

Insights from the PSCI Audit Findings

Global Audit Insights: PSCI Audit Findings Analysis 2025

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE

Building responsible supply chains

Welcome

Global Audit Insights: PSCI Audit Findings Analysis 2025



Introduction & Context

The seventh edition of the PSCI Audit Findings Analysis Report presents a review of supplier practices, reflecting the commitment of the PSCI and its Members to a responsible, resilient pharmaceutical and healthcare supply chain.

In 2025, pharmaceutical and healthcare companies carried out thousands of supplier site audits, each typically representing two to four days of dedicated on-site work from both auditors and suppliers. Members of the PSCI collaborate by sharing these audits, with their suppliers' permission, promoting greater transparency and creating efficiencies that benefit all parties involved. In 2025, Members and suppliers uploaded a record number of audits — over **240** — to the PSCI platform, reflecting a significant collective effort. These audits generated more than **2,500** findings identified by auditors across the five PSCI Principles: Governance & Management Systems, Ethics, Human Rights, Environment, and Health & Safety. The analysis presented in this report offers a snapshot of suppliers' real-world practices, highlighting recurring challenges and identifying areas where joint action can deliver the greatest impact.

Our analysis has three parts. First, a **deep dive** explores the most common findings within each Principle, supported by qualitative examples from auditor observations. Second, a **regional analysis** looks at patterns in China, India, the United States, Western Europe, and other regions represented in this year's audits. Third, the **additional insights** section further interpreting findings from the perspectives of supplier categories, audit topic coverage, and onsite-remote audits.

240

audits uploaded to the PSCI platform in 2025

"What stands out to me in this report is not only the scale of the effort behind these audits, but also the opportunity they create. Every finding tells us something important about where suppliers are making progress and where more support is needed. By sharing insights, identifying common challenges, and providing support through conferences, webinars, training materials, and practical tools, we can move beyond individual findings and drive broader, more consistent improvement across global pharmaceutical supply chains."

Birgit Skuballa

Director ESG Governance, Bayer and Audit Committee co-lead



→ PSCI Members' shared goal is to translate audit evidence into actionable insights.



As always, interpreting these findings requires nuance. Changes in the number of findings or their severity (Minor, Major, Critical) can reflect other factors — not only supplier performance[1]. However, several overall signals emerge. **Health & Safety** remains the largest source of findings by volume, reflecting consistent auditor focus on this business-critical and potentially life-threatening topic.

Environment findings nearly doubled, from 221 in 2024 to 435 in 2025, while **Governance & Management Systems** and **Human Rights** findings decreased, showing a slight shift of audit focus towards topics like hazardous waste handling and associated vendor qualification, as well as API discharge risk assessment. The relatively small numbers of findings in the **Human Rights** section, especially for topics related to Wage, Benefits, & Working Hours, were recorded at a high severity level, which flags basic labor practices as an important management theme for suppliers.

PSCI Members' shared goal is to translate audit evidence into **actionable insights**. These are used to prioritize the PSCI's provision of supplier training topics, practical guidance, and collaboration with regional partners, ultimately supporting safer work, stronger rights, reduced environmental impact, and responsible business conduct across global supply chains.

[1] Put another way, increases in findings do not necessarily indicate worsening performance; they may reflect growing auditor expertise, evolving regulations and/or business risk areas, or other heightened expectations that shape audit focus.

"The annual Audit Findings Analysis is a cornerstone of PSCI's commitment to fostering a responsible and resilient pharmaceutical and healthcare supply chain. By aggregating data from a record number of audits, this report provides a critical snapshot of our suppliers' real-world practices and highlights recurring industry challenges.

We undertake this comprehensive review annually to continuously monitor shifting trends – such as the recent pivot in focus toward environmental practices and the sustained severity of labor-related findings. More importantly, this yearly exercise allows us to translate audit evidence into actionable insights. By identifying where suppliers fall short, we can strategically prioritize our capacity-building programs, practical guidance, and regional collaborations to ensure our joint actions deliver the greatest possible impact. Ultimately, this continuous cycle of assessment and support drives meaningful progress toward safer work environments, stronger rights, and reduced environmental impact across our global supply chains."

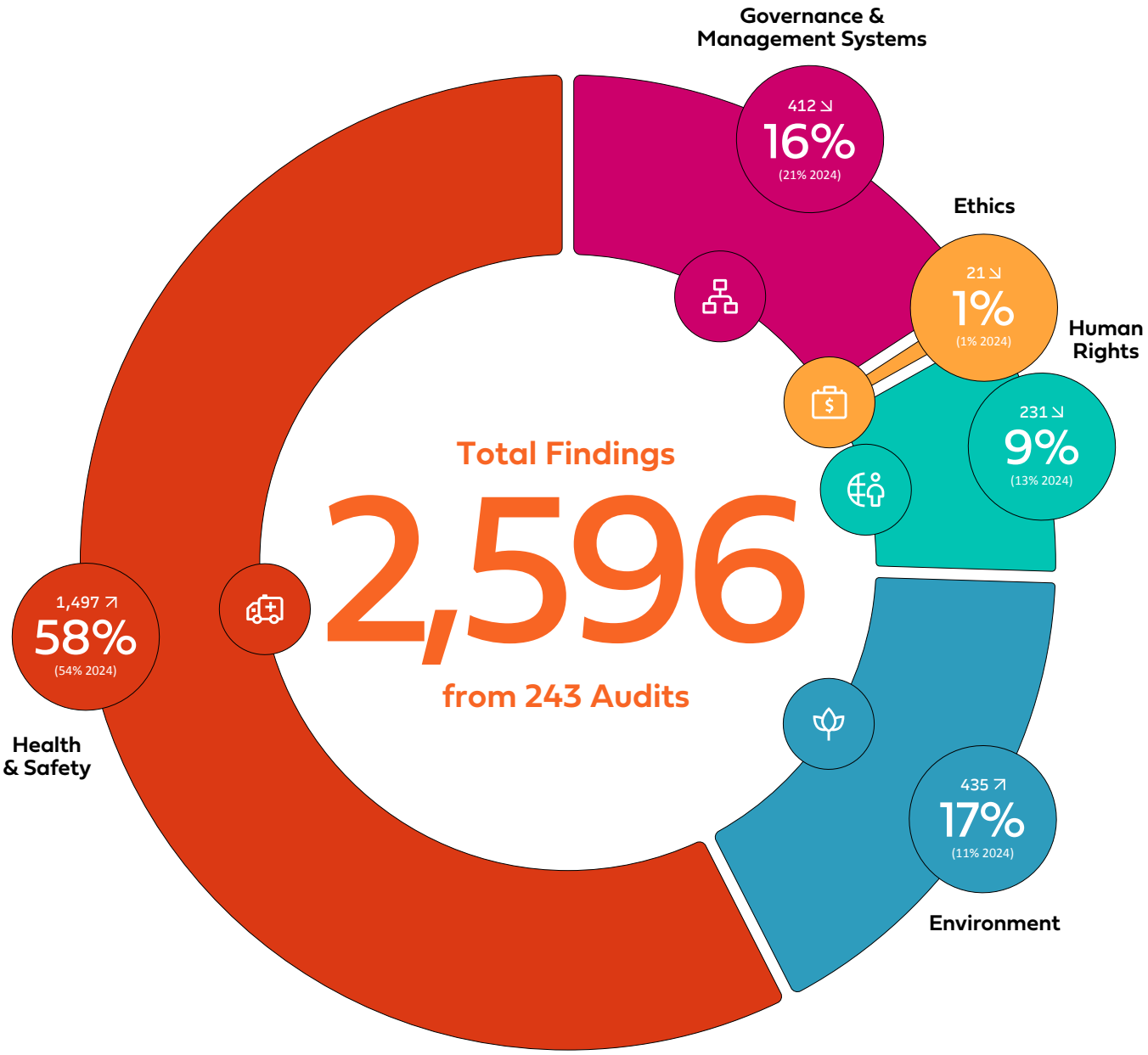
Dorota Wiacek-Trojanowska

Senior Procurement Risk Manager, Roche and Audit Committee co-lead



Overview of findings

For 2025, we analyzed 2,596 findings from 243 audits[2] uploaded to the platform. Consistent with previous years, more than half of the findings relate to Health & Safety, underscoring its business criticality. This is followed by Environmental findings, whose share of findings increased from 11% in 2024 to 17% this year, likely driven by a higher volume of dedicated health, safety, environment (HSE) audits. Findings on Governance & Management Systems (GMS) and Human Rights showed a slight decrease in their relative proportions compared to 2024.

