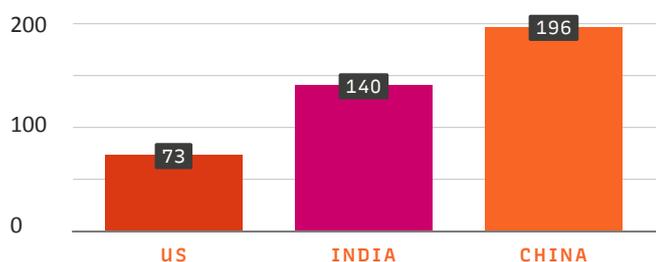
Total number of audit findings in 2022

→ **1955**

Main three Audit Findings topics

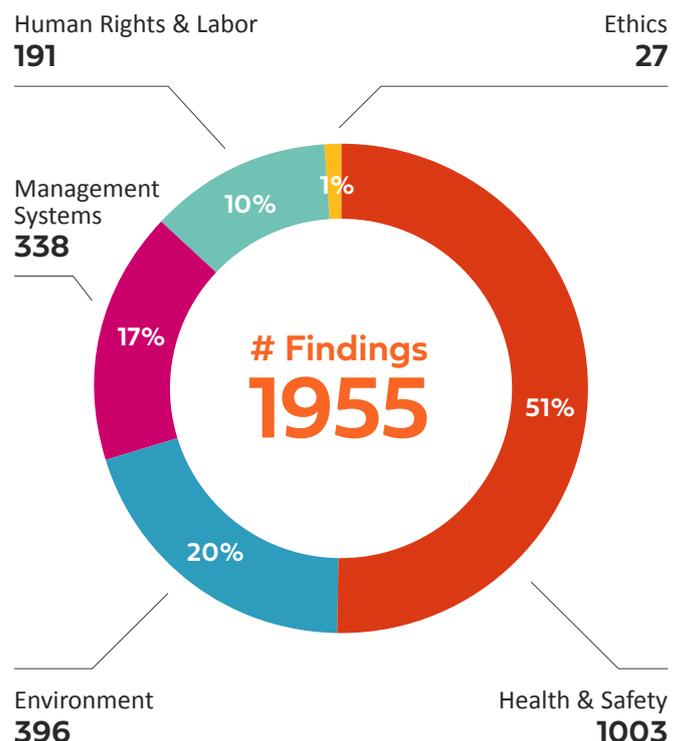
- Occupational Health and Industrial Hygiene**
 Health & Safety
- Hazardous Substances Environmental Risk Management**
 Environment
- Wages, Benefits, and Working Hours**
 Human Rights & Labor

Principal Audit Countries*



*Cumulative number of audits on the platform 2015-2022

PSCI Audits uploaded in 2022



Methodology

We undertook an in-depth qualitative and quantitative review of 3,500 findings from 339 PSCI audits conducted during 2020-2022 and uploaded to the PSCI platform by the end of 2022. The deeper dive analysis found later in this report analyzed 1,955 findings from 195 PSCI audits uploaded by the end of 2022. In both reviews, tags and sub-tags were assigned to each finding. These tags and sub-tags allow us to slice topics (e.g. electrical safety) even thinner and therefore capture more detailed risk points (e.g. whether an arc flash analysis has been conducted).

This level of detail provides our members with an accurate map of suppliers' practices against the PSCI Principles and where there may be specific areas to address. For example, our deep dive into Health & Safety findings identified 30 risk areas and captured more than 100 specific risk points.

Scope

Audits included in the analysis were PSCI audits uploaded to the PSCI platform by the end of 2022. These include PSCI audits covering all principles (HSE + Labor & Ethics) or parts of them (HSE or Labor & Ethics). This analysis does not include non-PSCI audits on the platform, or PSCI audits which have not been uploaded to our platform. In the future our aim is that all PSCI audits are uploaded to our platform in order to allow us to continue to drive responsible practices across the supply chain.

Number of suppliers covered

950+

Findings from 2020-2022 audits

3,500

Principle Audit Countries



What we found

Health & Safety continues to be the area with most findings (approximately 50%), followed by Environment (around 20%). This is partly because, in addition to the audits covering all five Principles areas, there are a higher number of PSCI audits only covering Health & Safety and Environment (HSE) sections than those covering only Labor & Ethics (L&E).

Among audits conducted in 2021, the number of Environment findings surged to account for 23% of all findings, an 8% increase on 2020 figures. Along with the increase, we see growing attention directed towards Indian suppliers' environmental performance, especially relating to the management of process wastewater / sludge and hazardous substances including active pharmaceutical Ingredients (APIs).

