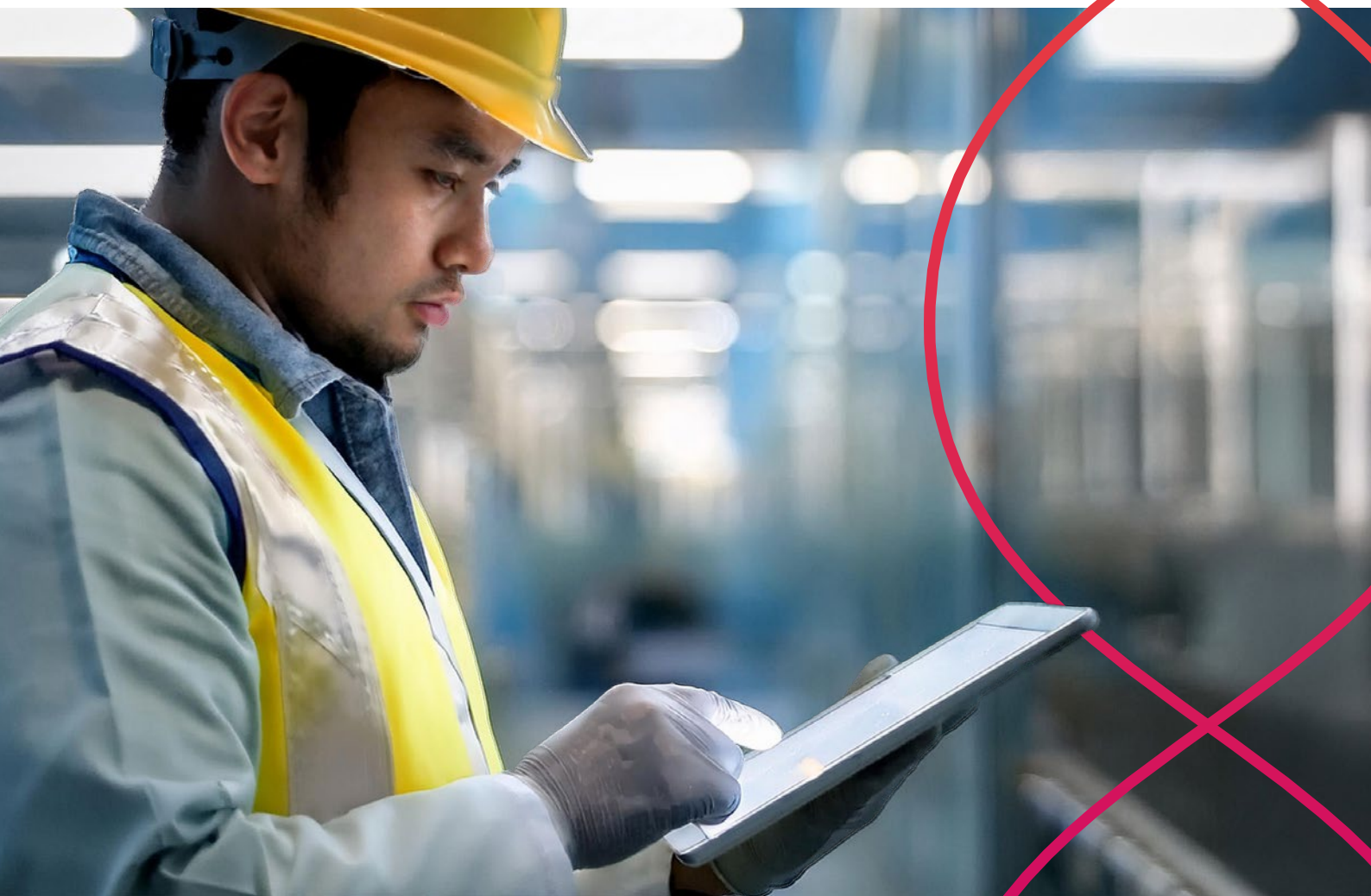
PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

Exploring the Pharma Supply Chain

Insights from the PSCI Audit Findings



Welcome

Audit Committee Co-Chairs

Birgit Skuballa Bayer
Roy Agostini Mallinckrodt

Every year, pharmaceutical and healthcare companies carry out thousands of audits around the world to ensure that their suppliers are meeting expectations around Health, Safety, and Environmental topics, amongst others. These audits represent a significant investment of time and financial resources both for the company and the supplier. At the PSCI, we aim to support companies and suppliers to collaborate on audits through our shared audit platform and framework. Through our platform, PSCI members can upload audits from their suppliers and share with fellow members. This creates efficiency, and more importantly redirects resource towards helping suppliers improve their practices.

This report shares our analysis of findings from PSCI audits available on our platform. Each year, we review these in line with the PSCI Principles and seek to identify trends, highlight improvements, and share recommendations. Overall, this analysis provides deep insight into supplier practices within the pharmaceutical and healthcare industry and guides us on developing targeted resources and trainings. This year's report analyzed 1,776 findings from 180 audits uploaded to the platform in 2023. Among these, there are 308 Management System findings, 7 Ethics findings, 169 Human Rights findings, 970 Health & Safety findings, and 322 Environment findings.

While this analysis identifies areas for improvement, it's important to emphasize its primary purpose: *to guide the development of targeted capability-building resources that support suppliers and foster a responsible supply chain*. PSCI audits are designed to identify opportunities for growth and improvement. By revealing on-the-ground practices and holding suppliers to high standards, we can create robust evaluation programs and capability-building resources to address common health & safety, environment, human rights, and ethical issues.

In this report, you can see a summary of the findings for each topic, as well as detailed breakdowns with recommended actions for suppliers and relevant PSCI resources.

You can also find a regional analysis focused on two major pharma manufacturing hubs, China and India, and our first-ever analysis by supplier type. Understanding our role in changes to supplier practices is of particular interest to us, so we conducted a deep-dive analysis of multiple audits from 13 suppliers over a three-year period. You can see a snapshot summary of this later on. Measuring our impact is an ongoing process and one that will evolve over time.

By sharing these findings and fostering transparency, we aim to empower suppliers to excel in responsible sourcing practices. We hope you enjoy our insights.

Sub-Team Leads

Audit Sharing

Mary Walsh
Pfizer

Audit Training

Birgit Skuballa
Bayer

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SAQ / Audit & Audit Guidance

Birgit Skuballa
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Methodology

We undertook an in-depth qualitative and quantitative review of 1,776 findings from 180 PSCI audits uploaded to the platform in 2023 to identify opportunities for development in suppliers' practices. The exercise involved reviewing each finding to assign relevant tags and sub-tags, allowing us to pinpoint the most prevalent points of concern and provide improvement support.

Scope

The PSCI Audit Findings Analysis includes audits uploaded to the PSCI platform during 2023. These include PSCI audits covering all Principles (Health & Safety and Environment [HSE] + Labor & Ethics) or parts of them (HSE or Labor & Ethics). These may also include audits conducted in prior years. PSCI Audits conducted by member companies but not uploaded to our platform, or audits conducted using non-PSCI formats are not included in the exercise. While this analysis offers valuable insights, it's important to note that it represents a partial view of the pharma supply chain. PSCI member companies employ various audit schemes to assess their supply chains, and the audits examined here represent a portion of the overall PSCI audit landscape. In the future, we hope to ensure that all PSCI audits are uploaded to our platform to allow us to continue driving responsible practices across the supply chain. For an analysis of audits uploaded before 2023, see our inaugural Audit Findings Analysis Report.

Classification of findings

When reviewing the number and severity of findings, it's important to acknowledge that increases in findings for certain areas do not necessarily reflect a decline in supplier practices. Several factors can contribute to these trends, such as auditor expertise[1], new regulations, or increased expectations, which may lead member companies to focus on different aspects during audits.

The PSCI Audit Guidance provides definitions and examples of classifying audit findings into critical, major, minor, and other based on the severity.

Critical Findings	Findings that are very high-risk and 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.
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 remark	Instances where the auditor wishes to raise an important comment, but this comment would not constitute any type of finding. Other Findings: Are all other major or minor audit findings, which need to be corrected by the supplier in an appropriate period of time.

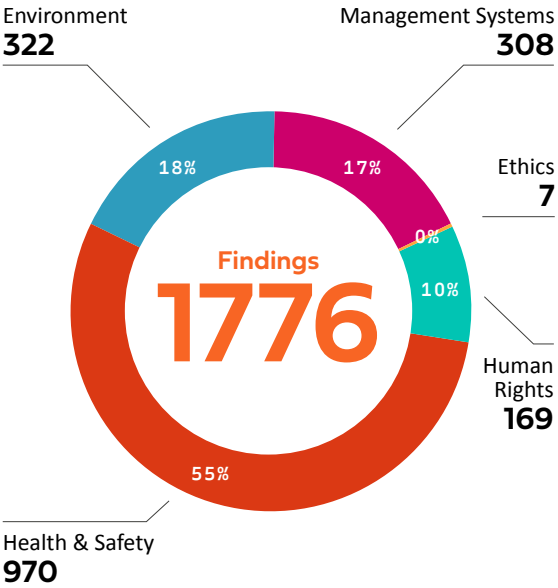
[1] PSCI audits can be conducted by PSCI member company auditors or approved third-party audit firms. Variations in training and background can influence audit styles and areas of focus. The PSCI actively provides training to ensure consistent audit quality across third-party firms.

Executive Summary

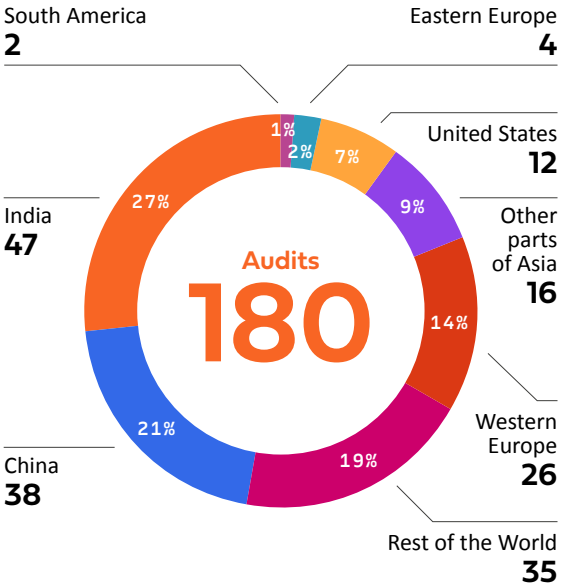
What we found

Overall, Health & Safety continues to be the area with most findings (55%), followed by Environment (18%). This is partly because, in addition to the audits covering all five Principles topics, there are a higher number of PSCI audits only covering Health & Safety and Environment (HSE) topics than those covering only Labor & Ethics (L&E).