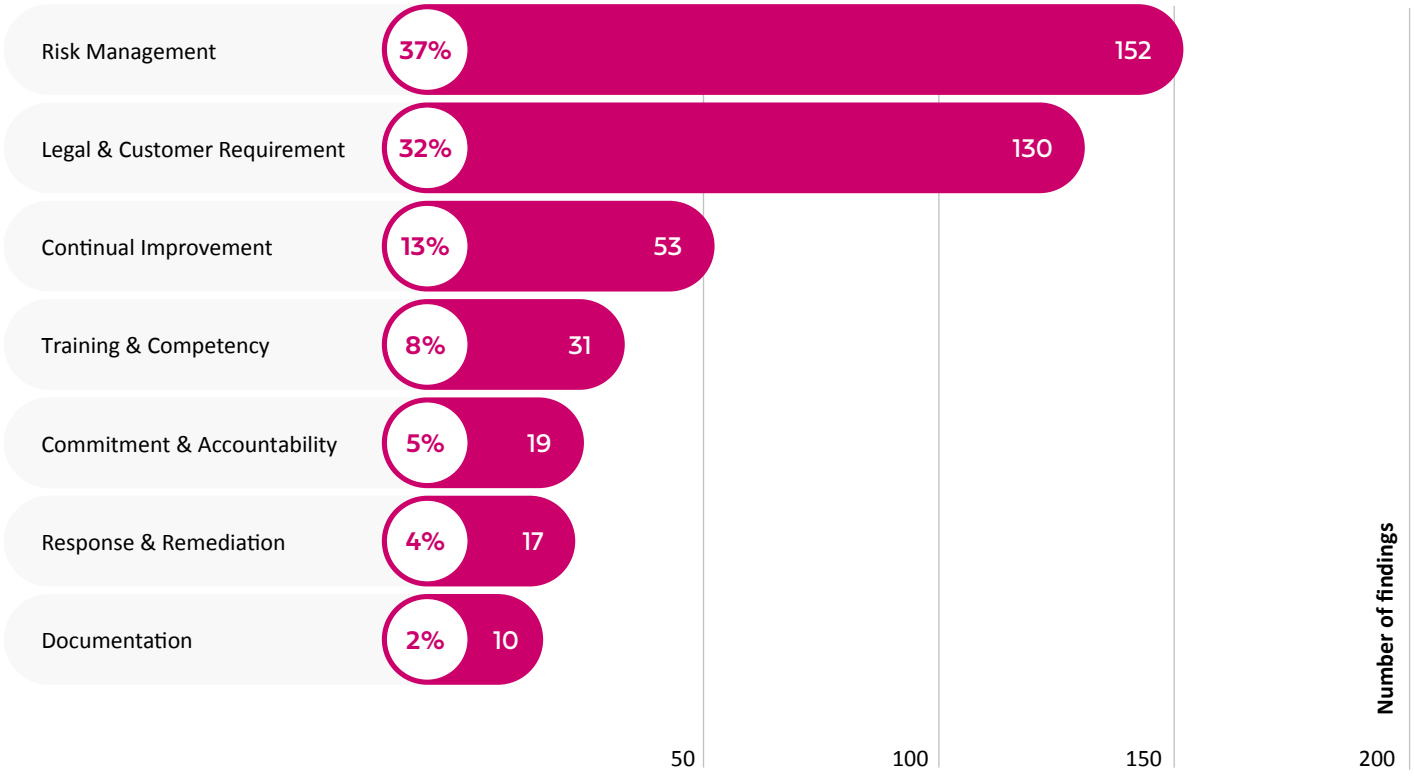


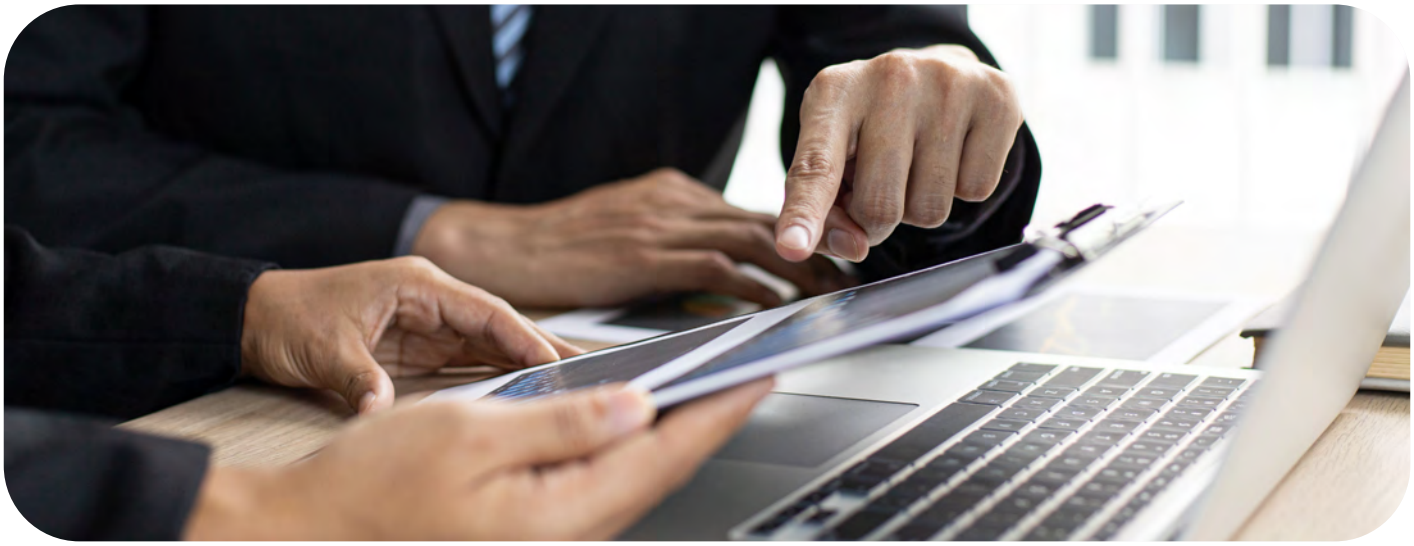
[2] Including audits using the PSCI audit templates and other recognized formats such as Sedex, BSCI, TfS.

Governance & Management Systems

412 Findings 16%

The GMS Principle focuses on the enabling systems and processes which support the implementation of good practices across other Principles topics.





GMS accounts for 16% of findings, primarily in Risk Management, with four themes accounting for most of these findings: **Business Continuity Planning (BCP), Supplier Management & Assessment, Regulatory Compliance, and Risk Assessment Scope & Methodology.**

Illustrative 2025 examples:

Supplier Management & Assessment

Of the 65 findings in this category, 36 focused on insufficient scope of evaluation; 23 on communication and monitoring gaps; and 6 on due diligence regarding sanctions and conflict-affected regions. Common gaps were the exclusion of governance, ethics, and human rights from supplier assessment processes (instead focusing solely on HSE or quality), lack of communication of responsible purchasing policies, and a lack of formal procedures to evaluate sourcing risks from conflict-affected regions.

Regulatory Compliance

We identified 41 findings relating to site-level compliance registration or tracking, and 24 specifically concerning expired or missing permits. Typical gaps include missing or incomplete systems for monitoring legislation changes, overlooked legal registration (e.g. hazardous substances) or disclosure, and expired fire or chemical storage permits.

BCP

Findings were split across three areas: 27 regarding incomplete content or scope; 24 where BCP review or testing practices were inadequate; and 23 where BCPs were completely missing. Recurring gaps include a lack of processes to notify customers during crisis, failure to account for situations such as IT breakdown, overdue BCP reviews, and a lack of BCP testing exercises.

Risk Assessment Scope & Methodology

Across 43 findings, the primary issues involved missing ethics, human rights or business interruption risk areas. Additionally, many sites lacked follow-up actions after risks were identified or used flawed internal risk classification systems.

Change Management Plans

29 findings in total, most of which highlighted incomplete scope, particularly in changes of infrastructure and equipment, as well as sustainability topics; execution gaps, such as delayed timelines for change management implementation, were also identified.

Internal Audit & Assessment

24 findings revealed that internal audit programs are frequently too narrow, focusing exclusively on quality and HSE topics, while neglecting governance, ethics, and human rights.

Why this matters

Robust management systems are the backbone of responsible operations. Gaps in BCP, risk assessment, and supply chain management increase the likelihood that events cascade into supply disruption or harm to people and the environment. Sites with mature systems not only mitigate their own risks but also manage their suppliers more effectively, which ultimately reduces risk exposure across the value chain.



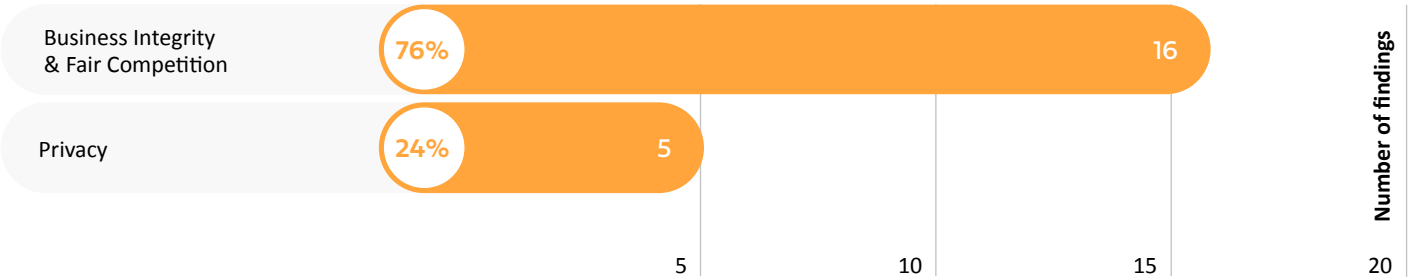
Practical actions for suppliers

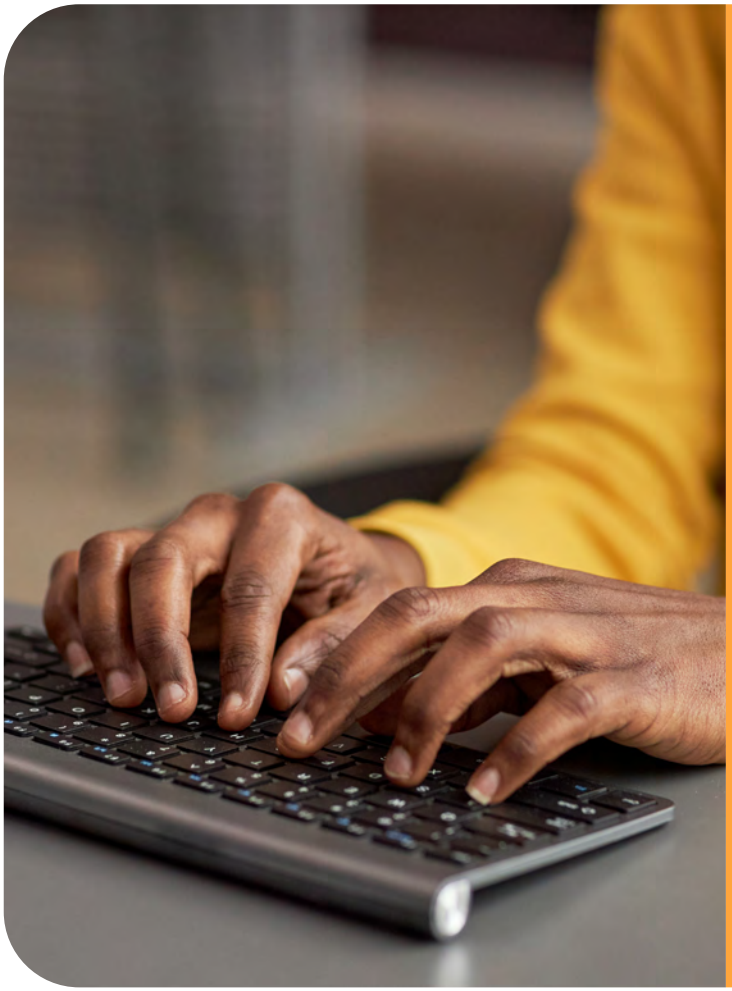
- Establish a comprehensive **responsible sourcing policy** for procurement team that covers at least corporate governance, ethics, human rights, environment, and health & safety clauses; and a **supplier code of conduct** that communicates the same set of expectations to suppliers.
- Formalize a system **that tracks permit status and relevant legislation changes**, including those related to safety and other sustainability topics (e.g. remuneration & social insurance, restricted hazardous substance, energy intensity).
- Maintain a dedicated and comprehensive framework for risk assessment and mitigation. Based on assessment results, incorporate a holistic risk portfolio into BCPs that **covers all isolated material risk themes** (e.g. natural disaster, expiry of license, IT data loss).