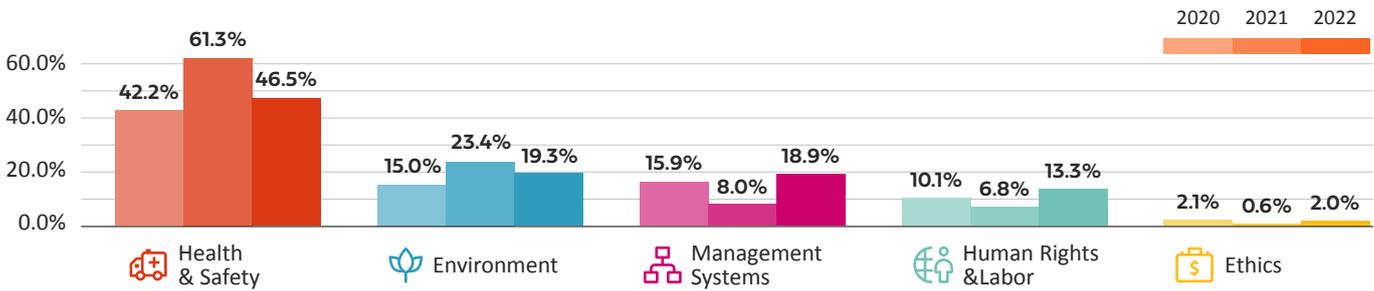
Among audits conducted in 2022, we see a slight increase in the number of L&E findings and a slight decrease in the number of HSE findings. Despite this change, HSE findings still account for 66% of all findings conducted in the year. A possible contributing factor to the increase in L&E findings is that auditors were able to conduct more on-site audits again (with employee interviews).

“ The annual analysis of audit results carried out by PSCI not only provides information enabling the identification of the most important challenges faced by both PSCI members and suppliers, but also shows new challenges that we must be able to face. Thanks to the diversity and constantly increasing number of audits carried out, we have the opportunity to observe how the reality and the response of our suppliers to new regulations and requirements are changing. From the published results, we still see that most post-audit observations concern health, safety and environmental topics, however, over the last 2 years we have observed an increasing number of reported non-compliances in the areas of management and human rights, which clearly shows the growing awareness of the importance of issues also in these areas. The audit results give us the opportunity to collect and analyze information on the biggest challenges in ensuring a sustainable supply chain in the whole pharma sector. Together with the audit committee and other topic teams at PSCI, based on the acquired knowledge, we build and adapt our tools and training materials to better prepare ourselves and our suppliers for the constantly changing reality, new legal regulations and growing customer requirements. ”

Dorota WiqceK-Trojanowska
Senior Supplier Sustainability Audit Program Manager, Roche



Number of findings by year of Audit



Audit Findings by PSCI Principle

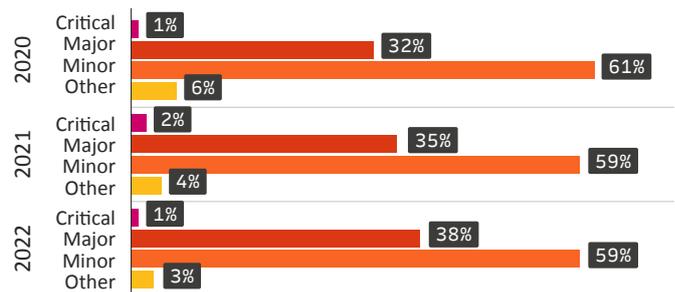
	2020	2021	2022	Average
Health & Safety	42%	61%	47%	50%
Environment	15%	23%	19%	19%
Management Systems	16%	8%	19%	14%
Human Rights & Labor	10%	7%	13%	10%
Ethics	2%	0.6%	2%	2%

We also identified hotspots and common areas for improvement, such as process wastewater and sludge management, and storage requirements for hazardous substances. Furthermore, it appears that auditors have been examining Ethics-focused topics such as data privacy, business integrity, and fair competition in greater detail than previously seen.

In general, the distribution of findings across the three classification categories* remain consistent with our previous analyses. As PSCI audits move towards embedding the use of

the ‘Critical - Major – Minor’ findings classification system, we expect a continued decrease in the use of the ‘Other’ classification. We further observed that similar audit findings are not classified by uniformly across supplier sites. Potential factors contributing to this include differences in supplier types, local regulation, and PSCI member requirements. The Audit Committee plans to review our Audit Finding Classification Guidance with examples to provide more support and clarity for auditors on findings classifications.

Audit Findings Classifications



Critical findings

Among the 35 critical findings identified in 2022, Environment is the area with most findings (54.29%), followed by Health & Safety (42.86%), reflecting an increasing concern on environmental issues. Only one critical finding is related to Management Systems, and no critical findings fall in the HR&L and Ethics area. Almost all critical findings were identified among supplier sites in India (34 out of 35), except one finding identified in Brazil.