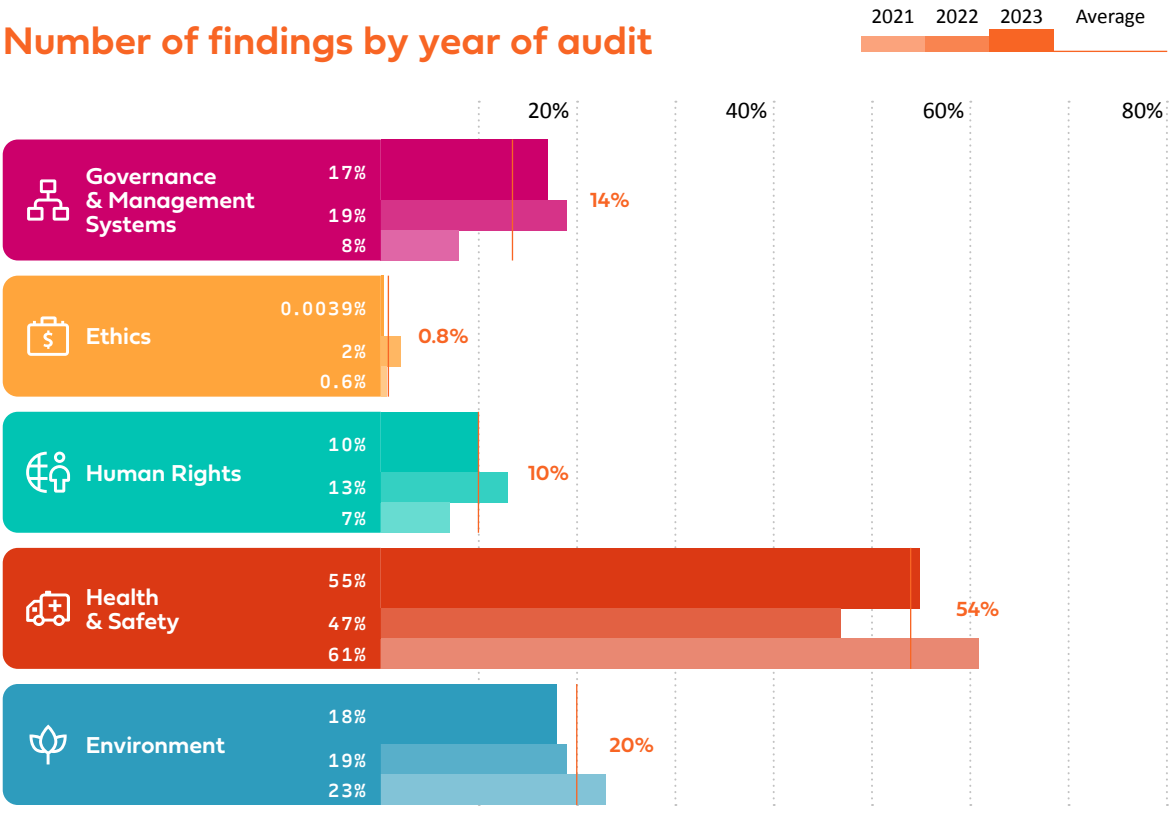
Findings by Principle



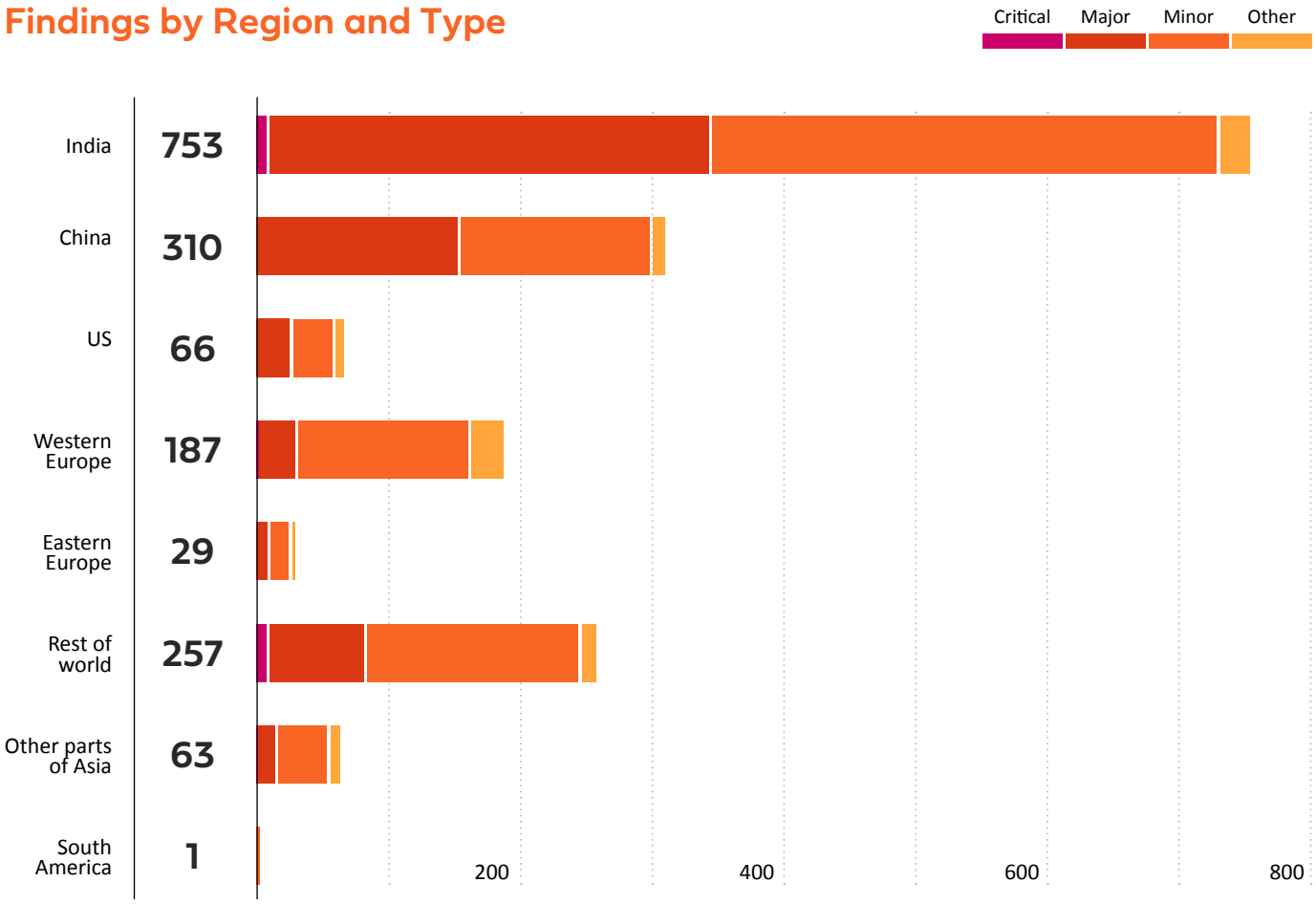
Audits by Region



Number of findings by year of audit



Findings by Region and Type



Findings

1776

Audits

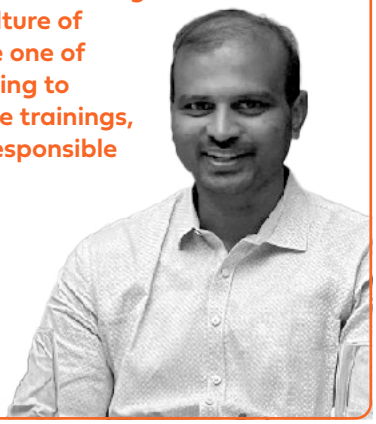
180

Audits from China and India

49%

"The annual analysis of findings from PSCI audits provides a greater understanding of the global and regional risks within the value chain. Our latest analysis indicates that Health & Safety continues to be an area for focus followed by Environment year-on-year. However, we also see significant focus on Human Rights & Management Systems, emphasizing the need for more robust and comprehensive policies. We widely encourage members and suppliers to upload audits, so we can keep enriching the database and striving for continuous improvement. An audit's main value is not based on its findings, but on how these insights are used and shared. Transforming data into dialogue fosters a culture of improvement. These results are one of the key pillars of the PSCI, helping to guide the prioritization of future trainings, projects, and tools that build responsible pharmaceutical and healthcare value chains."

Yathish Kolli
HSE Lead Auditor, Sanofi



Top Findings by Principle

Governance & Management Systems | 308

The majority of findings in this area reveal gaps in how suppliers manage risks. Specifically, many suppliers don't have systems to anticipate and plan for risks, do not adequately evaluate their own suppliers, and lack robust compliance systems.

- **Business continuity planning (BCP) | 91:** lack of documented business continuity procedures; opportunities to improve planning around risk assessments and communication procedures
- **Supplier evaluation | 62:** lack of assessment of upstream suppliers against responsible business practices; sourcing from sanctioned or conflict-afflicted regions
- **Risk management | 48:** exposure to unforeseen risks, e.g. business interruption, reputational damage, and ethical or labor risks

Recommendations for Suppliers

- Move beyond compliance and integrate management systems into core business functions.
- Evaluate upstream suppliers against responsible business frameworks.
- Establish continuous improvement cycle through period reviews and reports to management.

Ethics | 7

Ethics remains the area with the fewest audit findings. Those that were found related to Business Integrity, Fair Competition, and Privacy.

- **Business integrity & fair competition | 4:** lack of Codes of Conduct and Ethics policies; lack of widespread training
- **Data privacy | 3:** limited protection of workers' privacy and data; lack of General Data Protection Regulation (GDPR) policies.

Recommendations for Suppliers

- Develop, implement, and communicate Code of Conduct & Ethics Policies across the organization.
- Strengthen data management systems to protect the privacy of workers and operate in-line with data protection regulations such as the General Data Protection Regulation (GDPR).

Human Rights | 169

Issues relating to wages, benefits, and working hours, and Human Rights and Labor Policy are the top priorities to address based on the frequency of reported issues. Other notable areas include freely chosen labor, contract & migrant workers, and child labor & young workers.

- **Wages, benefits, and working hours | 73:** workers subject to excessive working hours beyond legal limits, inadequate overtime compensation, and negative impact on worker wellbeing; systemic payroll management issues
- **Human rights and labor policies | 35:** absence of policies around human trafficking prevention, grievance mechanisms, and freedom of association

Recommendations for Suppliers

- Strengthen Human Rights Policies within organizations and communicate these widely and in local languages.
- Increase awareness around child labor, forced labor, and the rights of contract and migrant workers and make commitments on these topics at the management level.

Health & Safety 970

Worker protection is a prominent issue highlighting concerns in occupational health and industrial hygiene, the management and enforcement of work permit systems, and safety concerns in specific practices such as pallet racking and identifying special storage requirements. Process safety also requires improvement, especially in terms of comprehensive process hazard analysis (PHA) and robust safety information management. Lastly, emergency preparedness and response draws attention to issues in emergency systems and response training, calling for better emergency planning and execution to effectively handle potential workplace incidents.

- **Occupational health and industrial hygiene | 222:** shortcomings in exposure monitoring and control, improvements in hazard assessments and protective equipment usage
- **Other worker protection | 161:** risks related to pallet racking, special storage requirements, pedestrian and material handling equipment aisles, machine guarding, contractor activity risk management, material handling equipment & elevation devices, trailer movement restraint during loading and unloading, and others
- **Emergency exits | 82:** shortcomings in emergency preparedness, such as drills and trainings, accessibility of exits, emergency response plans (ERPs), and emergency response teams

Recommendations for Suppliers

- Improve exposure monitoring and control practices, particularly through hazard assessments and consistent use of appropriate protective equipment.
- Implement and strengthen Process Safety Management systems through process hazard analysis (PHAs), risk assessments, and regular safety audits. Specifically for PHAs, suppliers should conduct detailed HAZOP (hazard and operability) studies, update safety information, and train staff on these measures and emergency response procedures.
- Review and update hazard classifications regularly and engineering controls.
- Upgrade fire protection systems in flammable liquid storage areas and regularly test fire safety equipment.

Environment 322

Waste and emissions management emerges as the area with the most findings in Environment, where inadequate hazardous waste storage and wastewater treatment practices are most concerning. Transport, storage, & spill prevention follows, highlighting gaps in the management of hazardous substances, especially insufficient spill prevention and containment measures. General Environmental policies and practices also present major issues, making up 19% of the findings, with gaps in implementation and monitoring.