Ethics

21 Findings 1%

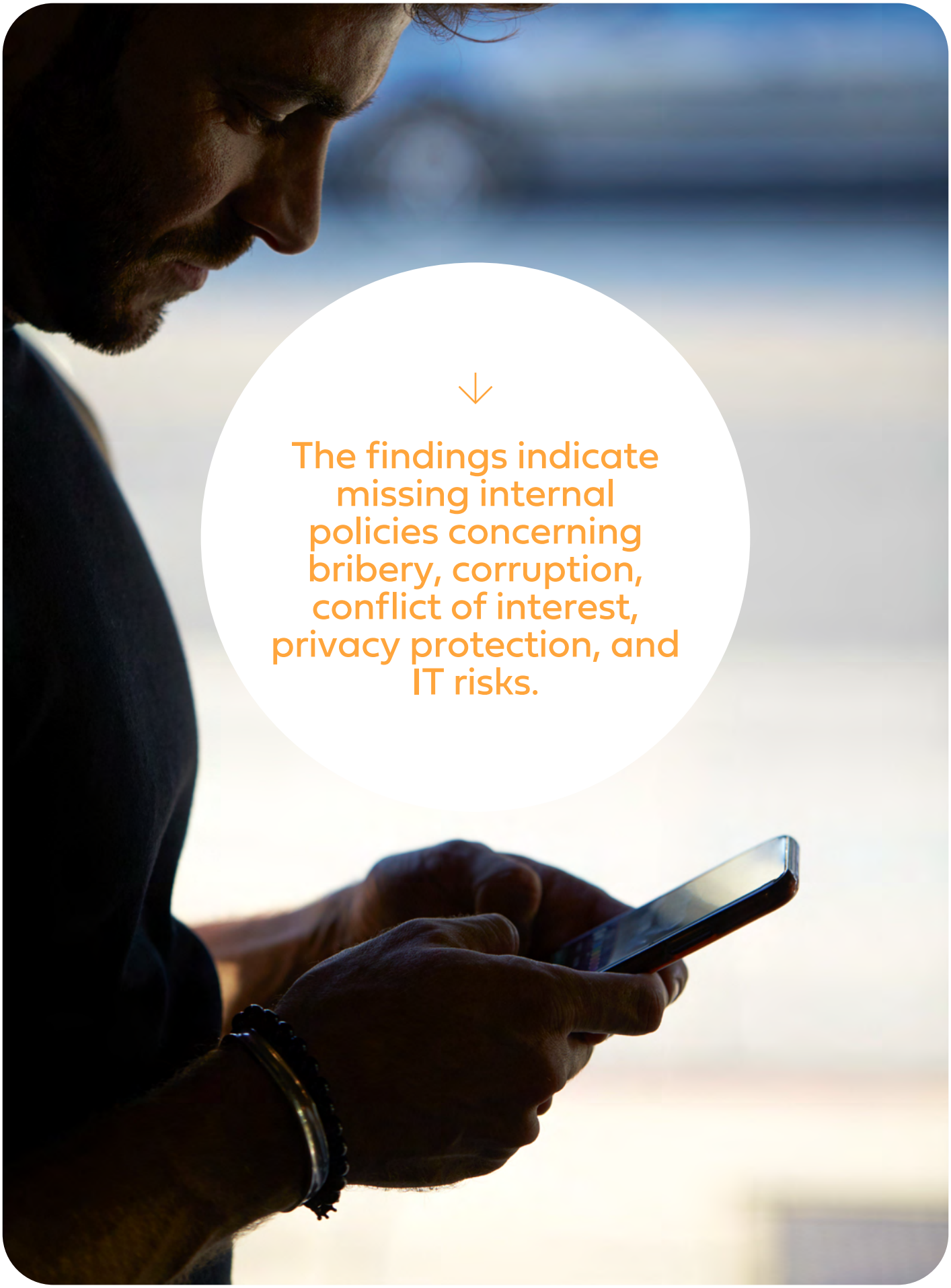
Ethics remains the smallest share of findings in 2025 (1%). Findings continue to focus on policy/code of conduct completeness, ethics training, and privacy or data protection. The findings indicate missing internal policies concerning bribery, corruption, conflict of interest, privacy protection, and IT risks, as well as insufficient training programs.





Practical actions for suppliers

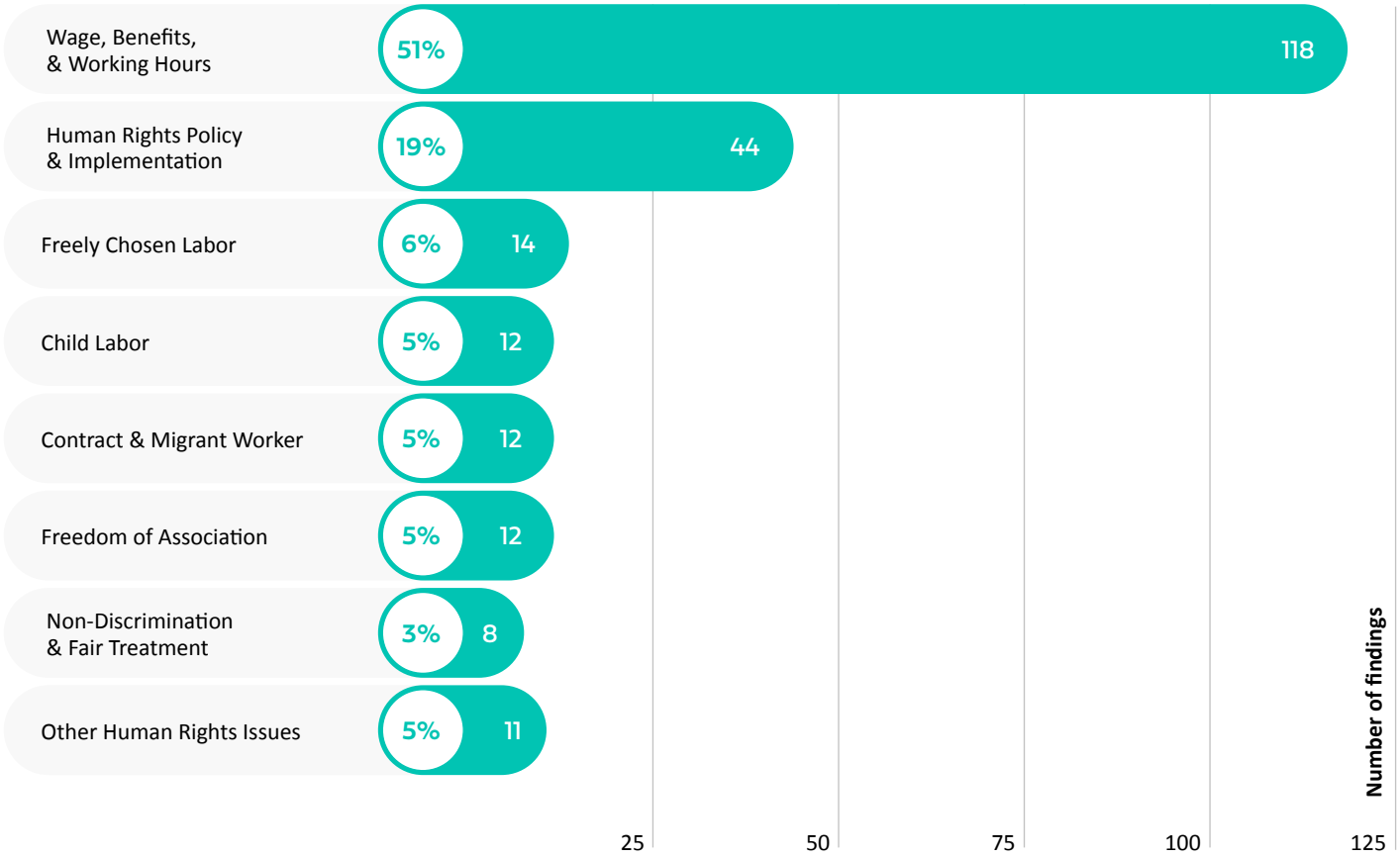
- Integrate ethical requirements including **business ethics** (e.g. anti-bribery, anti-corruption), **conflict of interest**, and **privacy protection** into policies and trainings.
- Consider **IT-related risks**, such as information breach and internet/power breakdown, in control procedures.
- For existing ethical policies and procedures, establish **periodic review procedures** to ensure standardization and alignment with external legislations/standards.


The findings indicate missing internal policies concerning bribery, corruption, conflict of interest, privacy protection, and IT risks.

Human Rights

231 Findings 9%

In 2025, Human Rights accounted for 9% of total findings. The dominant risk area was **Wage, Benefits, & Working Hours**, with findings related to excessive overtime, consecutive working days, and inadequate remuneration & benefits. Auditors also flagged gaps on **policy and implementation** (e.g. sites' human right policies missing essential elements such as the prohibition of child labor, anti-discrimination) and **forced labor prevention** (e.g. missing forced labor risk assessment).





Severity distribution

Although Critical findings under Human Rights in 2025 (2 findings) are less than that in 2024 (11 findings), the overall severity distribution still weighs heavily towards Major in main Human Rights topics: 96 of 118 (81%) of findings under Wage, Benefits, & Working Hours are classified Major, making it the subtopic with the highest Major proportion.

Illustrative 2025 examples:

Overtime

Within the 76 findings, 33 focused on excessive working hours; 29 involved insufficient rest days (no rest day over 7 consecutive working days). Notably, nearly 1 in 4 of the 29 findings reveal insufficient rest day for contract workers, security personnel, or other indirectly hired or non-production employees. For the remainder of the findings, 10 related to overtime wages not paid at the legally required premium rates; and the last 2 were on overtime work and night shifts for interns, contrary to legislation.

Policy Completeness & Presence

All 32 findings revealed that human rights policies at some facilities were either absent, incomplete in topic coverage (missing Prohibition of Child Labor, Freedom of Association, Non-discrimination, Non-harassment, Freely Chosen Employment, Anti-Human Trafficking, Labor Broker Recruitment Fees/Deposits, and Freedom of Movement), or not aligned with internationally accepted standards (e.g. OECD[3] guidelines).

Wage Compliance

18 wage-related findings include 7 on wages lower than local minimum wage; 5 relating to untranslated pay slips and missing pay slips for contract workers; 3 on wages not paid within legally mandated timescales; and another 3 related to delayed final wage payments for departing workers.

Benefit Management

14 findings in total address the lack of legally mandated leave entitlements, social security miscalculations, and workers paying for their personal protective equipment (PPE).

Risk Assessment for Forced Labor

14 findings reveal missing forced labor risk assessments, which is necessary to ensure that no forced, bonded, indentured or involuntary prison labor, human trafficking, or any form of modern slavery takes place in suppliers' operations and their supply chain.



Practical actions for suppliers

- Implement **automated time-and-attendance systems** that record actual clock-in and clock-out times for all workers, including contract staff, security personnel, and agency workers. Implement proper **work planning** processes, and if needed, configure **proactive alerts** for approaching daily, weekly, and monthly overtime limits. Ensure that all workers receive at least one full day off for every seven-day period, with particular attention to security services, catering contractors, and shift-based operations.
- Verify that all workers — including contract, agency, and security staff — receive **at least the applicable minimum wage**. Pay final wages to departing workers within the **timescales mandated by local regulation** rather than following standard payroll cycles.
- Ensure all legally mandated **leave entitlements** and **correctly calculated social security** are implemented for all employee categories.
- **Provide PPE free of cost** to all workers as an employer responsibility.
- Develop and maintain human rights policies that explicitly cover all topics set out in the **PSCI Principles**[4], including prohibition of child labor, non-discrimination, freely chosen employment, anti-human trafficking, freedom of movement, labor broker recruitment fees and deposits, freedom of association, and anti-harassment.

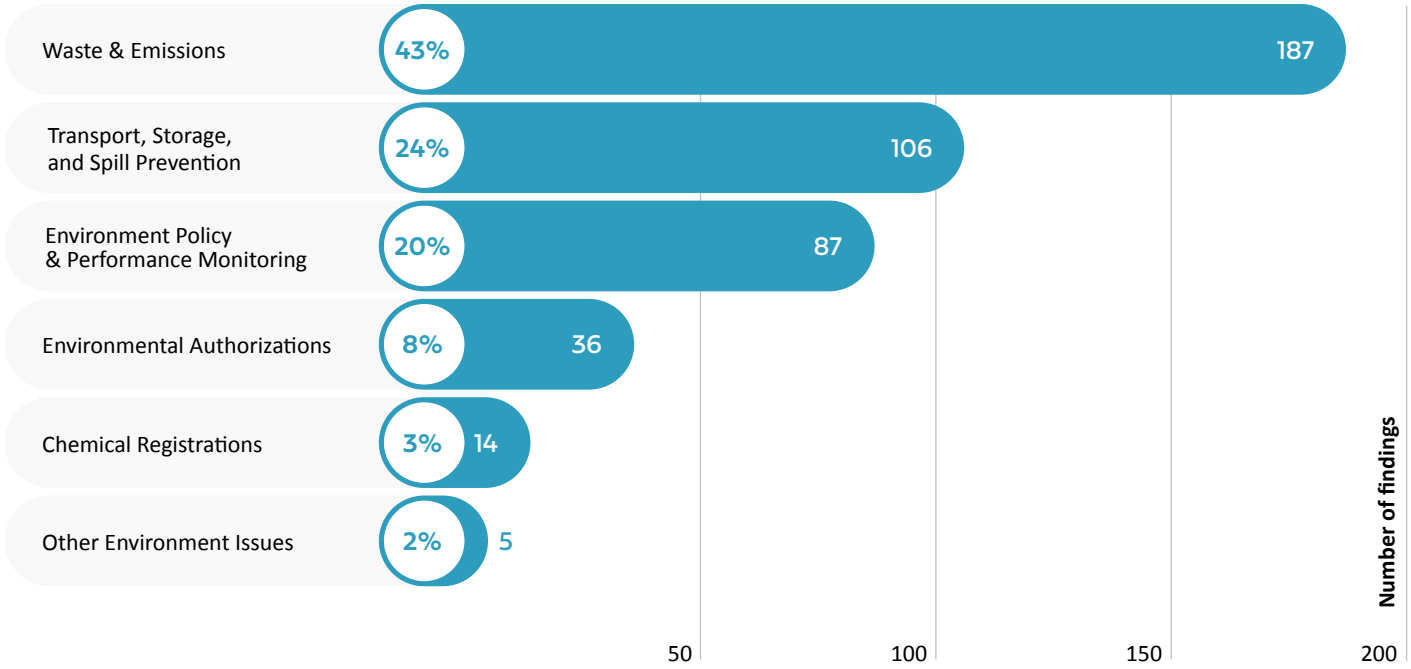
[3] https://www.oecd.org/en.html

[4] https://pscinitiative.org/resource?resource=1

Environment

435 Findings 17%

In 2025, auditors reported **435 findings** (17%) under the Environment section. The largest subtopic is **Waste & Emissions**, which highlights the importance of Active Pharmaceutical Ingredient (API) management, hazardous waste handling, stormwater controls, and air emissions. Findings related to **Transport, Storage & Spill Prevention** points to secondary containment and spill-control gaps.