The most common finding in the environment area is the lack of environmental permits and licenses (7 out of 19), including not complying with local laws, not obtained or renewed environmental permits, or the permits do not cover all discharged pollutants and emissions. The second most common area of critical findings is wastewater treatment and sludge management (5 out of 19), including not analyzing APIs and environmental risks in the effluent, and emitting waste containing toxic metals and acid at levels higher than permitted levels.

The most common finding in the Health & Safety area occurred in the safety permit system (7 out of 15), including the lack of clearly defined roles and responsibilities within issued work permits, and some necessary safety permits or certificates are missing for certain operations (e.g. entry into confined spaces). Another common critical finding is the lack of proper procedure for the storage of hazardous chemicals (3 out of 15).

The single critical finding related to Management Systems involves the failure to track and address audit and incident investigation findings for improvement.

* Critical Findings are very high-risk findings that require immediate action to protect human life, the health of employees, or the environment. Major Findings are findings that may pose major impacts to workers, the community, or the environment. Minor Findings are findings that may pose minor impacts to workers, the community, the environment. Other Findings are all other major or minor audit findings, which need to be corrected by the supplier in an appropriate period of time.



Health & Safety

649 findings

Worker protection and occupational health and industrial hygiene continue to be the two topics with most audit findings across audits uploaded in 2022 (consistent with 2021). They account for 30.6% and 25.8% of all Health & Safety findings, respectively and when combined account for more than half of all Health & Safety findings.

- Occupational risk exposure monitoring & control, including missing or insufficient information on Occupational Exposure Limits (OEL) / Occupational Exposure Banding (OEB) for APIs and hazardous substances (14%)
- Work permit systems, e.g. issues related to permits for confined space, energy isolation, Lock Out Tag Out (LOTO) (7%)
- Electrical safety programs, e.g. arc flash analysis not conducted (6%)
- Explosion risk assessment & engineering controls, e.g. EX zones not identified, risks with combustible dusts and powders not assessed, pressure relief valves not provided (6%)
- Pallet racking practices, e.g. stretch wrapping not provided or maintained (5%)



Environment

396 findings

Similar to previous analyses, waste & emissions as well as transport, storage & spill prevention continue to be the two topics with most findings. They respectively account for 47% and 32.5% of all Environment findings and, when combined together, account for 79% of all Environment findings.

- Hazardous substances storage and spill prevention, e.g. secondary containment not provided or capacity insufficient, leak detection systems not in place, improper storage of flammables (30%)
- Process wastewater and sludge management, including API risk assessment and mitigation (18%)
- Storm water management, e.g. insufficient retention capacity and contamination monitoring (10%)
- Environmental authorizations and permits not covering all discharged pollutants, not renewed after expiration, or not obtained in the first place (8%)
- Environmental objectives, goals, and roadmaps either not established yet or established but not specific and measurable nor being monitored and reported (7%)



Management System

338 findings

Supplier evaluation (22%), regulatory compliance (17%), and Business Continuity (17%) accounted for the majority of the findings in Management Systems area.

- Supplier evaluation system not aligned with the PSCI Principles or missing important components (22%)
- Regulatory compliance issues, e.g. permits or licenses not obtained or renewed (17%)
- Business continuity plans not established or missing important components such as recovery time objectives (RTO), mitigation measures, and business reputational risks (17%)
- Internal audits were either not performed or insufficient in scope, audits were not followed-up by corrective actions and proper reviews (13%)
- Employee training system does not cover Human Rights, Labor, Ethics; not providing regular, refresher training to all employees including contractors (10%)
- Risk assessment scope not covering key risks identified by the PSCI (8%)
- Management of Change not established or missing critical components (7%)



Human Rights & Labor 191 findings

Wages, benefits & working hours accounts for the highest number of findings (51%), followed by general issues related to policies, grievance mechanisms, and whistleblowing (21%).

- Overtime exceeding legal maximum, not properly recorded and compensated (26%)
- Human Rights and Labor policy does not cover important components required by local laws and/or the PSCI Principles, e.g. freedom of association, anti-trafficking, non-harassment (14%)
- Benefits and leave (e.g. maternity, family, annual, sick) not provided according to local laws (12%)



Ethics 27 findings

The largest area of findings was a lack of comprehensive Ethics policies at supplier sites (63%). Policies and codes of conduct were often missing elements around anti-bribery and corruption or fair competition.

- Business integrity and fair competition not covered by supplier site or company policy (63%)
- Improvement needs identified in the areas of data privacy and employee personal information confidentiality, especially in relation to grievance mechanisms and whistleblower systems (37%)



Measuring our Impact

The Question:

Can we see patterns in audit data that show positive change on suppliers due to their engagement with the PSCI?