- **Waste management (including hazardous waste and environmental risks) | 214:** secondary containment measures and poor labelling practices, leak detection and management, and hazardous chemicals management; inadequate management of APIs in wastewater, gaps in quantifying and controlling pharmaceutical contaminants, lack of comprehensive sewage, drainage, and treatment systems; lack of proper assessment and auditing of third-party waste treatment and disposal services
- **General Environmental policies & practices | 62:** incomplete policy implementation and reviews; lack of dedicated environmental policy and inadequate baseline environmental impact assessments to track performance or meet objectives

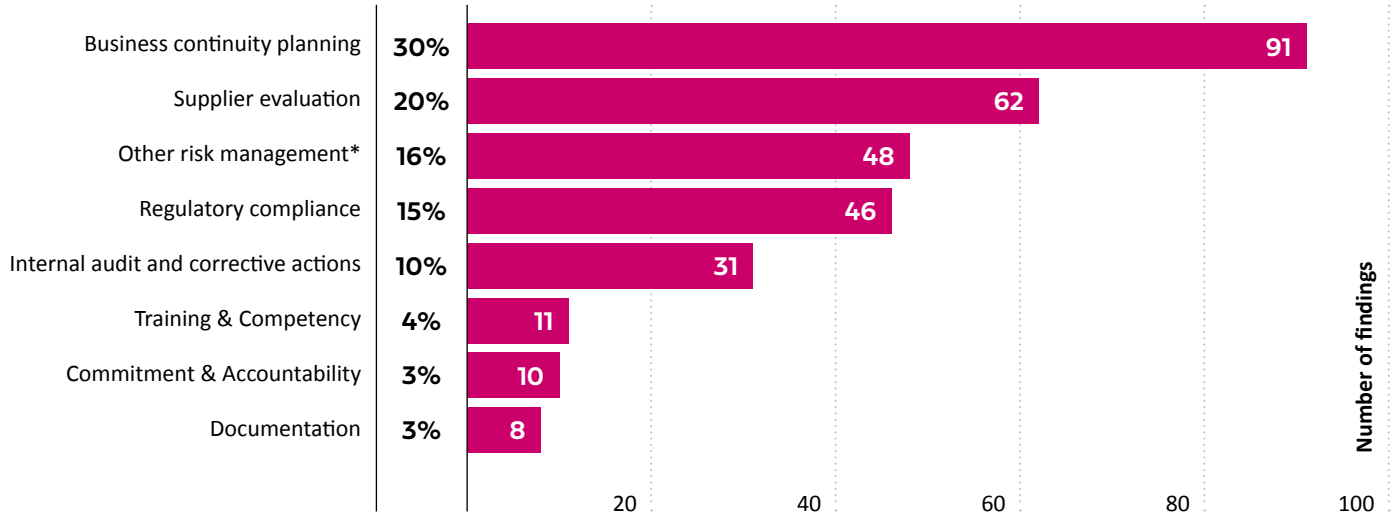
Recommendations for Suppliers

- Hazardous substances: Implement stricter controls and storage protocols for hazardous substances. Enhance leak detection systems and secondary containment measures to prevent accidental releases and pollution. Conduct regular risk assessments and audits.
- Wastewater and sludge management: Develop comprehensive strategies that include API handling and upgrades to existing sewage, drainage, and treatment systems. Introduce regular training for staff on the importance of wastewater management and the consequences of non-compliance.
- Waste disposal: Ensure all hazardous waste areas are properly labelled and managed. Strengthen oversight and internal controls to prevent non-compliance and environmental hazards. Conduct rigorous assessments and audits of suppliers' third-party waste treatment and disposal services to ensure compliance with environmental standards.
- General Environmental policies & practices: Develop & implement comprehensive policies with clear objectives, targets, and metrics. Communicate these across the organization and in local languages. Undertake periodic reviews & update policies and protocols based on performance, regulatory changes, and evolving best practices.

Detailed Findings by Principle

Governance & Management Systems | 308 Findings**

The majority of findings in this area reveal gaps in how suppliers manage risks. Specifically, many suppliers don't have systems to anticipate and plan for risks, do not adequately evaluate their own suppliers, and lack robust compliance systems.



* Other risk management includes risk assessment methodology & scope (26), change management (20), and security systems (2). The business continuity planning (BCP), while related to broader risk management, is analyzed separately due to the significant findings identified.

** There was one finding with an unclear description, which could not be categorized.

Business Continuity Planning

91 findings including 27 major ones highlight areas for improvement in Business Continuity Plans (BCPs). Many sites lack documented BCPs, leaving them unprepared for disruptions, or have plans that are inadequate, failing to address crucial aspects like risk assessments, supply chain disruptions, and communication procedures.

Supplier Evaluation Systems[2]

62 findings including 16 major ones reveal weaknesses, with many upstream suppliers not being assessed against responsible business practice expectations and the full scope of HSE, Labor, and Ethics often not being covered. Additionally, the evaluation of sourcing from conflict regions and civil war zones / screening business partners against international sanctions lists was more frequently discussed in auditor comments compared to previous years. This heightened focus likely stems from a combination of factors, including the shifts in the geopolitical landscape, evolving regulations and changing priorities within member companies in recent years.

[2] Supplier evaluation in this context refers to the assessment by pharmaceutical suppliers of their upstream suppliers or vendors (e.g. raw material providers and waste disposal vendors).

Risk Management
Risk assessments frequently lack comprehensiveness, not considering crucial areas like business interruption, reputational damage, and ethical / labor risks as indicated by 21 findings including 7 major ones. Suppliers are potentially exposed to unforeseen risks. Change management processes also exhibit weaknesses, with incomplete Management of Change (MoC) coverage and inadequate assessments such as not incorporating temporary change types.

Regulatory Compliance
A significant portion of findings within legal & customer requirements relate to regulatory compliance issues. These 46 findings include missing or expired permits, posing risks of production stoppages and sanctions; inadequate legal registers, which could weaken a supplier's ability to track legal requirements, potentially leading to violations and reputational damage; and non-adherence to specific regulations, mostly concerning safety.

Internal Audit and Corrective Actions
Internal audit and management reviews rarely cover the full scope as demonstrated by 17 findings including 4 major ones. Specifically: Labor, Ethics, and Human Rights are most often missing in the scope. Common issues of incident management and record keeping (13 findings) include ineffective root cause investigation processes and incident management and reporting systems (incomplete incident investigation may hinder effective root cause analysis and prevent learning from past incidents).

Trainings
6 findings including 1 major finding indicated that suppliers rarely provide training programs covering sufficient scope, particularly regarding Labor and Ethics. While HSE related trainings are generally in place, missing periodic refresher training on HSE topics can still pose a potential safety risk. Additionally, training not being provided in local languages creates a barrier to effective learning for some employees. Finally, maintenance of the training records can be improved.

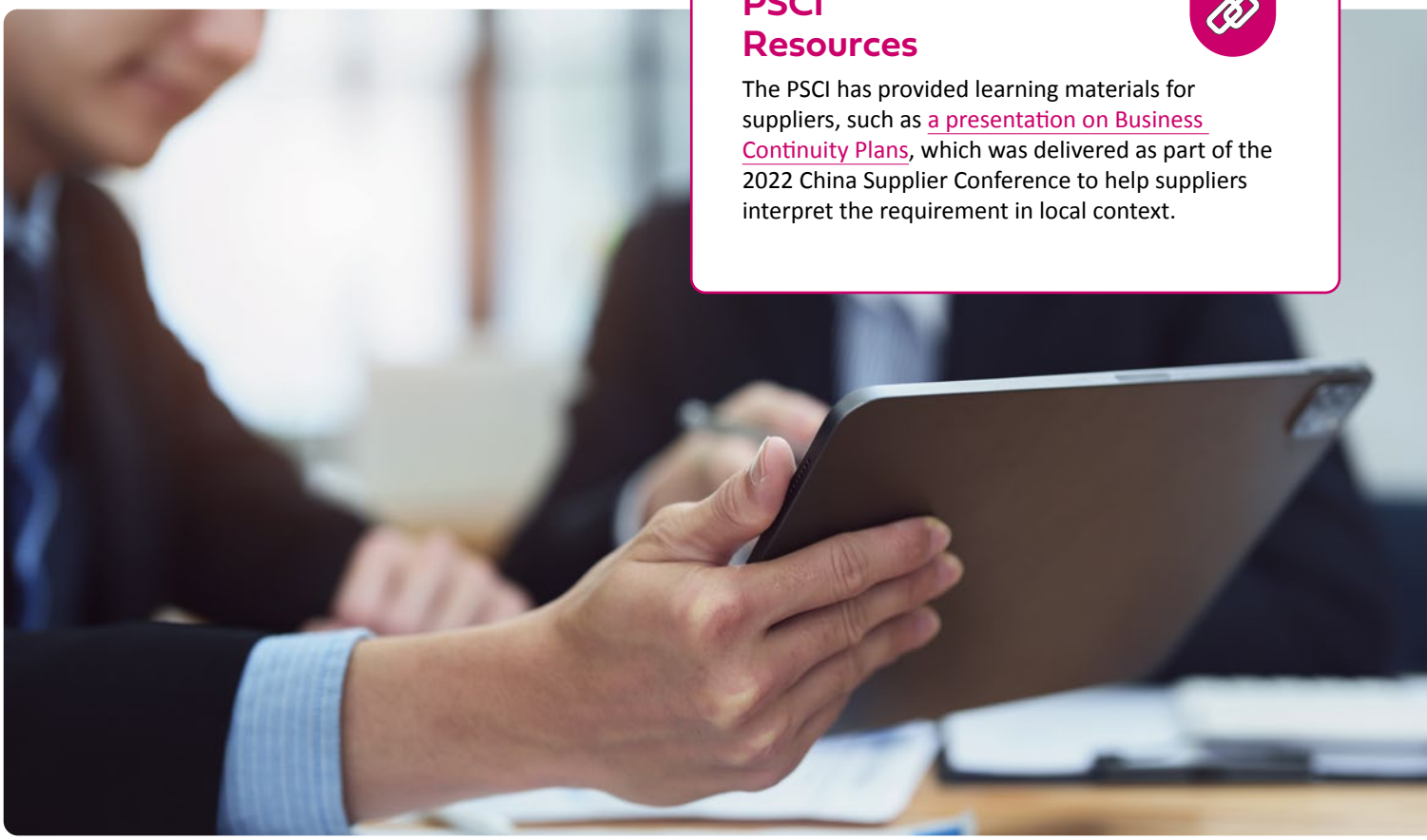
Recommendations for Suppliers

Suppliers can use the above findings to enhance their practices by integrating management systems into core business functions, moving beyond a solely compliance-driven approach. Suppliers with established systems are encouraged to evaluate their own suppliers against broader responsible business practice expectations, including HSE, Human Rights, and Ethics.

Additionally, consider continuous improvements through regular reviews, updates to management systems, developing internal audit processes, and improving documentation practices.

PSCI Resources

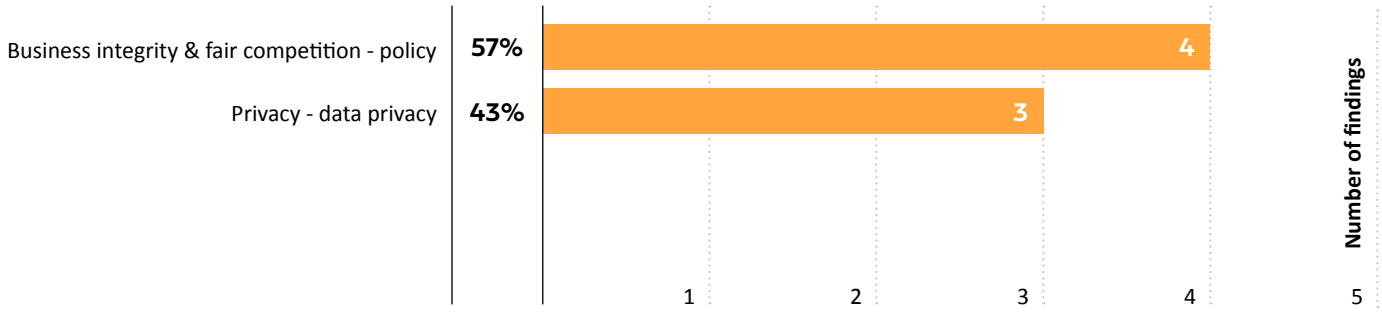
The PSCI has provided learning materials for suppliers, such as a presentation on Business Continuity Plans, which was delivered as part of the 2022 China Supplier Conference to help suppliers interpret the requirement in local context.