Illustrative 2025 examples:

Hazardous Waste Management

This risk area contains 70 findings. 19 of them address the absence of formal vendor selection and audit programs for third-party waste disposal facilities; 18 involved issues on hazardous waste storage and segregation, including labelling gaps, security risks, and storage limit exceedances; 15 findings revealed gaps in regulatory reporting and documentation; 14 findings regarded inadequate handling and disposal practice for hazardous waste (e.g. hazardous waste disposed as general waste); and the last 4 on noncompliant sludge disposal.

Pharmaceuticals in the Environment (PiE)

62 findings were identified for PiE issues. 38 suggested the absence of PEC (Predicted Environmental Concentration)/ PNEC (Predicted No-Effect Concentration) assessment and API quantification in wastewater; 21 pointed to more general wastewater management issues, such as releasing process wastewater to sewer without a wastewater discharge permit.

Environmental Objectives

Out of a total of 58 findings, 27 were explicitly on missing or incomplete greenhouse gas (GHG) related targets, such as lacking performance improvement metrics or Science Based Targets Initiative (SBTi) alignment. The other 31 were related to the absence of more general environmental targets, such as waste minimization, or comprehensive ones covering waste, water, and resource efficiency.

Secondary Containment Systems

52 findings, with the majority (46) related to the absence of secondary containment at tanker loading/unloading and storage areas, with a recurring issue of sites not providing containment equivalent to 110% of the largest transportation unit. The other 6 were on gaps of secondary containment for chemicals stored in laboratories and Effluent Treatment Plant (ETP) chemical rooms.

Spill Prevention & Control

Within the 33 spill/leak-related findings, 19 addressed equipment topics, such as missing overflow protection, insufficient retention capacity, and missing spill kits; 14 were on management/procedural issues, such as incomplete Leak Detection and Repair (LDAR) studies.

21

findings pointed to more general wastewater management issues



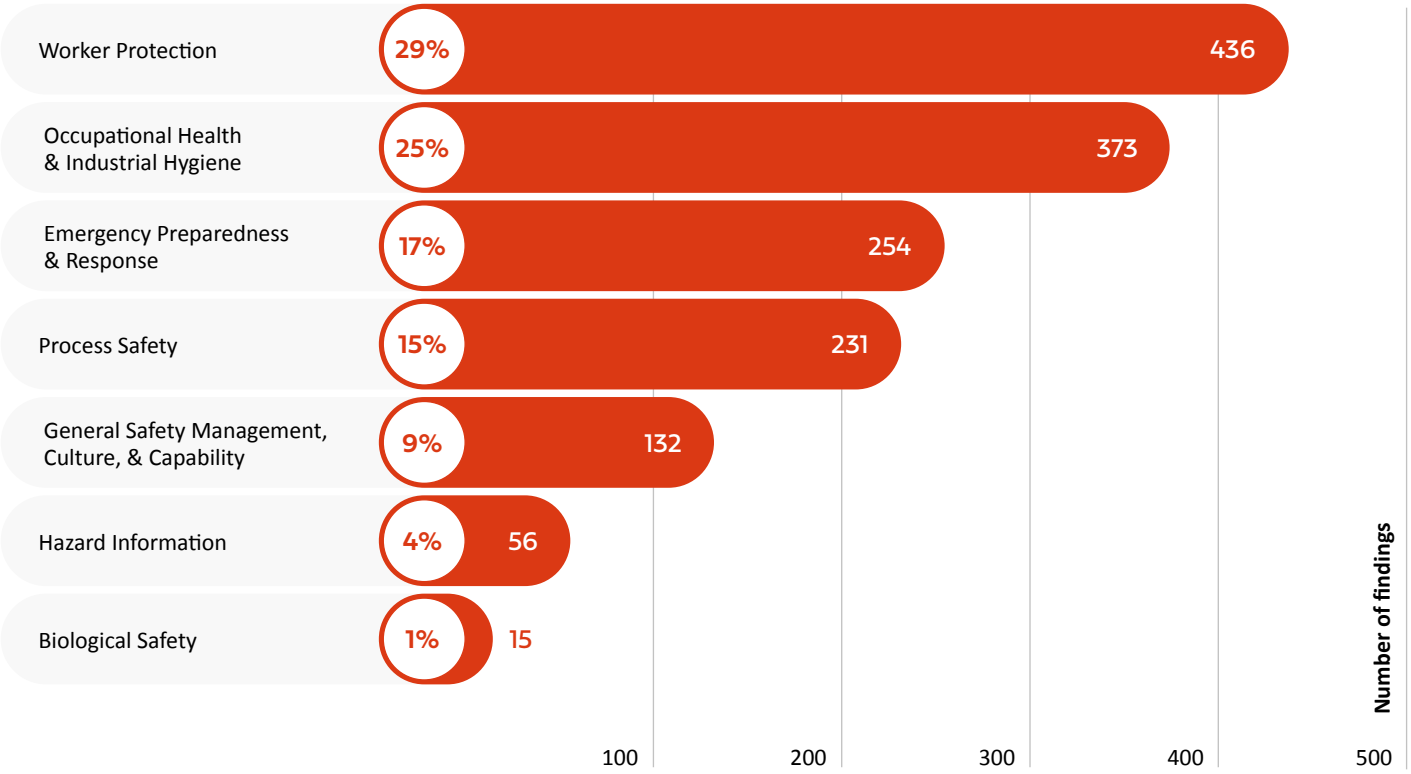
Practical actions for suppliers

- Establish PiE management programs that include **PEC/PNEC assessment** for all APIs discharged in wastewater, using either analytical testing with sufficiently sensitive methods or mass balance calculations. Where PEC/PNEC ratios exceed 1, implement additional treatment measures or process controls to reduce API concentrations below PNEC.
- Develop formal programs for the **selection, qualification, and periodic auditing** of all third-party waste treatment and disposal vendors, including recyclers. Ensure **full traceability** of waste from point of generation to final disposal.
- Establish documented environmental objectives with measurable targets and metrics covering, at a minimum, **energy consumption**, **water consumption**, **waste reduction**, and **GHG emissions**. Review and refresh objectives annually, with progress tracked and reported upon request.
- Conduct a comprehensive review of all chemical storage, handling, and transfer locations to verify that **secondary containment** is in place and provides for **110% capacity** of the largest container or transportation unit used.
- Develop and implement documented **spill management procedures** covering all areas where chemicals are handled, with formal training provided to all relevant employees. Install **overflow protection systems** — including level indicators, audible/visual alarms, and automatic shut-off devices — on above-ground storage tanks to reduce reliance on manual monitoring.

Health & Safety

1,497 Findings 58%

Health & Safety remains the largest topic area with **1,497 findings (58%)**. The majority of findings related to **Worker Protection**, **Occupational Health & Industrial Hygiene (OH & IH)**, **Emergency Preparedness & Response**, and **Process Safety**.





Severity distribution:

Process Safety is the subtopic under Health & Safety with the highest proportion of Major findings (94 out of 231, 41%) and the most Critical findings (10 Critical findings within 27 total).

Illustrative 2025 examples:

Site OH & IH Risk Assessment

With 132 findings, this marked the most prevalent single risk area in 2025. 79 findings were on sites lacking processes to establish Occupational Exposure Limit (OEL) values or Occupational Exposure Band (OEB) classifications for chemicals; having inadequate exposure monitoring procedures; and overly relying on PPE rather than engineering controls for exposure control. 16 findings were about carcinogenic, mutagenic, and reprotoxic (CMR) substances not being identified, categorized, or incorporated into risk assessments. Another 16 findings were on risk assessment for vulnerable populations (such as pregnant workers) and workplace-specific exposures. 9 findings addressed the absence of personnel exposure monitoring and validation of dust control measures in powder handling environments.

Electrical Safety

79 findings were identified in total, with 28 on Lock-Out-Tag-Out (LOTO) procedures not applied during maintenance; 23 on insulation and energy isolation gaps such as unmaintained electrical panels and untested insulation mats; and 16 highlighting incomplete or absent arc flash assessment.

Fire Protection Systems

Within the 73 findings, 26 revealed issues related to fire suppression systems like obstructed extinguishers, missed inspection schedules, malfunctioning hydrants, and unlocked sprinkler valves; 20 were on the lack of fire and smoke detectors; and the other 19 related to design flaws or complete absence of fire suppression systems.

Pallet Racking Systems

72 findings indicated gaps related to pallet racking systems. 43 of them addressed the lack of measures to prevent falling of stored goods (e.g. missing wrapping or strapping of stored materials); or rack protection issues, like damaged protection plates and unprotected rack feet. 14 findings indicated missing or damaged weight capacity labels on racking systems. 10 other findings pointed to missing or incomplete racking inspection programs.

132

findings for Site OH & IH Risk Assessment marked the most prevalent single risk area in 2025

Process Hazard Analysis (PHA)

64 findings were identified in total, with 34 indicated quality issues of PHA, including HAZOP (Hazard and Operability Analysis) not covering all risk scenarios, overdue PHA review, and LOPA (Layer of Protection Analysis) that only consider hazardous processes. 16 findings were about missing PHAs. Another 14 findings address sites not evaluating the potential impact of their operations on neighboring businesses, or vice versa.

Work Permit Programs

61 findings were made up of 26 covering confined space permits including missing confined space hazard classifications and missing rescue provisions; 9 relating to hot work permits, including missing post-work surveillance requirements; and another 9 on work-at-height permits, with issues such as unverified vertigo tests, and permits not available during active work.

Emergency Response Training & Plans

For the 61 findings relating to gaps in emergency preparedness, 34 indicated drills not covering all shifts, all areas, or all emergency scenarios, and that lessons learnt are not tracked to corrective actions. 19 findings related to incomplete or outdated emergency response plans. The remaining 8 findings related to insufficient capability building (trainings) for sites' emergency teams.