The Scope:

4 API suppliers that uploaded multiple audits over the last five years.

The Method:

An in-depth qualitative review of 15 audits of five sites in China using the auditor comments and findings in each report.

The Findings:

Improved supplier practice. By learning the expectations embedded in the PSCI audit framework, suppliers have a more comprehensive view of sustainable supply chain practices. Notably, the sample suppliers have built in new risk assessment measures and developed internal policies, particularly around Ethics and Labor.

Driving improved practices in the supply chain

The PSCI aims to build responsible supply chains for the pharmaceutical and health industry in line with the PSCI Principles. Our Audit Tools enable the industry to support suppliers via a common framework and our complementary capability building work provides suppliers with expert guidance and resources to help improve their practices over time.

We're developing our approach to measuring our impact on the supply chain and in 2021 undertook an analysis on our audits to identify any positive trends. The initial results were promising and we plan to build on this in the future through stakeholder interviews with engaged suppliers and additional audit analysis.



A focus on China & India

A majority of PSCI audits and suppliers to PSCI member companies are based in China and India. For that reason, our analysis of the findings investigates audits conducted in each of the countries more deeply in order to identify common findings and provide insights for our members. As part of the PSCI's wider focus on supplier capability building and collaborative impact projects, we deliver annual conferences locally for suppliers in China and India, partner with national associations, and have regionally based Sub-Teams to ensure that expert, local knowledge is embedded into our approach.

We observe that, compared to Chinese suppliers, Indian suppliers on average show 10% more audit findings in the areas of Health & Safety and Environment. At the same time, Chinese suppliers show 13% more audit findings in Labor, especially around wages, benefits, and punitive fines.

In addition to differences in local policy and culture, a key contributing factor is the scope of the PSCI audits conducted on suppliers. Among all audits conducted on Indian suppliers and uploaded to the PSCI platform in 2022, up to a third of the audits only cover HSE areas, while less than a quarter cover Labor & Ethics only topics.

43%
of all PSCI audits uploaded in 2022 are for suppliers in China or India

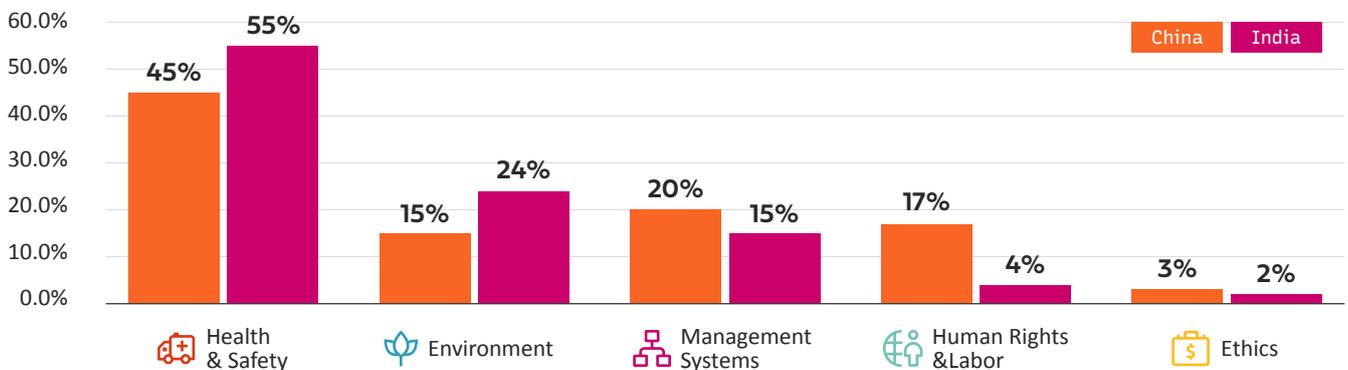
China - Audit findings uploaded in 2022

Health & Safety	157	45%
Management Systems	71	20%
Environment	53	15%
Human Rights & Labor	58	17%
Ethics	10	3%
Total findings	349	100%

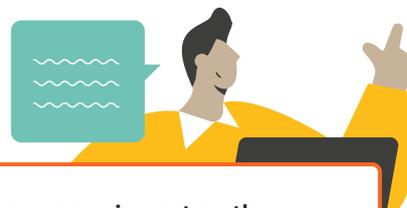
India - Audit findings uploaded in 2022

Health & Safety	388	55%
Management Systems	106	15%
Environment	170	24%
Human Rights & Labor	27	4%
Ethics	13	2%
Total findings	704	100%

Distribution of audit findings (2022)



Our plans for the future



2024

Increase the number of audits uploaded to the PSCI platform

Measure our impact on the industry via changes in audit findings

Maturity Models and resources available on our new e-learning platform, Learnster