Ethics

7 Findings

With only 3 questions in the Audit questionnaire, **Ethics** remains the area with the fewest audit findings. There are a total of 7 Ethics findings, related to **business integrity, fair competition, and privacy**. This topic did not record any critical findings.



Business Integrity & Fair Competition
4 findings about business integrity & fair competition, 2 of these are major findings, marking the absence of a Code of Conduct and Ethics policy, and the gap in the provision of trainings (only senior leadership has received anti-bribery training). 1 minor finding marked the lack of fair competition policies.

Privacy - Data Privacy
3 findings suggest that the GDPR policy is still under preparation; room for improvement in protecting workers' privacy and data management.

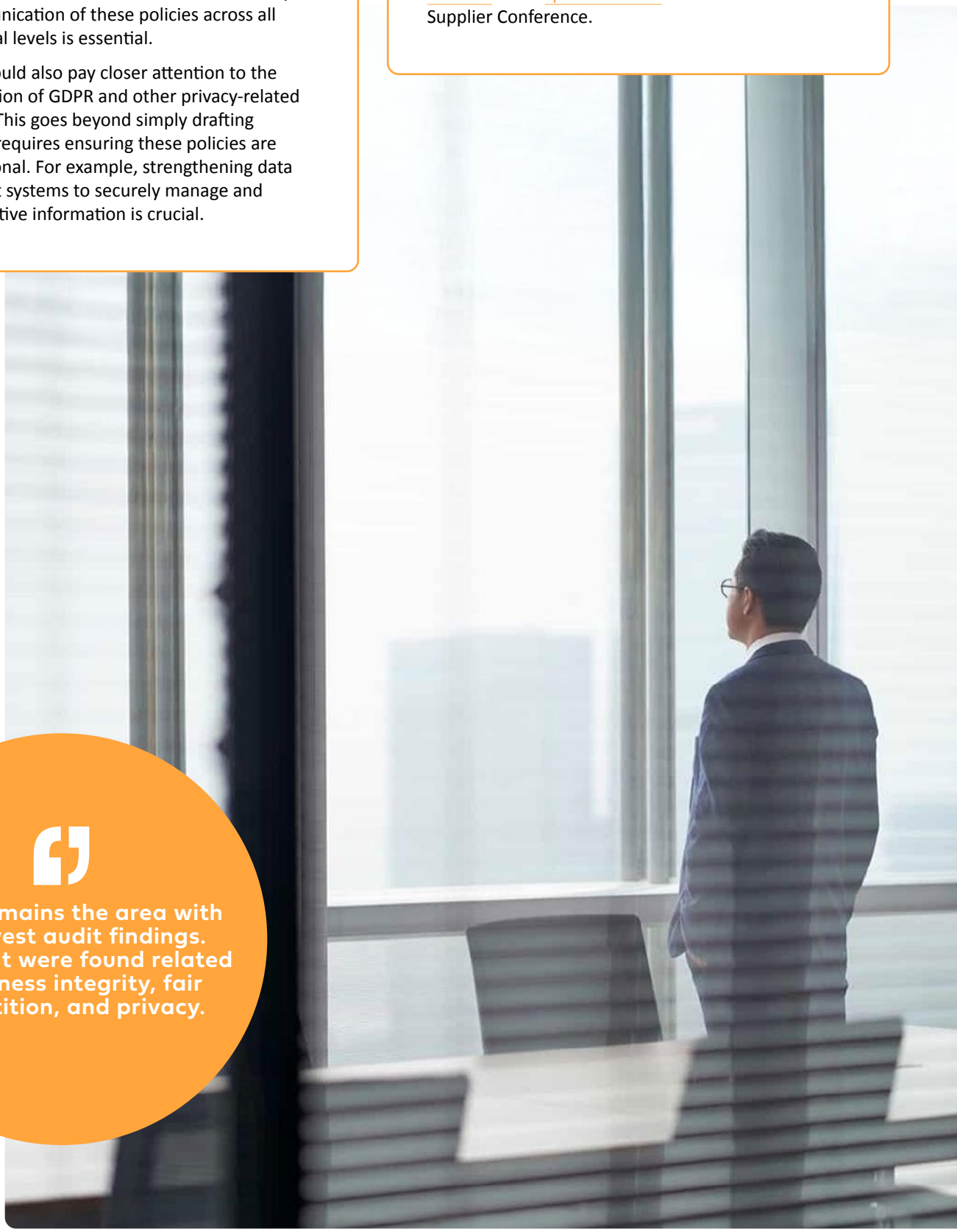
Recommendations for Suppliers

For beginner-level suppliers, the initial focus should be on developing and implementing a comprehensive Code of Conduct and Ethics Policy. Clear communication of these policies across all organizational levels is essential.

Suppliers should also pay closer attention to the implementation of GDPR and other privacy-related regulations. This goes beyond simply drafting policies and requires ensuring these policies are fully operational. For example, strengthening data management systems to securely manage and protect sensitive information is crucial.

PSCI Resources

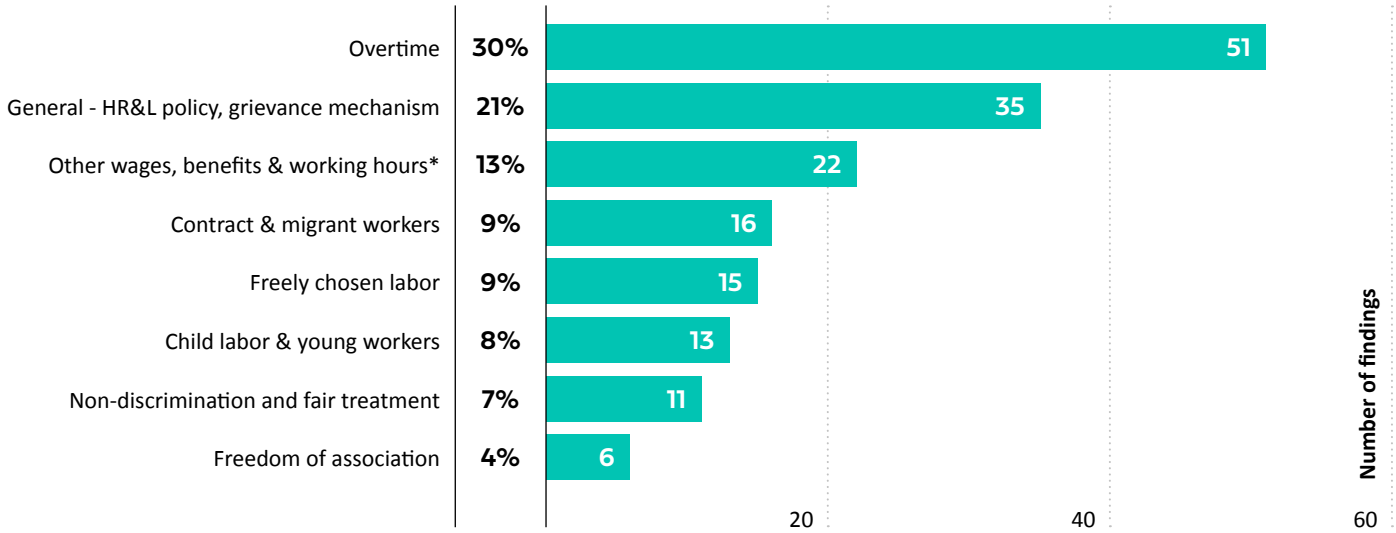
The PSCI has provided useful resources on the topic of anti-bribery and corruption, including a 2020 webinar and a special session at the 2023 Global Supplier Conference.



Ethics remains the area with the fewest audit findings. Those that were found related to business integrity, fair competition, and privacy.

Human Rights | 169 Findings

Regarding Human Rights, issues relating to **wages, benefits, and working hours**, and **Human Rights and Labor Policy** are the top priorities to address based on the frequency of reported issues. Other notable areas include: freely chosen labor, contract & migrant workers, and child labor & young workers. Notably, there were 6 critical findings in Human Rights topics: 4 about overtime and 2 about wage payment.



* Other wages, benefits & working hours includes wage payment (9), punitive measures (2), benefits (9), and other (2). Overtime is singled out in the chart due to the significant findings identified.

Overtime, Wages, Benefits, and Working Hours
Wages, benefits, and working hours is the most concerning area with 73 findings accounting for 43% of all Human Rights findings. Within this, overtime is the most pressing issue with 51 findings including 42 major findings and 4 critical findings marking consecutive working without one day off every week, excessive working hours that breach legal limits, and inadequate overtime compensation, severely affecting worker well-being and organizational integrity, as well as posing significant compliance risks. Wage payment findings presented systemic payroll management issues at some supplier sites. 2 out of 9 findings in wage payment are critical and highlighted that verifying compliance with payment timelines was not possible due to the lack of bank transfer statements for both company and contract employees across all sampled months.

Human Rights and Labor Policies
The Human Rights and Labor Policies area highlights gaps in comprehensive and accessible policies among suppliers. The majority of the findings relate to the absence of key elements like anti-human trafficking and freedom of association policies. Additionally, 6 findings point to specific issues with grievance mechanisms.

Fair Treatment of Contract and Migrant Workers
Fair treatment of contract and migrant workers raises concerns with 16 findings including 9 major findings. Most findings in this area reported not issuing appropriate employment contracts and lack of good maintenance of employment records, which are essential for ensuring fair treatment of contract and migrant workers within supplier operations.

Freely Chosen Labor
Freely chosen labor had 14 findings including 2 major findings reporting missing risk assessment mechanisms to identify forced, bonded, or involuntary prison labor.

Child Labor and Young Workers
Child labor and young workers remains an area for improvement, as evidenced by 13 findings. Among those, 10 findings identified a lack of documented remediation measures and clear policies to protect vulnerable populations and maintain ethical standards. It is worth noting that compared to previous years, most of the findings represent a shift towards the requirement of clear remediation measures, beyond having the child labor policies in place.

Freedom of Association
The idented 6 issues included inadequate representation of employee interests, an invalid trade union certificate, and not establishing the required committees for worker-management communication.

Recommendations for Suppliers

The Human Rights findings indicate a need for more robust and comprehensive policies that cover all aspects of human rights standards among suppliers. These policies must be easily accessible, and communicated effectively across all levels of the workforce, especially in local languages to ensure broad understanding and compliance. Company management needs to raise awareness and commit to emerging issues like child labor, forced labor, and the rights of contract and migrant workers.