Practical actions for suppliers

- Establish processes to derive **substance-specific OEL values and OEB classifications** for all APIs, intermediates, and hazardous chemicals handled. Conduct both **qualitative and quantitative exposure assessments** using API-specific analytical methods rather than relying solely on gravimetric total dust analysis.
- Develop equipment-specific **LOTO procedures** covering all energy sources (electrical, mechanical, thermal, pneumatic, hydraulic). Establish periodic testing and certification schedules for **insulation mats** and maintain **electrical panel rooms** in a locked and clean condition.
- Include all fire suppression and detection equipment — including newly acquired items — in **preventive maintenance programs**. Reinstate any out-of-service systems promptly and provide **interim fire protection** where repairs are ongoing.
- Implement a documented program requiring all **overhead-stored materials** to be secured by wrapping, strapping, netting, or containment frames. Display **weight capacity labels** on all racking sections and establish scheduled inspections by competent persons covering racking in all facility areas.
- Ensure **HAZOP studies** are conducted for all products and critical reactions, with process safety information — including thermal stability data, powder safety properties, and Piping and Instrumentation Diagram (P&ID) - developed prior to study initiation. Establish **formal review cycles** for PHAs and track all recommendations to closure with documented verification of effectiveness.
- Expand **confined space inventories** to cover all areas meeting the confined space definition, including wastewater pits, process vessels, and retention basins. Record **post-work surveillance** times and signatures on hot work permits.
- Document **lessons learned** from each drill and track corrective actions to closure with defined timescales.

Health & Safety findings in top 4 regions



United States

Worker Protection (maintenance for pallet racking systems, comprehensiveness of electrical safety programs); Emergency Preparedness & Response (regular dills, accessibility of emergency plans).



Western Europe

Worker Protection (pallet racking security, work permit management); OH & IH (material and population-specific exposure risk assessments); Process Safety (ventilation & ignition control, ATEX studies & zoning).

China

OH & IH (API/chemical-specific OEL/exposure risk assessments); Worker Protection (LOTO, energy isolation, and insulation equipment testing); Emergency Preparedness & Response (accessibility/usability of emergency exits, emergency signage and assembly points clarity).

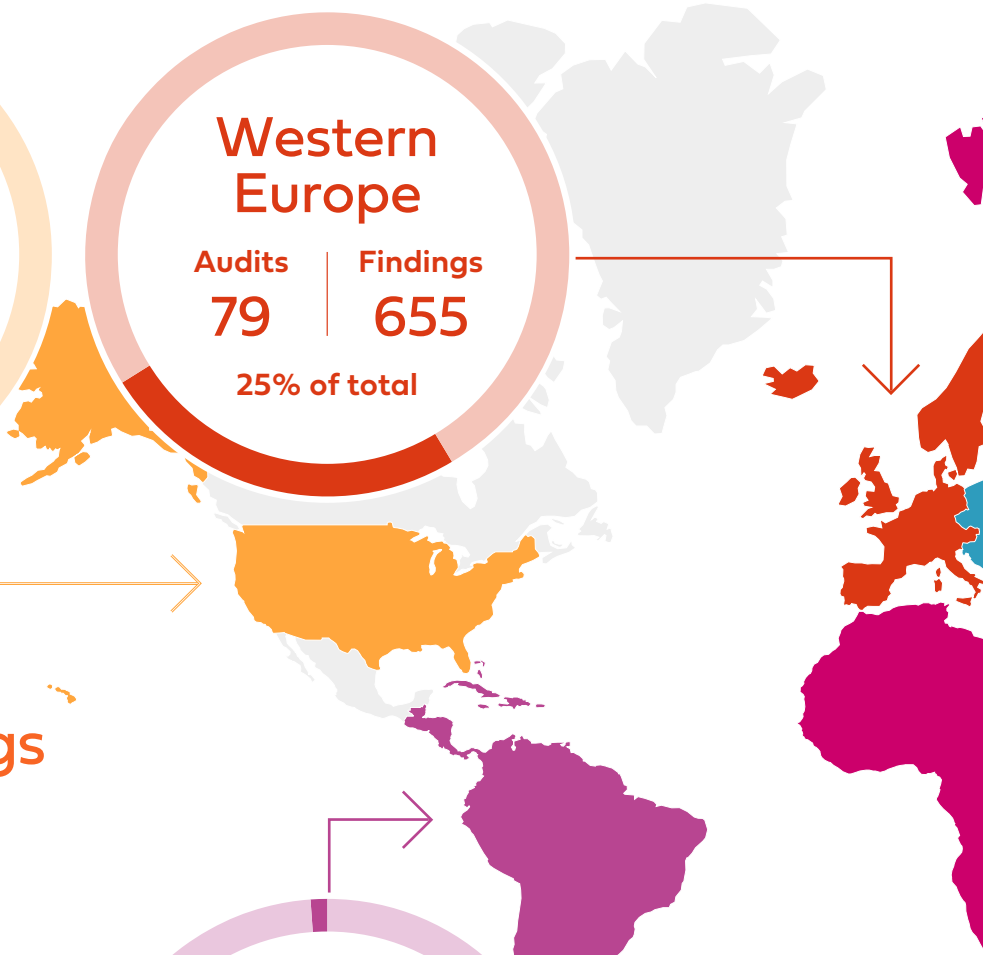


India

Worker Protection (compliant LOTO and arc flash analysis procedures); OH & IH (OELs and OEBs for APIs and intermediates, including CMR compounds); Emergency Preparedness & Response (fire detection and suppression system availability).

Regional Analysis

In 2025 we reviewed 243 audits, which we clustered into eight regional groupings: China, India, United States, Western Europe, Eastern Europe, South America, Rest of Asia, and Rest of the World. Health & Safety findings dominate most regions, but the subtopics vary.



United States

Audits	Findings
19	203

8% of total

Western Europe

Audits	Findings
79	655

25% of total

Total

243 Audits
2,596 Findings

11 Findings per audit

Rest of the World

Audits	Findings
13	101

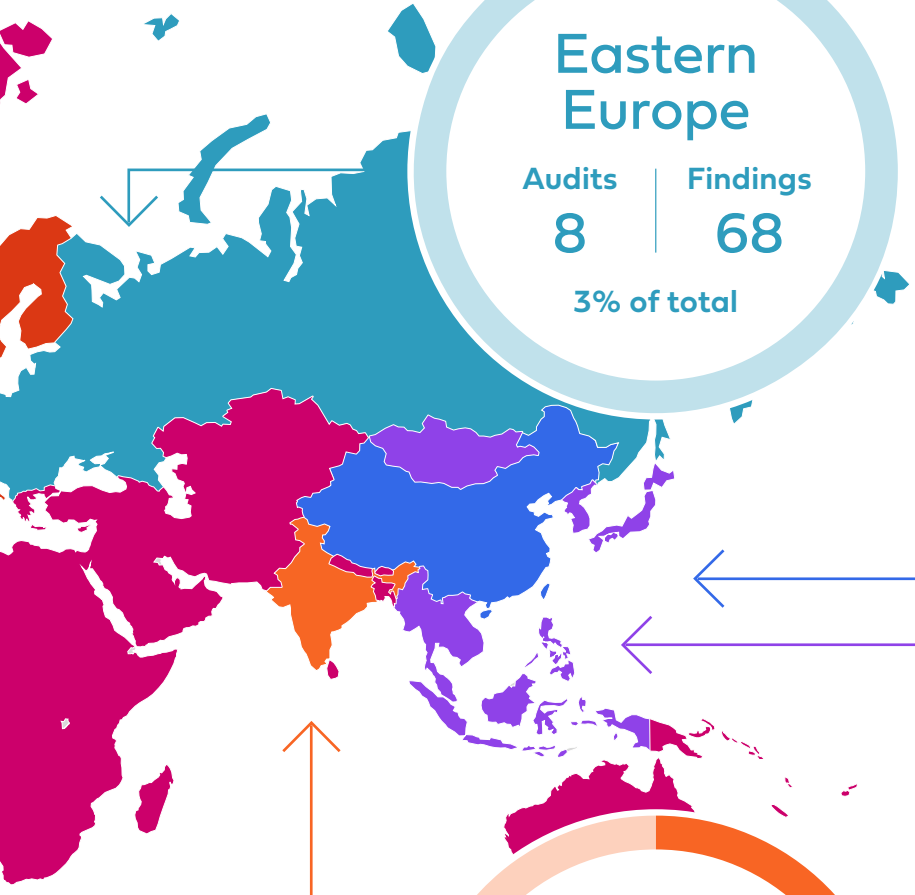
4% of total

South America

Audits	Findings
4	21

1% of total

Compared to 2024, India had the most notable increase in both audit number, finding number, and finding per audit: there were **45** audits, **584** findings, and on average **12.98** findings per audit in 2024; while there were **69** audits, **1,087** findings, and on average **15.75** findings per audit in 2025. For China, the number of audits and findings had reduced from **64** audits and **435** findings in 2024, to **37** audits and **330** findings in 2025. Nonetheless, the number of findings per audit in China, had increased from 6.80 in 2024 to **8.92** on average in 2025. No significant change in terms of total number of audits and findings was observed for other regions.



Eastern Europe

Audits	Findings
8	68

3% of total

China

Audits	Findings
37	330

13% of total

India

Audits	Findings
69	1,087

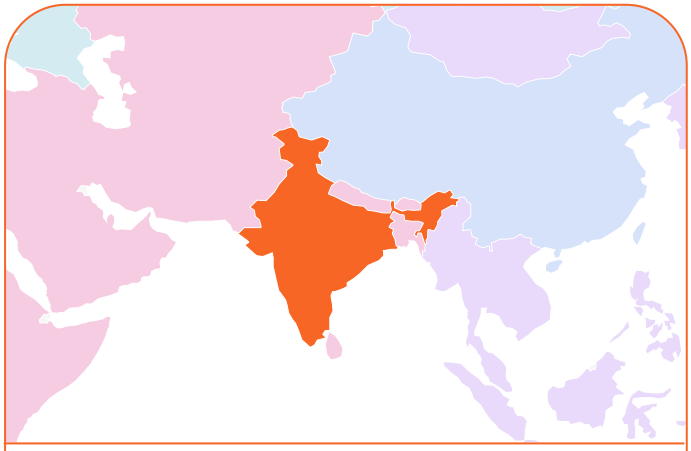
42% of total

Rest of Asia

Audits	Findings
14	131

5% of total

India



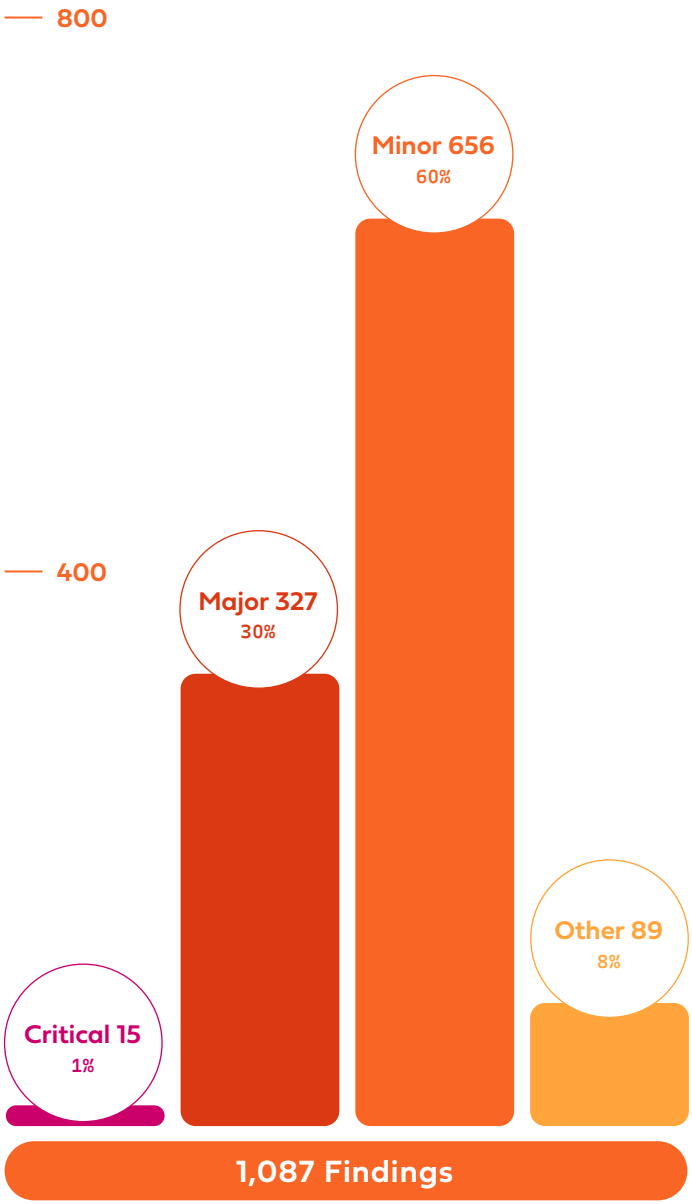
69 Audits
1,087 Findings
16 Findings per audit
42% of total

India recorded 1,087 findings across 69 audits, with 15 Critical and 327 Major.