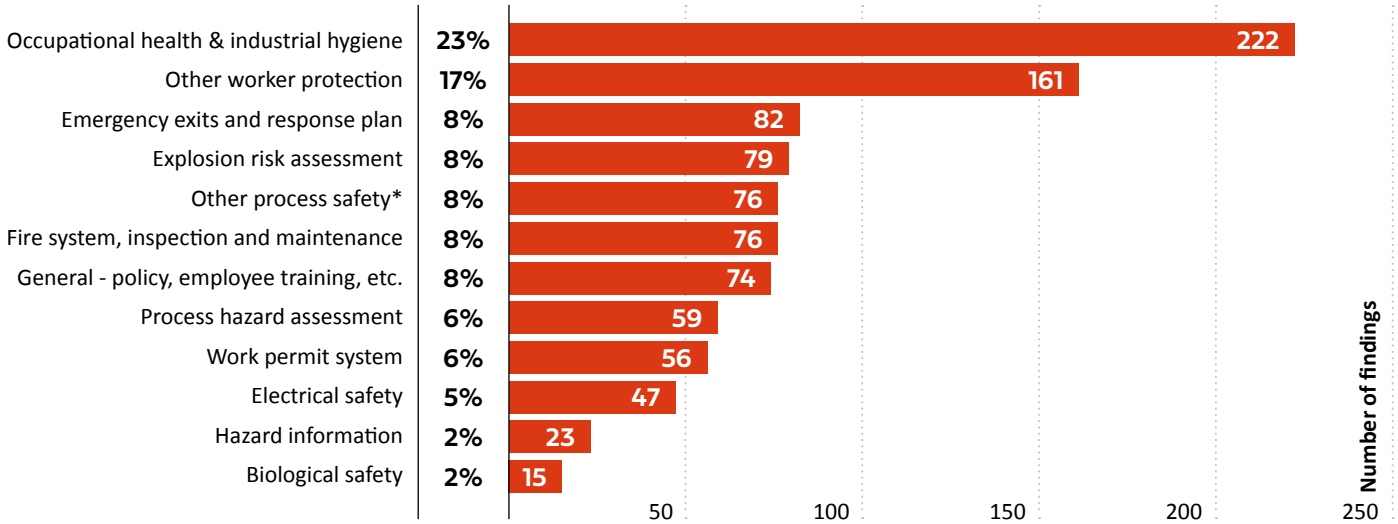
PSCI Resources

The PSCI Capability Committee has provided useful resources around Human Rights topics including Wages, Benefits, and Working Hours, Non-Discrimination, and Freely Chosen Labor. The resources are available on both the Supplier Learning Plans and Learnster, the PSCI's interactive e-learning platform.

Health & Safety | 970 Findings

Worker protection is a prominent issue highlighting concerns in occupational health and industrial hygiene, the management and enforcement of work permit systems, and safety concerns in specific practices such as pallet racking and identifying special storage requirements. **Process safety** also requires improvement, especially in terms of comprehensive process hazard analysis and robust safety information management. Lastly, **emergency preparedness and response** draws attention to issues in emergency systems and response training, calling for better emergency planning and execution to effectively handle potential workplace incidents.

There are 12 critical findings in this section, including issues regarding contractor activity risk management (2), identification of special storage requirements (1), exposure monitoring & control (1), PPE/RPE (1), process hazard assessment (2), explosion risk assessment (3), fire system, inspection and maintenance (1), and emergency exit & evacuation (1).



* Other process safety includes preventive maintenance of safety-relevant equipment (35), impact on neighbouring businesses and the local community (10), safe handling of compressed gases (19), bulk chemical handling (7), and other (5). Explosion risk assessment also belongs to process safety, and is singled out due to its significant reported findings.

Occupational Health & Industrial Hygiene

The topic of occupational health and industrial hygiene, with 222 findings, reveals shortcomings in exposure monitoring and control, demanding improvements in hazard assessments and protective equipment usage to safeguard worker health.

Other Worker Protection

Other worker protection findings reported specific risks in relation to pallet racking (43), identification of special storage requirements (29), pedestrian and material handling equipment aisles (27), machine guarding (17), contractor activity risk management (13), material handling equipment & elevation devices (13), trailer movement restraint during loading and unloading (12) and other issues.

Emergency Exits and Response Plan

The audits revealed shortcomings in overall emergency preparedness. There are 82 findings, 32 of which specifically addressed emergency exit & evacuation, with the other 50 noting observations about drills, emergency response plans & response teams. Key issues include insufficient drills and training exercises, not updating or finalizing emergency response plans (ERPs), and a lack of necessary qualifications for emergency response team members. Additionally, the display of emergency plans and accessibility of exits were found to be inadequate at some sites. A critical finding revealed that a warehouse exit was locked, and another was blocked from use, posing risks to employees.

Explosion Risk Assessment

Explosion risk assessment is another primary concern with 79 findings. 45 findings of these highlight deficiencies in engineering controls and hazard classifications, including 2 critical findings related to not having ATEX requirements implemented. In addition, gaps also exist in flammable storage areas management and hazard assessment of the combustible dusts and powders handled. The other one critical finding reported “poor understanding of solvent vapour explosion risks, required controls and system for risk mitigation.” These gaps in assessing and managing explosion risks reflect a substantial risk to workplace safety, demanding immediate attention to enhance control measures and safety protocols.

Fire System, Inspection and Maintenance

Critical and major findings having observed issues with fire protection/suppression systems, fire detection and alarm

placements, and maintenance practices. The one critical finding pointed out that "flammable liquid storages (tank farm and containers for drums) have no fire protection or detection."

Process Hazard Assessment
Process hazard assessment is yet another important topic with 59 findings. A significant number of major findings underscores lapses in conducting comprehensive hazard analyses, which is essential for process safety. The issues range from incomplete HAZOP studies to the absence of detailed quantitative risk assessments. Deficiencies in the management of process safety information and pressure relief sizing calculation also warrant attention.

Recommendations for Suppliers

- **Hazard assessment and control:** Exposure monitoring and control practices need improvement, particularly regarding thorough hazard assessments and consistent use of appropriate protective equipment.
- **Process safety management (PSM):** Actions are needed to implement or strengthen existing PSM systems. This includes conducting thorough process hazard analysis (PHAs), risk assessments, and regular safety audits to proactively identify and mitigate potential hazards. Specifically for PHAs, suppliers should conduct detailed HAZOP studies, update safety information, and train staff on these measures and emergency response procedures.
- **Explosion prevention and fire safety:** Suppliers need to regularly review and update hazard classifications (e.g., ATEX) and engineering controls. This ensures that all areas handling flammable substances and combustible dust have up-to-date and effective explosion protection measures, compliant with ATEX or equivalent standards. Additionally, fire protection systems in flammable liquid storage areas must be upgraded, and routine maintenance enforced to ensure all fire safety equipment is regularly tested and compliant.
- **Electrical safety:** Protocols need strengthening through regular risk assessments, improved lockout/tagout procedures, and ensuring ongoing training and strict maintenance schedules for all electrical systems.
- **Work permit systems:** Comprehensive work permit systems should be established, including stringent checks, thorough training on permit protocols, and a robust monitoring process to ensure adherence during high-risk activities.

Work Permit Systems
The management and enforcement of work permit systems had 56 findings. The majority of findings reveal gaps in general work permit systems, such as insufficient management and monitoring processes, and energy isolation and lockout/tagout procedures, underscoring risks in ensuring worker safety during maintenance. Additional concerns include inadequate systems for work at height, confined space operations, and hot work permits, pointing to a broader need for stringent oversight and comprehensive safety protocols.

Electrical safety
Electrical safety emerges as a major concern as well, with 47 findings. 17 findings of these are related to arc flash risk assessments including not conducting arc flash risk assessment, lack of arc flash analysis information, etc. Issues such as unlocked electrical panels and inadequate safety equipment inspections at some supplier sites highlight systemic lapses in maintaining electrical safety standards at the sites.

PSCI Resources

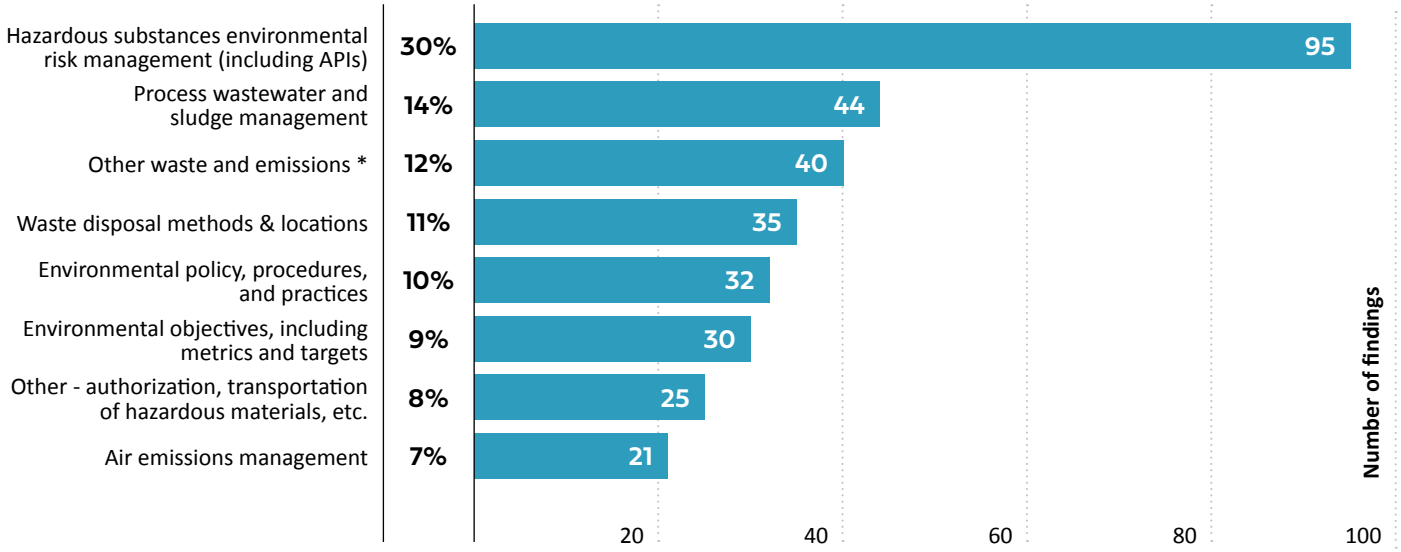
Process safety management: The PSCI has provided capability-building resources in the area of PSM from the general introduction to more advanced presentation on process safety hazards for pharma operations, available on both the Supplier Learning Plans and Learnster.

Explosion protection: The PSCI has provided capability training on hazardous area classification relating to this topic.

Work permit systems: The capability-building document on Permit to Work on the PSCI platform provides useful information for suppliers to understand and develop in this area.

Environment | 322 Findings

Waste and emissions management emerges as the area with the most findings in Environment, where inadequate hazardous waste storage and wastewater treatment practices are most concerning. **Transport, storage, & spill prevention** follows, highlighting gaps in the management of hazardous substances (1 critical finding), especially insufficient spill prevention and containment measures. **General environmental policies and practices** also present major issues, making up 19% of the findings, with gaps in the implementation and monitoring of environmental policies.



* Other waste and emissions includes management of third-party waste treatment and disposal facilities/providers (7), hazardous chemicals management program (6), stormwater management (25), and other (2).

Hazardous Substances Environmental Risk Management (including APIs)

Hazardous substances environmental risk management (including APIs) records the highest number of findings, emphasizing concerns about the handling and management of hazardous substances. These concerns include deficiencies in secondary containment measures, leak detection and management, and hazardous chemicals management. A critical finding reported that "there is a risk of pollution or other major event due to improper storage of chemicals in drums: lack of containment or retention, storage in non-dedicated or segregated areas for hazardous materials (flammable, API, hazardous for environment) etc."

Process Wastewater and Sludge Management

Handling and treatment of process wastewater and sludge present considerable challenges, with 44 findings reported. There are 23 findings, including 11 major ones, addressing inadequate management of APIs in wastewater, underscoring gaps in quantifying and controlling pharmaceutical contaminants. Broader issues with wastewater treatment systems are highlighted in 21 findings, with the majority of findings concerning the lack of comprehensive sewage, drainage, and treatment systems, reflecting non-adherence to wastewater management standards.

Waste Disposal Methods & Locations

Waste disposal methods & locations are discussed in 35 findings. There are 15 major findings concerning the mismanagement of hazardous waste areas, including issues like inadequate secondary containment and poor labelling practices that can lead to serious environmental hazards and non-compliance. Findings also indicate a lack of proper assessment and auditing of third-party waste treatment and disposal services.

Environmental Policy, Procedures, and Practice

32 findings discussed incomplete policy implementation and periodic reviews. The lack of a dedicated environmental policy and inadequate baseline environmental impact assessments highlight a need for robust policy frameworks and more proactive environmental management practices.