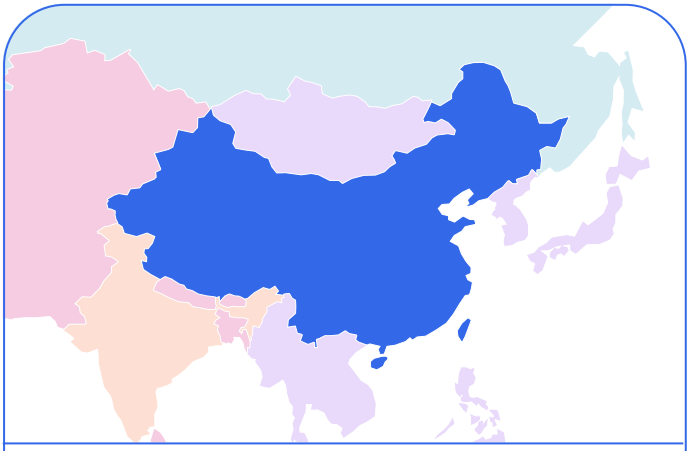
Health & Safety comprised 58% of issues, led by **Worker Protection** (27%), **OH & IH** (26%), and **Emergency Preparedness & Response** (18%). Critical findings cover **Worker Protection** (missing centrifuges lack lid interlock systems and absence of main electricity safety practices), **Process Safety** (incomplete PHA, such as missing thermal stability studies, unapproved P&IDs, and untracked HAZOP recommendations; as well as unauthorized toluene storage), **OH & IH** (compressed air used as breathing air, no exposure control capabilities, and no asphyxiation assessment), **Waste & Emissions** (data report and compliance gap of ETP), **Transport, Storage, & Spill Prevention** (no secondary containment for acid containing drums), and **Legal & Customer Requirement** (received noncompliance direction from state pollution control board).

Future areas of focus for Indian suppliers include establishing **OELs and OEBs** for APIs and intermediates, including **CMR compounds**; checking **fire detection and suppression system availability**, especially at high-risk areas like warehouses, hazardous waste storage areas, raw material stores, and manufacturing blocks; conduct more comprehensive **HAZOP studies** with recommendations followed and impacts from neighboring business and local communities covered; and conduct compliance **LOTO and arc flash analysis** procedures.

India findings by type 2025



China



37 Audits
330 Findings
9 Findings per audit

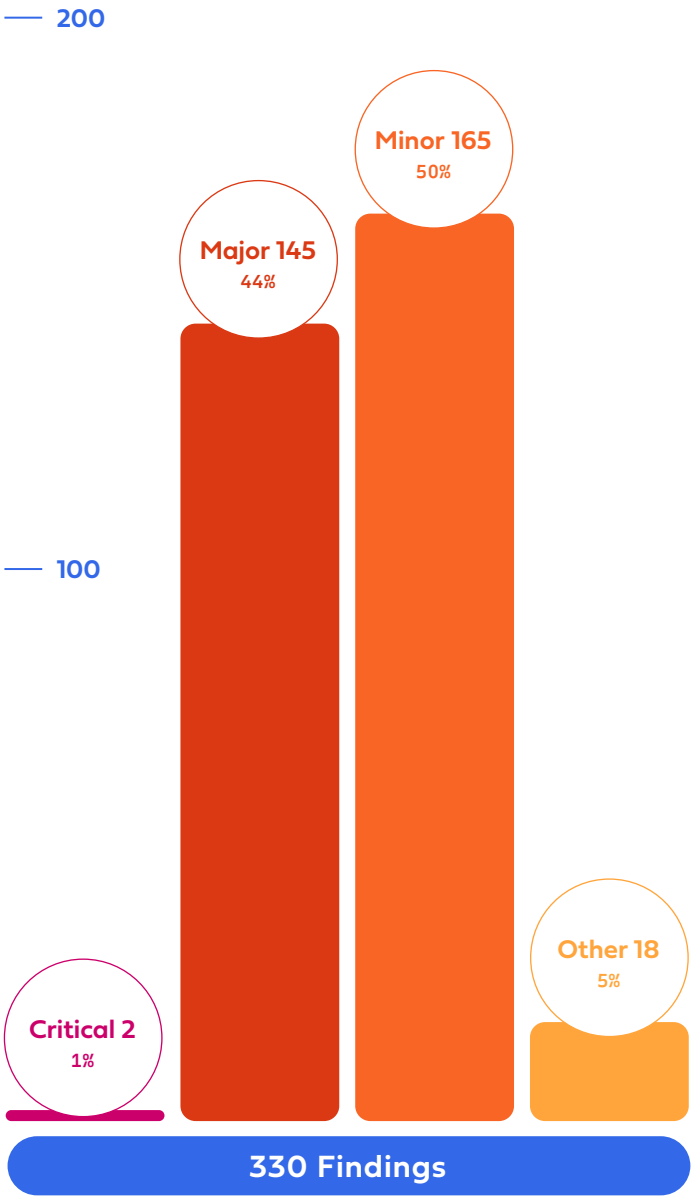
13% of total

Auditors in China reported 330 findings across 37 audits, with 2 Critical (1%) and 145 Major (44%).

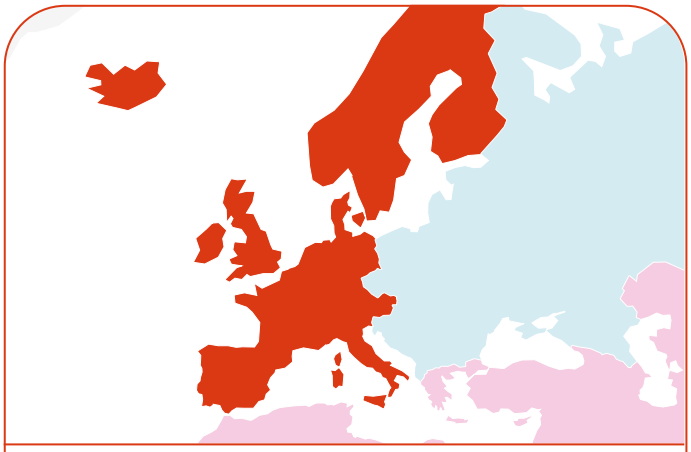
Health & Safety represents 51**%**, followed by **Human Rights** at **19%**. The most common subtopics included **OH & IH (15%)**, mainly indicating exposure level assessment not covering specific substances; **Wage, Benefits, & Working Hours (12%)**, with excessive overtime being the dominant issue**; Worker Protection (12%),** revealing issues on electrical safety practice, and **Emergency Preparedness & Response (11%)**, mainly pointing out emergency exit/route and fire suppression system maintenance issues. The 2 Critical findings reveal issues on **Emergency Preparedness** (locked & inward opening, as well as missing emergency exits) and **Contract & Migrant Workers** (foreign migrant workers paying paid recruitment fees and other related costs).

Priorities for suppliers in China include providing API/chemical-specific **OEL/ exposure risk assessments**; closely monitoring employees' **daily and monthly overtime** and ensuring at least one **rest day** per seven-day period; fully implement **LOTO, energy isolation, and insulation equipment** testing; and ensure full accessibility/usability of **emergency exits** and **fire suppression systems**, with clear **emergency signage and assembly points**.

China findings by type 2025



Western Europe



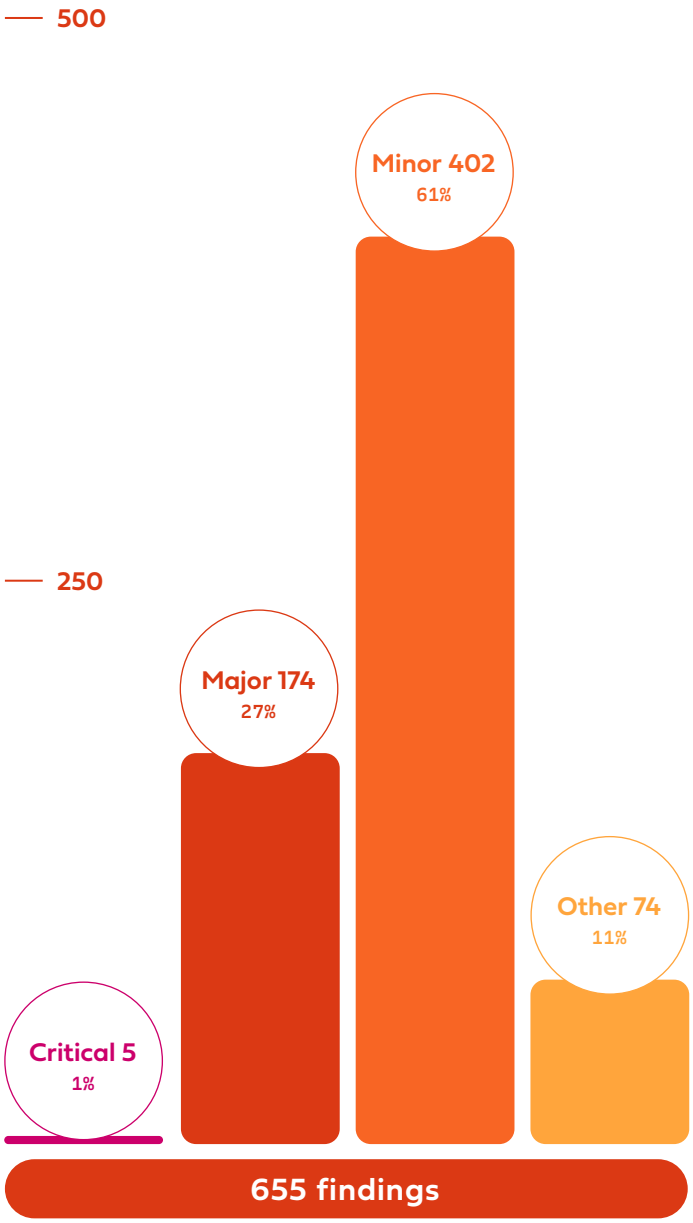
79 Audits
655 Findings
8 Findings per audit
25% of total

Auditors in Western Europe reported 655 findings across 79 audits, with 5 Critical (1%) and 174 Major (27%).

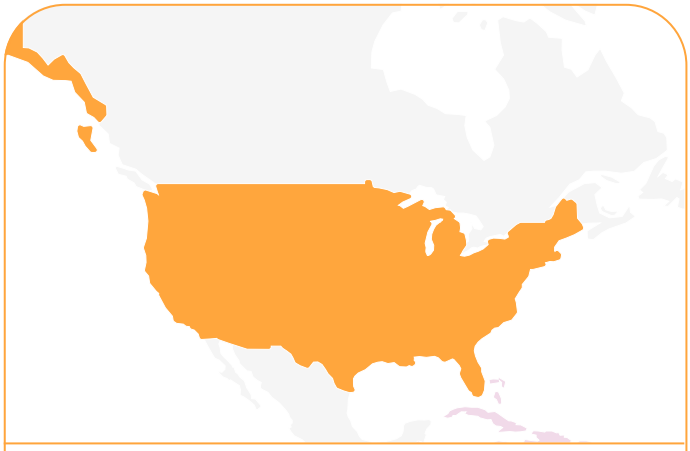
Health & Safety represents **58%** of total findings, with **Worker Protection (20%)** as the largest proportion, suggesting unsecured pallet racking/poorly communicated max rack load; incomplete and inconsistently applied permit process; and incomplete electrical risk control practices. **OH & IH (10%)** highlights workplace and chemical risk assessments lacking clear criteria and not performed based on specific substances or fully covering vulnerable populations. **Risk Management (9%)** pointed to issues including missing or incomplete BCPs, as well as risk assessment processes that did not cover governance, ethics, and human rights categories. Critical findings involve **Waste & Emissions** (missing toxic dust emission analysis, and lack of wastewater discharge permit as well as API risk assessment for wastewater); **Process Safety** (lack of grounding practices such as grounding clamps, and site having no ATEX zoning, overdue ATEX study, and poorly maintained gas detection systems); and **Training & Competency** (training not covering PiE and AMR topics).

Improvement priorities include **rack securing and labelling**, **permit content and execution**, enhancing **electrical risk assessment and safety equipment maintenance**, offering **material and population-specific** exposure risk assessments, and including **comprehensive set of risk scenarios** into BCPs.

Western Europe findings by type 2025



United States



19 Audits
203 Findings
11 Findings per audit
8% of total

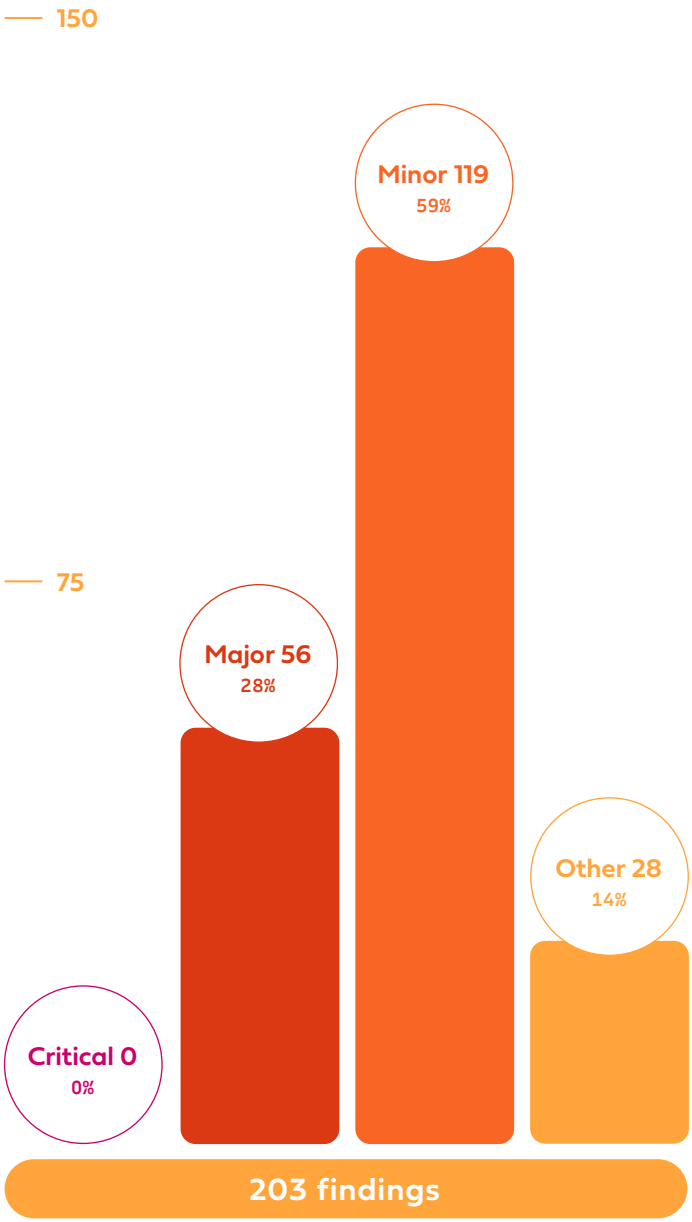
Auditors in the United States recorded 203 findings across 19 audits with no Critical findings and 56 Major findings (28%).

Health & Safety represents **64%**, followed by Environment with **23%**. Hotspot subtopics include **Worker Protection** (missing load capacity labeling and inspection for pallet racking, absence of electrical safety programs and unlocked panels/unlabeled switches and outlets, lack of key safety work permit procedures); **Waste and Emissions** (inadequate hazardous waste storage documentation and labelling, incomplete waste traceability, incomplete PiE risk assessments for APIs); and **Emergency Preparedness** (overdue drills, unavailable emergency action plans).

Actions for suppliers in the United States include **maintenance for pallet racking systems** with clear labeling; ensuring compliance **electrical safety programs** that include necessary arc flash analysis, LOTO, and energy isolation; fully implementing work permit SOPs; enhancing **hazardous solid waste and wastewater management** with labeling/tracking and risk assessment; and maintaining up-to-date **drills** and **accessible emergency plans**.

Notably, the proportion of HSE-only audits in the US is **63%** - much higher than the global figure of **44%**. This contributes to less labor and ethics findings in the US: they contribute to **4%** of all US findings, while the proportion is **9%** in India, and **20%** in China and Western Europe.

United States findings by type 2025



Eastern Europe



8 Audits
68 Findings

9 Findings per audit

3% of total

68 findings, 0 Critical, across 8 audits, with most prevalent gaps in **Worker Protection** (electrical safety and work permit management), **OH & IH** (respiratory protection equipment fit testing), and **Emergency Preparedness** (training and response plan gaps).

South America



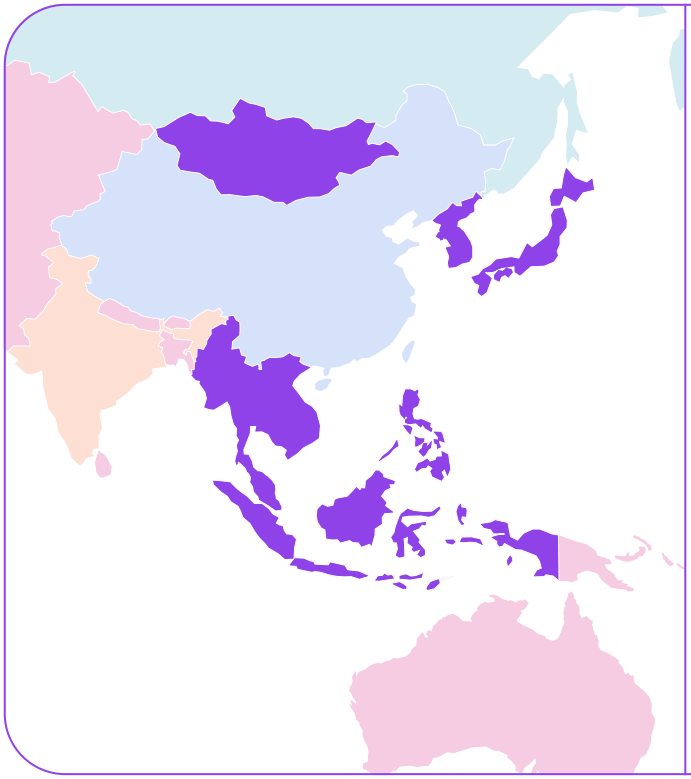
4 Audits
21 Findings

5 Findings per audit

1% of total

21 findings, 0 Critical, across 4 audits. Findings concentrate on **OH & IH** (exposure assessment), **Waste & Emissions** (PEC/PNEC assessment), and **Worker Protection** (electrical safety management).

Rest of Asia



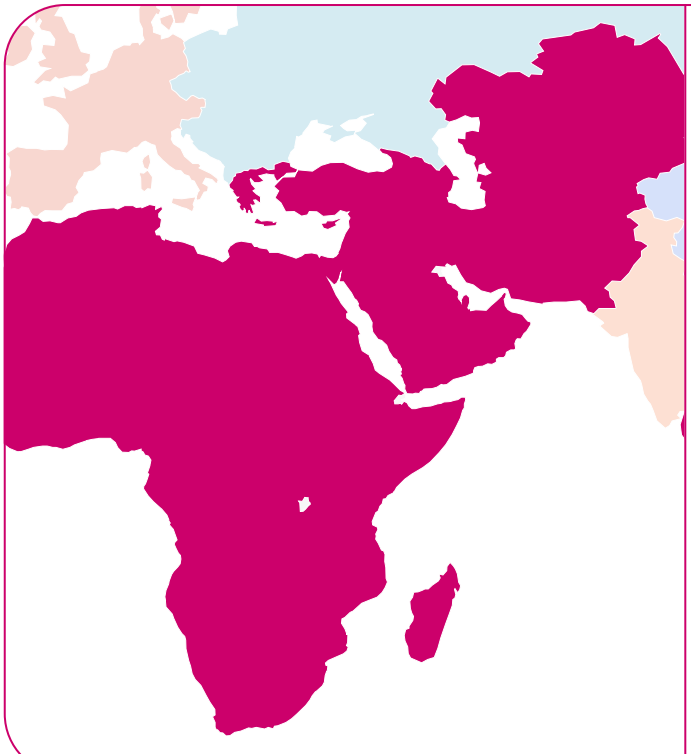
14 Audits
131 Findings

9 Findings per audit

5% of total

14 audits containing 131 findings, **5 of which were Critical**. Critical findings focus on missing hazardous waste permits, machine guarding, hazardous area classification, and inadequate explosion risk management. Other findings are primarily focused on **OH & IH** (exposure monitoring, particularly for dust), **Process Safety** (overdue or incomplete PHA), and **Worker Protection** (workers' knowledge of permits).