Development of Environmental Objectives, Including Metrics and Targets

Development of environmental objectives, including metrics and targets is discussed in 30 findings, of which 15 major findings suggest that formalized environmental objectives, metrics, and targets are often absent or inadequately defined, especially concerning greenhouse gas emissions and resource consumption, undermining the ability to track performance and drive improvements.

Air Emissions Management
Air emissions management including air quality management and emissions control is another topic of concern with 21 findings. Several sites haven't implemented adequate emission controls, such as properly maintained or effective scrubber and stack systems. This lack of proper emission management leads to exceedances of permitted levels and poses compliance and health risks.

Recommendations for Suppliers

At the management commitment and policy level, suppliers need to develop comprehensive policies that include clear objectives, targets, and metrics. These policies should be effectively communicated throughout the organization and translated into all applicable local languages to ensure widespread understanding and compliance. Periodic reviews and updates are essential, particularly for policies and protocols pertaining to hazardous waste management and spill prevention. This ensures adaptation to regulatory changes and evolving best practices.

Regarding specific implementations, suppliers need to focus on:

- **Hazardous substances:** Implement stricter controls and storage protocols for hazardous substances. Enhance leak detection systems and secondary containment measures to prevent accidental releases and pollution. Conduct regular risk assessments and audits.
- **Wastewater and sludge management:** Develop comprehensive strategies that include API handling and upgrades to existing sewage, drainage, and treatment systems. Introduce regular training for staff on the importance of wastewater management and the consequences of non-compliance.
- **Waste disposal:** Ensure all hazardous waste areas are properly labelled and managed. Strengthen oversight and internal controls to prevent non-compliance and environmental hazards. Conduct rigorous assessments and audits of suppliers' third-party waste treatment and disposal services to ensure compliance with environmental standards.

A further expectation is for suppliers to invest in fostering greater transparency and engagement with local communities and other stakeholders. This can be achieved through regular disclosure of environmental performance and sustainability practices.

PSCI Resources

The PSCI has a wide range of capacity-building resources to help suppliers with environmental risk management. The relevant resources such as the Spill Containment & Prevention presentation and a training resource Setting Environmental Goals & Targets, developed externally by the Supply Chain Solutions Center are available on both the Supplier Learning Plans and Learnster.

In addition, the PSCI PiE/AMR Tool Deck consolidates all available tools and resources of this topic and provides detailed information on various tools, including their purposes, applications, and benefits.

Regional Analysis

In addition to analyzing the findings from individual topics, we've segmented the data to gain insights into supplier performance in specific regions, particularly India and China, which together comprise half the PSCI supplier base. As part of the PSCI's wider focus on supplier capability building and collaborative 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 also deliver an annual Global Supplier Conference for suppliers across the rest of the world.

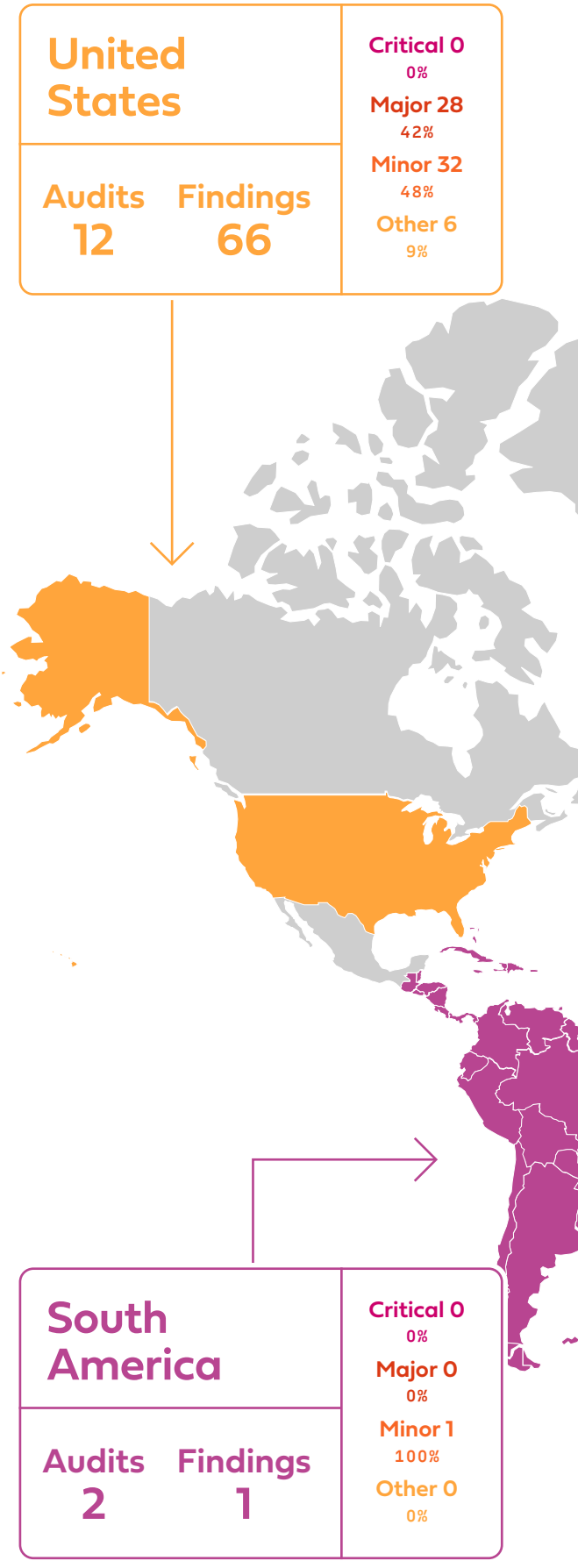
Methodology

We analyzed the individual areas with the highest number of findings for each country/region. This process identified frequent and noteworthy themes and topics. When analyzing the themes for each region, we considered not only the frequency (number) of findings but also their severity (critical, major, minor), while ensuring a balanced representation of both HSE and social concerns.

It is crucial to interpret these regional observations within context. Development stages, local laws and regulations, and auditor focus can significantly influence the findings. For example, Human Rights policy emerged as a primary theme in Western Europe's findings but did not feature prominently in India's findings. This doesn't necessarily indicate better or worse performance, but reflects stricter regulations and stakeholder expectations in Western Europe than India, leading auditors to prioritize this topic during inspections.

Scope

The regions included in the analysis and their respective share (percentage) of total uploads for 2023 are detailed on the right.



Eastern Europe

Audits	Findings
4	29

Critical 0
0%
Major 11
38%
Minor 16
55%
Other 2
7%

Rest of the World

Audits	Findings
35	257

Critical 7
3%
Major 75
29%
Minor 166
65%
Other 9
4%

Western Europe

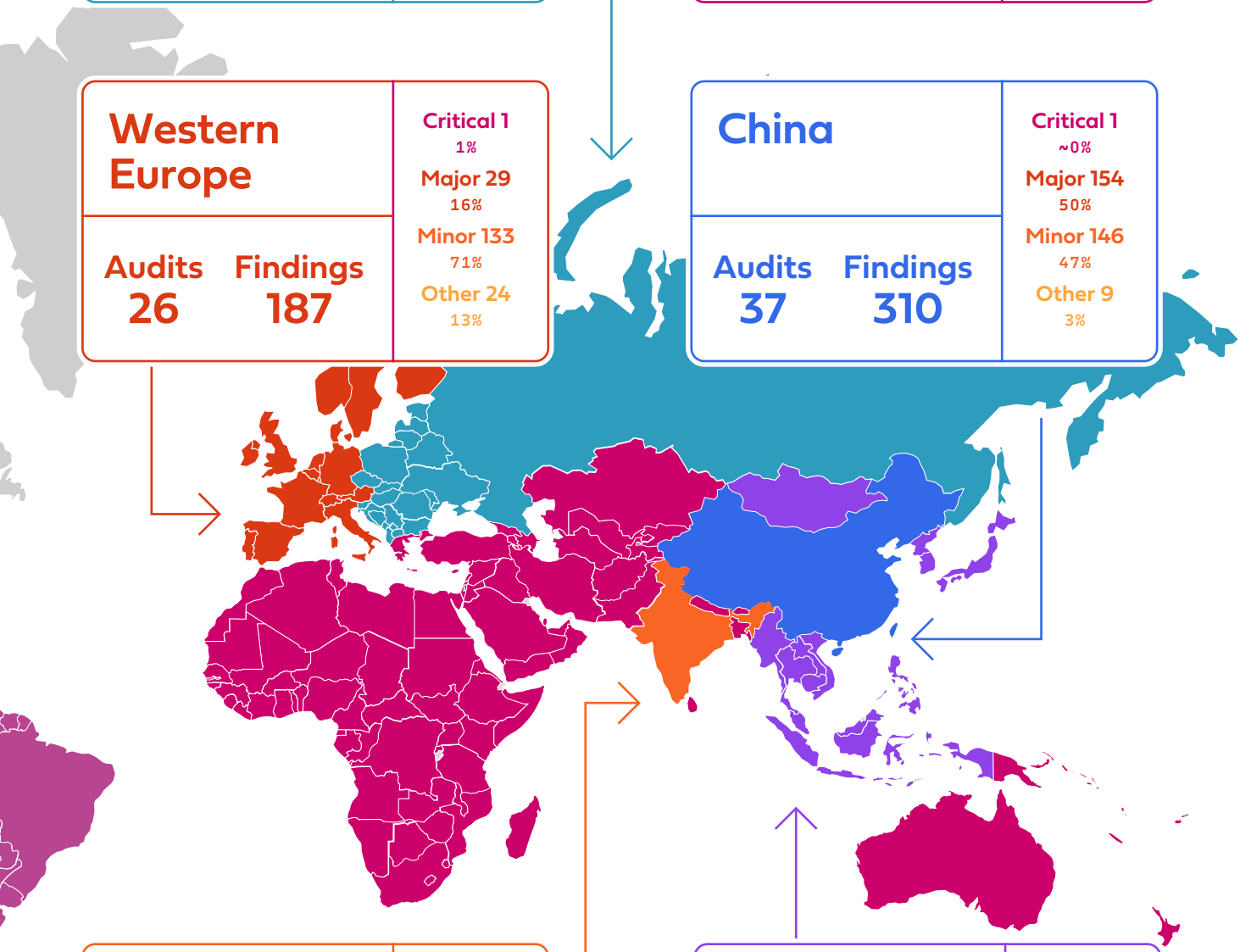
Audits	Findings
26	187

Critical 1
1%
Major 29
16%
Minor 133
71%
Other 24
13%

China

Audits	Findings
37	310

Critical 1
~0%
Major 154
50%
Minor 146
47%
Other 9
3%



India

Audits	Findings
48	753

Critical 7
1%
Major 338
45%
Minor 389
52%
Other 19
3%

Other parts of Asia

Audits	Findings
16	63

Critical 1
2%
Major 16
25%
Minor 39
62%
Other 7
11%

India

Findings
753

Audits
48

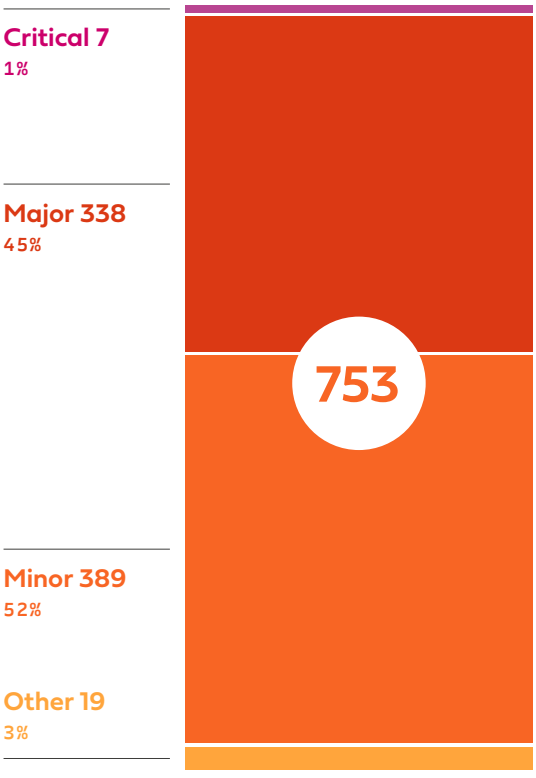
Most Common Findings

1. **Fire system, inspection and maintenance** (38, 5%)
   The majority of findings on this topic involved fire suppression systems, including inadequate fire suppression in critical areas, insufficient fire extinguishers, and lack of internal hose reels and hydrants in essential service floors. Following this, the fire detection and alarm system and fire equipment maintenance, inspection, and audits both represent significant proportions of the findings.