Rest of the World



13 Audits
101 Findings

8 Findings per audit

4% of total

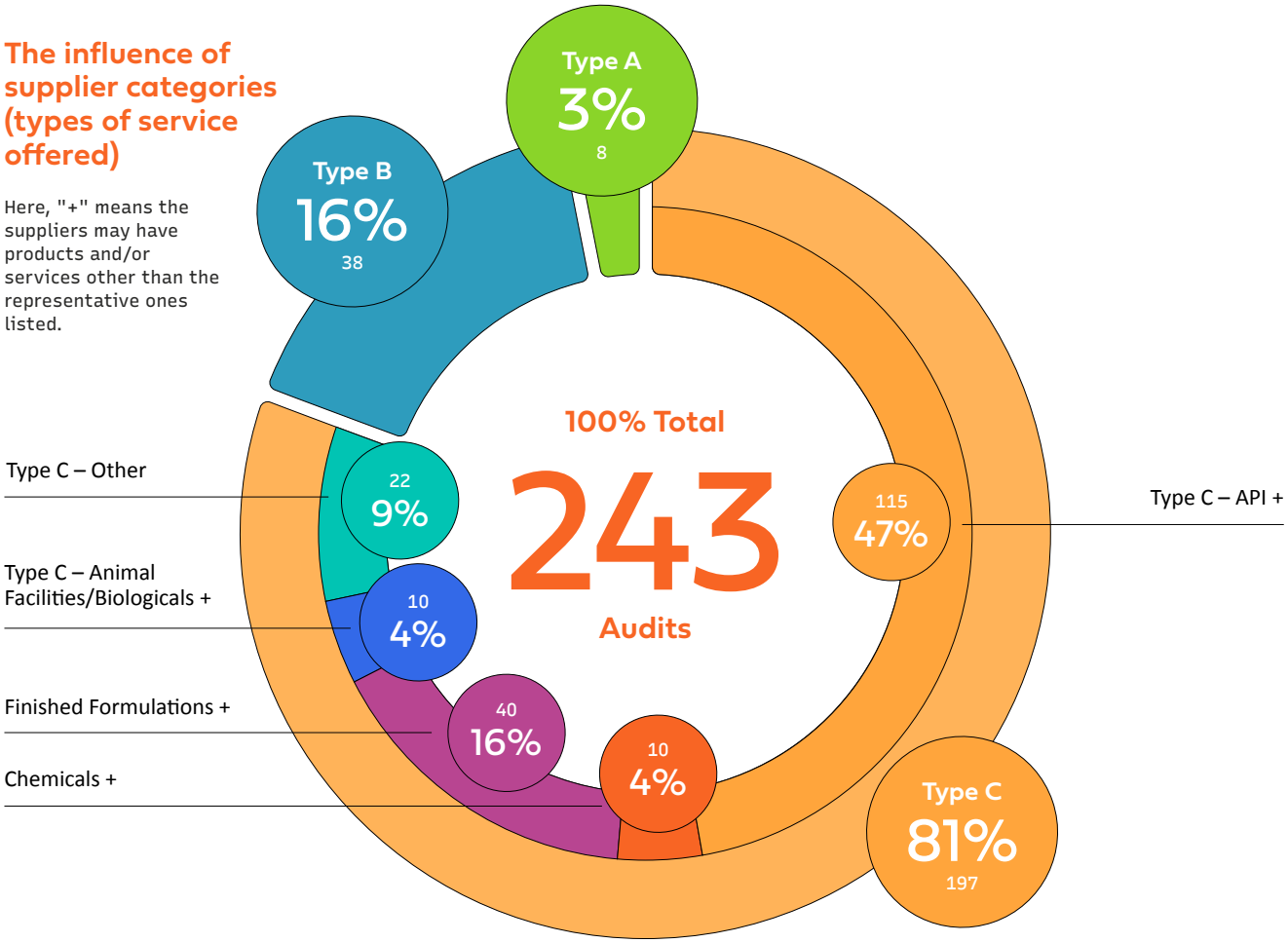
101 findings, 0 Critical, across 13 audits. Most findings relate to **OH & IH** (PPE wearing, exposure assessment), **Worker Protection** (LOTO procedures, work at height protection), and **Emergency Preparedness** (incomplete/ overdue drill and associated improvement actions, as well as fire marshal arrangement).

Additional Insights

This section explains the other factors that influence the distribution of findings by topic.

The influence of supplier categories (types of service offered)

Here, "+" means the suppliers may have products and/or services other than the representative ones listed.



Definitions of supplier categories

Type C Suppliers

- API (active pharmaceutical ingredient)
- Finished Formulations
- Chemicals
- Biologics
- Pilot Plants
- Contract Research Labs
- Animal facilities (breeding, testing)
- Primary Packaging
- Logistics / Warehouse (open handling of chemical materials)

Type B Suppliers

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

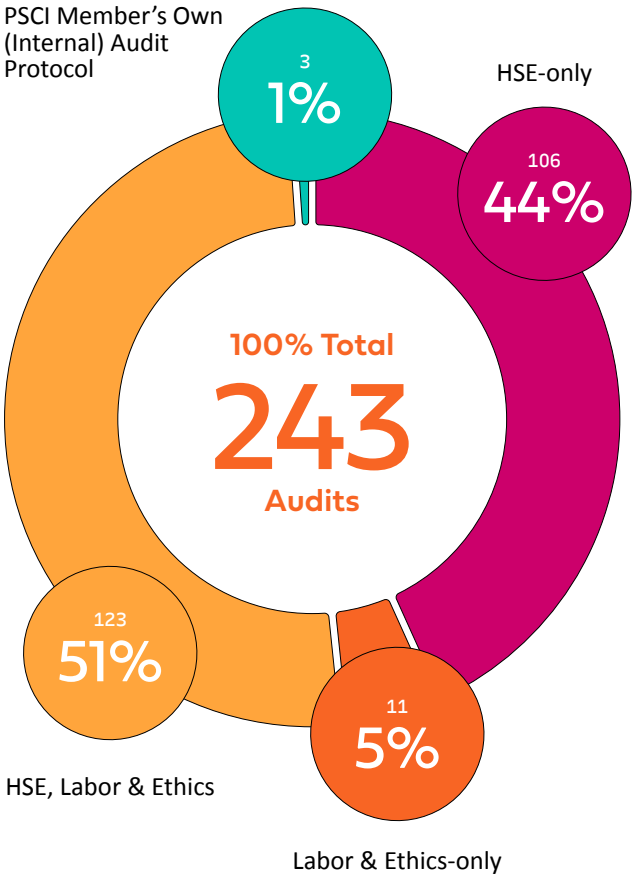
Type A Suppliers

- 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)

The distribution of findings across the HSE, Human rights and Ethics topics (discussed in previous sections) can be attributed to the services of the suppliers being audited.

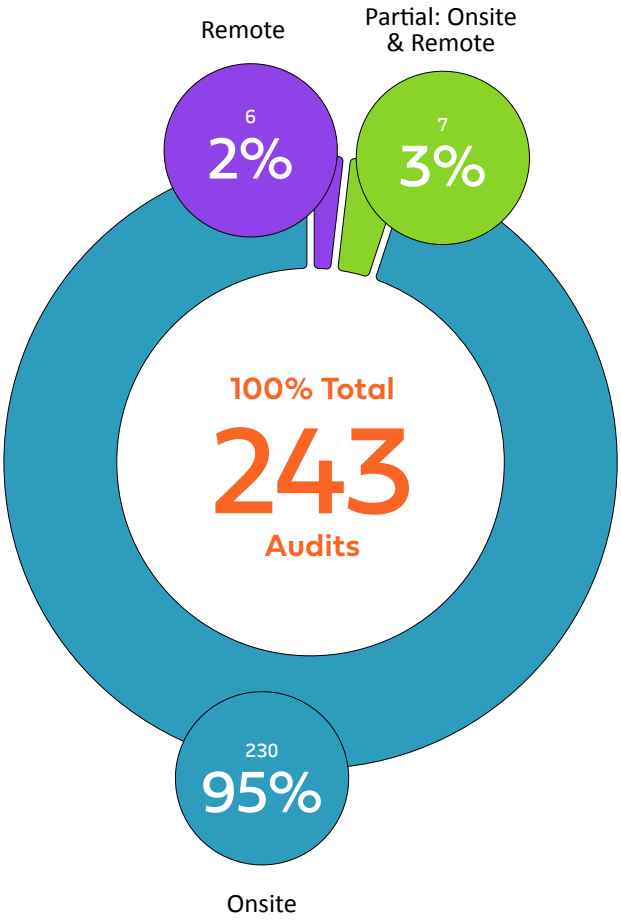
In this audit uploading cycle, 81% of all uploaded audits were conducted for **Type C suppliers**, whose core operations involve active pharmaceutical ingredients (APIs) and finished formulations. Because these suppliers operate directly within pharmaceutical-specific technical areas, they are assessed against the metrics designed to capture the HSE risks primarily relevant to core suppliers, such as PiE and Antimicrobial Resistance (AMR). These audits naturally yield a higher density of HSE findings. By comparison, Human rights and Ethics topics, such as information security or data privacy, apply more universally across all supplier types.

The influence of audit scope (topic coverage)



44% of all audits targeted HSE compliance alone, with only 5% dedicated exclusively to Human Rights and Ethics. This necessarily influences the total proportion of findings toward the HSE topics.

The influence of audit delivery method (onsite or remote)



95% of the audits were conducted onsite. Physical site walkthroughs and face-to-face worker interviews remain highly effective methodologies, allowing auditors to uncover nuanced issues across Governance, Ethics, Human Rights, and HSE alike. Onsite audits support a rigorous approach and typically yield more audit findings.

81%

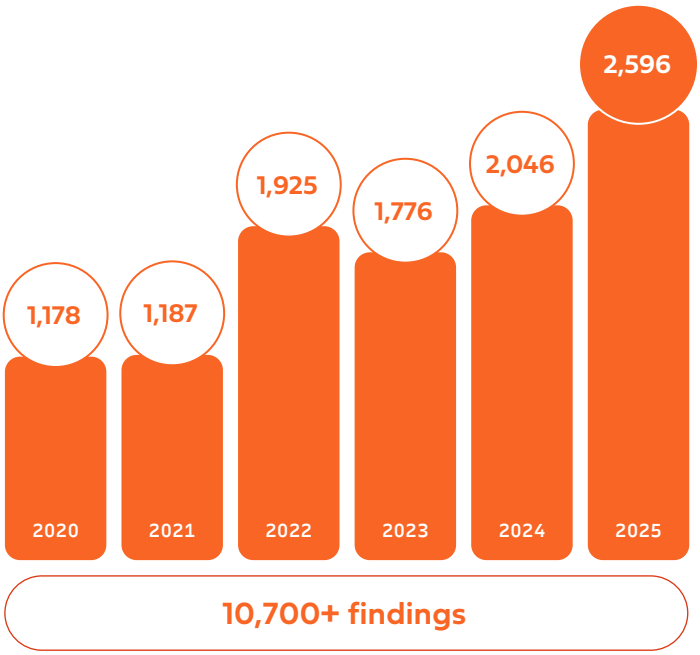
of all uploaded audits were conducted for Type C suppliers

Understanding our Impact

The Audit Findings Analysis assists PSCI and its Members to prioritize capacity-building areas based on supplier performance.

This year, with record-high number of audits and findings, the PSCI confirmed hot spots to refine its supporting programs. The higher severity of findings related to labor practices (overtime, wages and benefits) and process safety management highlighted the need for increased attention. Common areas where suppliers fall short, such as BCP, contractor management, PiE, and exposure risk assessment, require ongoing support.

Findings in 2025 also returned to a greater focus on Environment, with fewer findings under the Governance & Management Systems and Human Rights topics. Although this does not necessarily indicate growing or declining importance of certain topics, we will continue to monitor changes in total finding numbers and subtopics to capture important changes and formulate our strategy.





Building Capability

The PSCI translates findings into targeted learning resources and regional programs, prioritizing topics with the greatest potential to reduce risk and those of highest importance to our Members.

Our capability-building program is designed to strengthen suppliers' knowledge and expertise, enabling them to meet international standards. PSCI resources help suppliers understand, identify, and address safety, social, environmental, and ethical issues. We deliver this through interactive courses, industry-tailored tools and resources, and practitioner-led events.

Our e-learning courses feature interactive elements and quizzes to reinforce learning outcomes. Biweekly webinars provide suppliers with direct access to subject matter experts and opportunities to ask questions in real time. Our annual in-person supplier conferences in India and China, along with technical workshops in India, enable expert-led and peer learning. Across the programme, we prioritize topics aligned with key audit findings and measure impact by tracking improvements in suppliers' knowledge.

Our training curriculum is structured across four levels of maturity, enabling suppliers to navigate the learning library and access resources tailored to their specific needs. In particular, it helps direct suppliers to learning resources which support the effective closure of audit findings.

We encourage Members and suppliers to integrate these learnings into their management-system reviews, supplier due-diligence programs, and improvement plans, tracking closure effectiveness and sharing what works across the community.









Join us to build responsible supply chains

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May 2026. Design by nineteenseventyone