2. **Hazardous substances environmental risk management (including APIs)** (36, 5%)
   A significant number of major findings highlighted the lack of secondary containment with a capacity equivalent to at least 110% of the largest transportation unit / tank or vessel. This indicates the need for improved containment infrastructure to effectively manage potential spills or leaks during transportation and storage. Other notable findings include broken secondary containment systems, the lack of secondary containment for drums, etc.

3. **Exposure monitoring & control** (33, 4%)
   The key issue found was the lack of exposure assessment and monitoring for hazardous substances. This includes missing qualitative and quantitative assessment and neglecting solvent vapors and ergonomic. These are followed by observations regarding Occupational Exposure Limits (OEL) and Occupational Exposure Banding (OEB) for APIs and hazardous substances.
   An additional concern raised in major findings was the absence of appropriate personnel (e.g. full-time Factory Medical Officer or nurse).

Findings by type



China

Findings
310

Audits
37

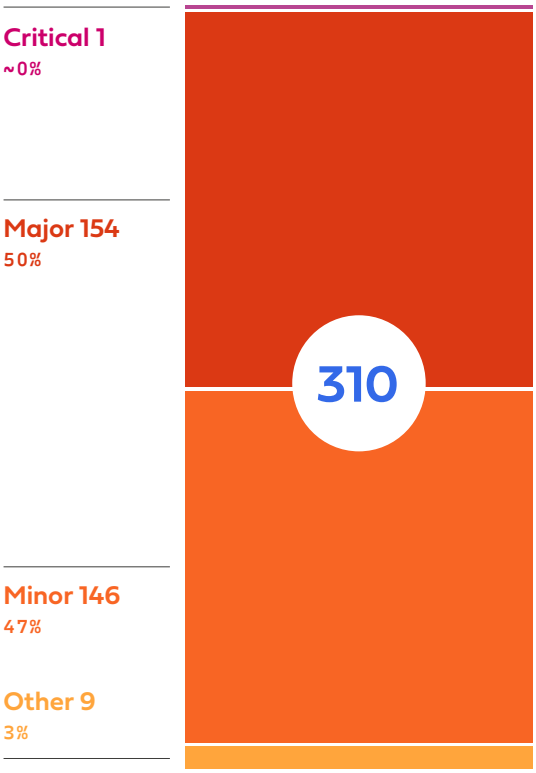
Most Common Findings

1. **Overtime** (26, 8%)
   Excessive consecutive work and exceeding legal overtime limits were the most common findings, with one critical finding where daily and monthly working hours of sampled workers exceeded legal limits. These findings highlight the need for improved scheduling and enforcement of breaks to prevent worker fatigue.

2. **Business continuity plan (BCP)** (25, 8%)
   The most significant issue involved the absence of a proper BCP. Major findings included BCPs lacking clear disruption scenarios and recovery times, or a complete lack of a documented plan.

3. **Supplier evaluation** (22, 7%)
   Incomplete evaluation scope was a primary issue, with a major finding where supplier evaluations didn't cover Labor and Ethics topics. Another 36% of supplier evaluation-related findings (mostly minor) involved supplier evaluation systems not meeting PSCI requirements (e.g., only monitoring major suppliers, missing periodic assessments).

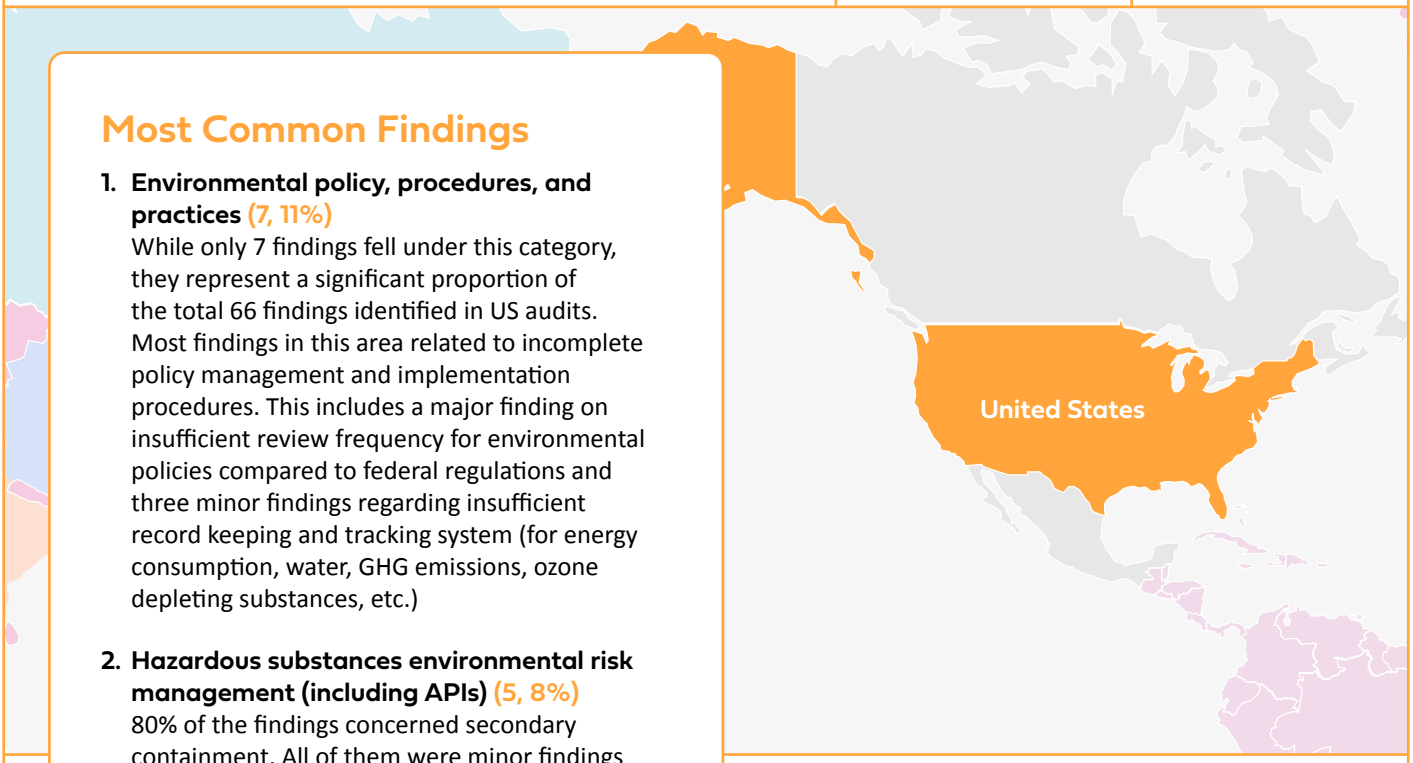
Findings by type



United States

Findings
66

Audits
12



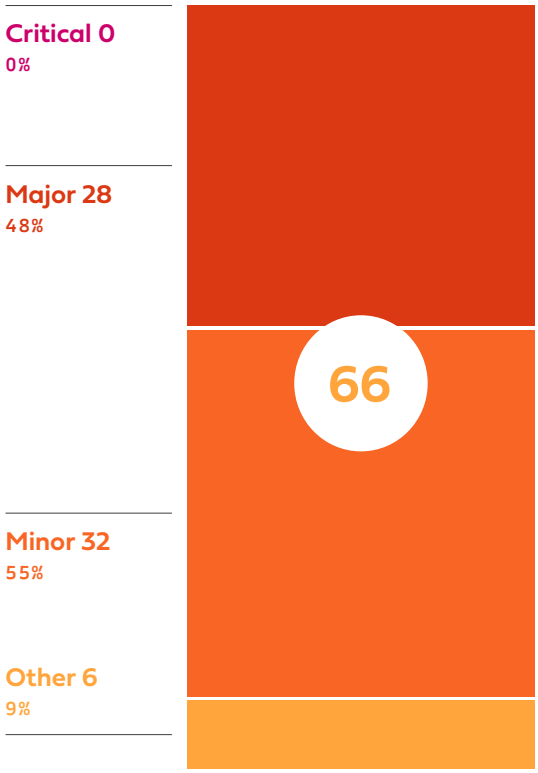
Most Common Findings

1. **Environmental policy, procedures, and practices** (7, 11%)
   While only 7 findings fell under this category, they represent a significant proportion of the total 66 findings identified in US audits. Most findings in this area related to incomplete policy management and implementation procedures. This includes a major finding on insufficient review frequency for environmental policies compared to federal regulations and three minor findings regarding insufficient record keeping and tracking system (for energy consumption, water, GHG emissions, ozone depleting substances, etc.)

2. **Hazardous substances environmental risk management (including APIs)** (5, 8%)
   80% of the findings concerned secondary containment. All of them were minor findings related to the absence of appropriate secondary containment (with a capacity equivalent to 110% of the largest tank or vessel), for stored hazardous waste, and waste and chemical storage.

3. **Environmental objectives, including metrics and targets** (4, 6%)
   All findings were major, highlighting the lack of formalized and documented environmental objectives with metrics and targets.

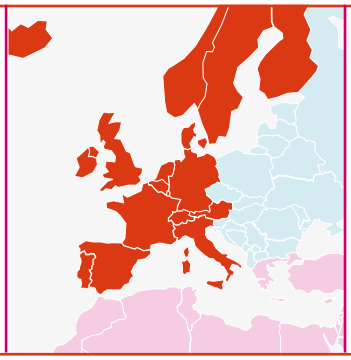
Findings by type



Western Europe

Audits 26 Findings 187

Critical 1 1%
Major 29 16%
Minor 133 71%
Other 24 13%



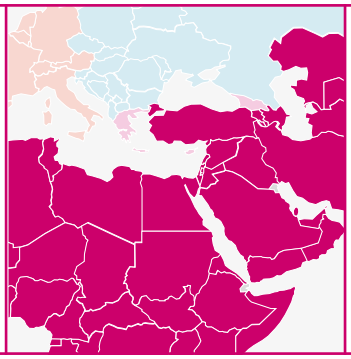
Areas of concerns

1. Explosion risk assessment
2. Pallet racking
3. Business continuity plan (BCP)
4. Human Rights and Labor policy

Rest of the World

Audits 35 Findings 257

Critical 7 3%
Major 75 29%
Minor 166 65%
Other 9 4%



Areas of concerns

1. Hazardous substances environmental risk management (including APIs)
2. Explosion risk assessment
3. Business continuity plan (BCP)
4. Supplier evaluation

South America

Audits 2 Findings 1

Critical 0 0%
Major 0 0%
Minor 1 100%
Other 0 0%

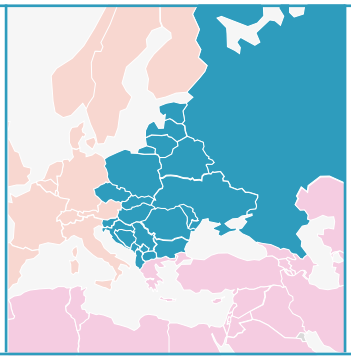
Areas of concerns

1. Safety showers and eyewash equipment

Eastern Europe

Audits 4 Findings 29

Critical 0 0%
Major 11 38%
Minor 16 55%
Other 2 7%



Areas of concerns

1. Fire system, inspection and maintenance
2. Electrical and lightning safety inspection

Other parts of Asia

Audits 16 Findings 63

Critical 1 2%
Major 16 25%
Minor 39 62%
Other 7 11%

Areas of concerns

1. Hazardous substances environmental risk management (including APIs)
2. Explosion risk assessment
3. Business continuity plan (BCP)
4. Supplier evaluation

Analysis by Supplier Type

A new focus for the PSCI this year, we investigated the connection between audit findings and the types of services suppliers provide. To achieve this, we segmented the data and looked for common findings for different supplier groups, categorized as API (and plus) suppliers, Chemical (and plus) supplier, Finished Formulations (and plus) supplier, Biologicals (and plus) supplier, other Type C suppliers, Type B (only) supplier, Type A (only) supplier.

Here's what we found

Areas of concerns for different supplier types

While the chart provides a valuable overview of findings across supplier types, it's important to consider the following when interpreting the results:

- Shared risk areas: The chart effectively identifies common areas for improvement across all supplier types.
- Risk severity by category: We can analyze which areas pose the greatest risk within each supplier category. For example, for API+ suppliers, hazardous substances management and fire systems are the priority areas.
- It's important to acknowledge the varying number of audits conducted per supplier type. For instance, with 75 audits for API (and plus) suppliers compared to only 6 for Chemical (and plus) suppliers, direct comparisons of finding counts will be misleading.

Overall, the analysis of the top findings across these categories didn't yield significant insights. The results showed minimal variation between supplier categories. Here are some potential reasons:

- Overlapping services: Suppliers often provide multiple services, making it challenging to categorize them definitively.
- Lack of detail in findings: Even when we analyze suppliers without overlapping services, the level of detail provided in the descriptions of the findings themselves may be insufficient. This lack of granularity might prevent us from identifying issues specific to different supplier types.

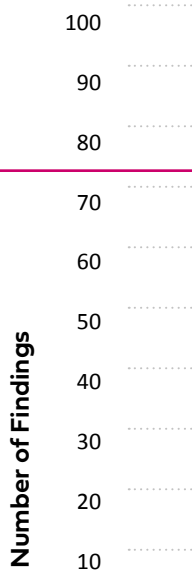
Nevertheless, the analysis results are largely consistent with the overview of findings and are still useful in providing a broad indication of the risks commonly shared among specific supplier types. We look forward to building on this analysis in the future.

Type A

- Facility & Engineering Services
- Temporary Labor Agency
- Travel & Fleet services
- IT Services or hardware supply
- Other Materials (e.g. marketing, IT hardware, lab equipment, garments)
- Other Services (e.g. IT, marketing, travel, fleet, research, catering)

How to read the bars:

For example, 92 findings recorded for suppliers of all types, among these, 53 were identified within the API+ supplier group.



Supplier Type

- Type A
- Type B
- Type C
  - Type C - Biologicals
  - Type C - Finished Formulations+
  - Type C - Chemicals+
  - Type C - API+

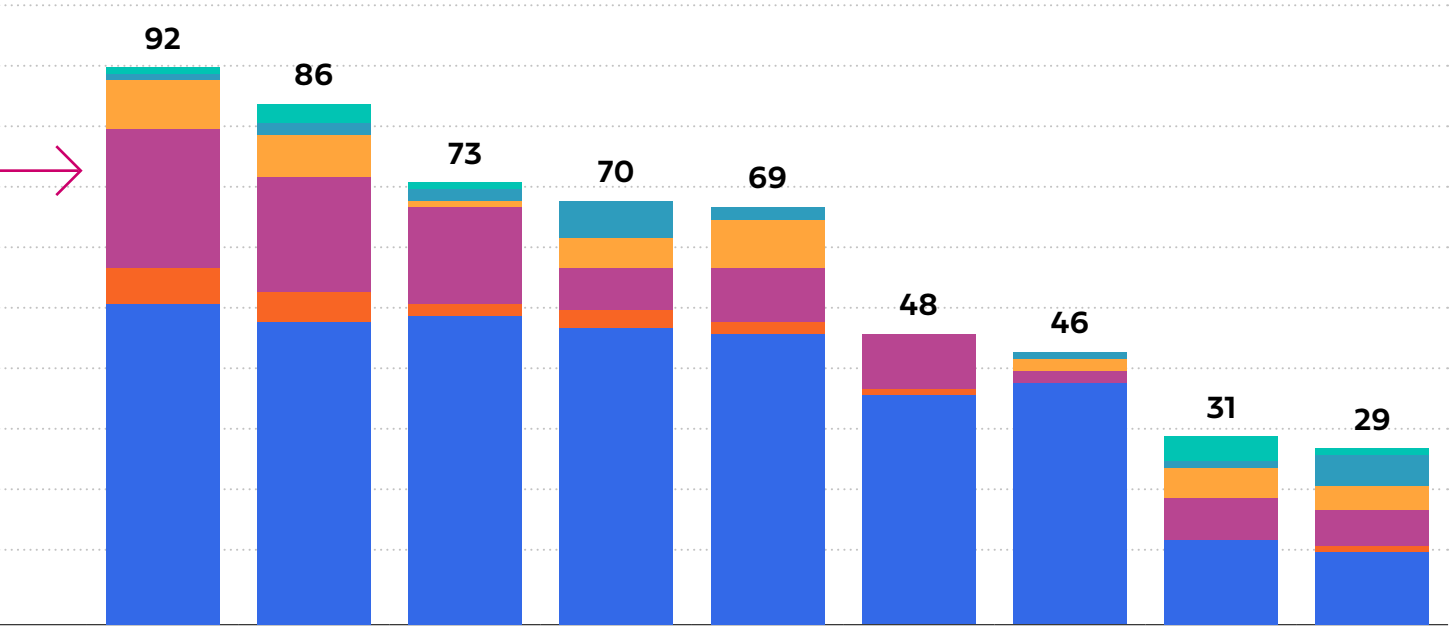
Type B

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

Type C

- 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)

Areas of concerns by supplier type



	Hazardous Substances Environmental Risk Management	Business Continuity Plans	Fire Systems	Exposure Monitoring & Control	Explosion Risk Assessment	Overtime	Process Hazard Assessment	HR & Labor Policy	Environmental Objectives
	1	3	1	0	0	0	0	4	1
	1	2	2	6	2	0	1	1	5
	8	7	1	5	8	0	2	5	4
	23	19	16	7	9	9	2	7	6
	6	5	2	3	2	1	0	0	1
	53	50	51	49	48	38	41	14	12

Understanding our impact

Tracking change in supplier practices over time

As part of this year's analysis, we looked more in-depth at audits from a sample of 13 suppliers that were audited more than once between 2020 and 2023. The summary below provides a snapshot of where we can see suppliers have made progress. We believe that ongoing engagement with the PSCI's tools and resources, including audits, leads to positive change in suppliers' practices.

Whilst we can see improvements in some areas, there are others where practices did not show improvement or preparation for new and emerging issues. For example, third-party and supplier evaluation processes related to selection, assessment, and monitoring for Labor and Ethics risks remained an issue across this sample group, and in several instances the management of hazardous materials including storage and disposal was a consistent finding.

These findings and others that were critical or major were subject to normal correction and closure procedures.

It's important to acknowledge that increases in findings for certain areas do not necessarily reflect a decline in supplier practices. Several factors can contribute to these trends, such as auditor expertise, new regulations, or increased expectations, which may lead member companies to focus on different aspects during audits.

Measuring and evidencing our impact is an ongoing process and one that we will continue to develop and refine over time.

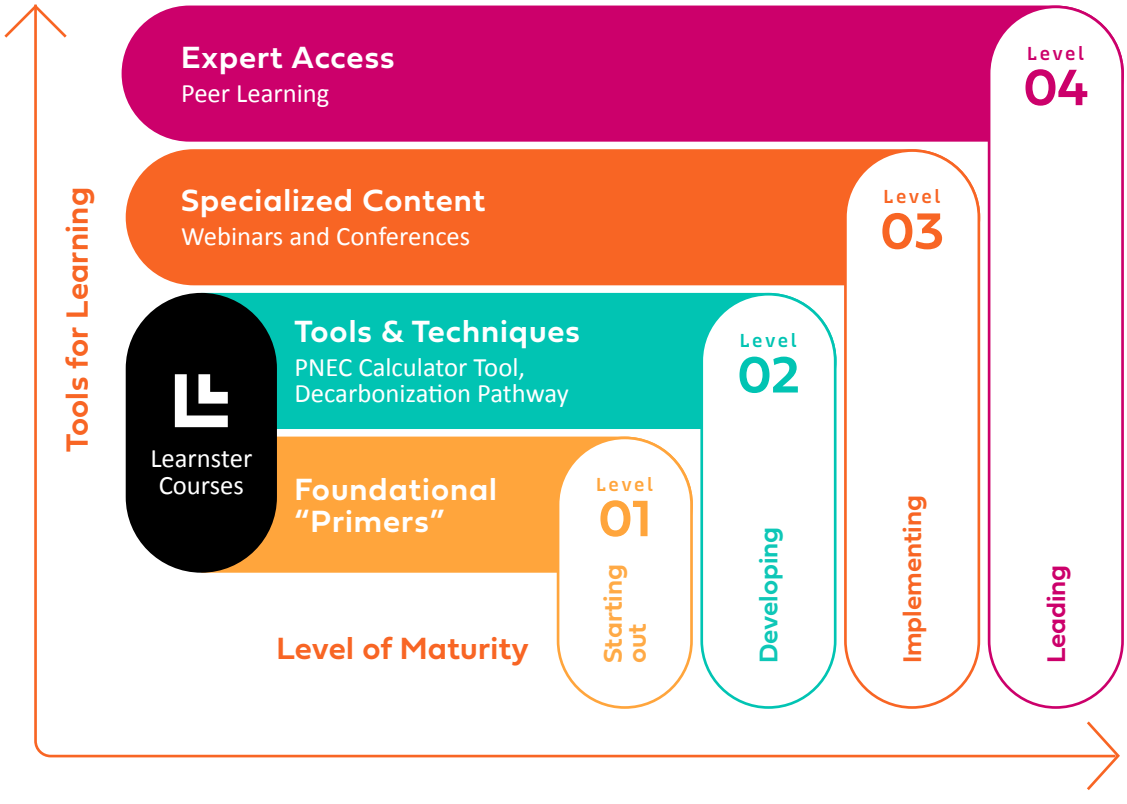
Principle Area	Impact Area	Improvements Shown: China	India	Other Asia	US	Western Europe
Governance & Management Systems	Improved and more developed management systems aligned with PSCI expectations, including documented risk assessments, change management processes, and internal audit procedures	✓	✓	✓	✓	
	Inclusion of ethical considerations in supplier assessments			✓		
Ethics	Enhanced ethics policies that include fair competition	✓				
Human Rights	Creation of a training programs on forced labor	✓		✓	✓	
	Development of policies around freedom of association and human trafficking	✓				
Health & Safety	Implementation of enhanced measures around worker protection, hazard identification, and other safety measures	✓	✓	✓	✓	✓
Environment	Improved practices around wastewater management	✓	✓			✓
	Establishment of decarbonization goals and wider environmental policies	✓			✓	

Building Capability

The PSCI Maturity Model

We provide a range of capability-building resources for pharma and healthcare suppliers to improve their practices in line with the PSCI Principles. Our aim is to promote continual improvement through high-quality, impact learning and development opportunities. We run monthly webinars, host three EHS & Sustainability Conferences for suppliers in China, India, and the Rest of World, and create specialist tools.

Our Maturity Model and Learning Plans provide a structured curriculum for suppliers to understand the maturity of their practices, and focus in on specific topics areas such as biodiversity, electrical safety, or anti-bribery and corruption. Guides and tools are available, and complemented by longer courses which are available on our e-learning platform, Learnster.



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