Catalyst Group

ADDRESSING PHARMACEUTICAL SUPPLY CHAIN CHALLENGES THROUGH EXPERT PSCI AUDITING

Executive Summary

The Pharmaceutical Supply Chain Initiative (PSCI) Audit Findings 2025 report reveals critical insights into manufacturing excellence across the global pharmaceutical supply chain. This comprehensive analysis of 2,046 findings from 228 audits conducted in 2024, combined with five-year trend data encompassing nearly 7,700 findings from 641 audits, illuminates persistent challenges in Health & Safety, Governance & Management Systems, Human Rights, Environment, and Ethics. While these findings reflect the current state of supplier practices, they also underscore an essential truth: the quality, expertise, and approach of the auditing firm directly determine whether these challenges translate into meaningful improvements or remain persistent vulnerabilities. This paper examines the key findings from the PSCI 2025 report and demonstrates how partnering with the right PSCI auditing firm can transform audit observations into sustainable operational excellence and risk mitigation.

Overview of PSCI Audit Findings 2025

Scope and Methodology

The sixth edition of the PSCI Audit Findings Analysis Report represents an unprecedented commitment to transparency and collaborative improvement within the pharmaceutical and healthcare supply chain. In 2024, PSCI members uploaded over 200 audits to the platform, generating more than 2,000 findings across five core Principle areas. These audits typically require two to four days of intensive on-site assessment, examining supplier practices against the PSCI Audit Template standards.

The findings are distributed across five Principles: Health & Safety (54%, 1,098 findings), Governance & Management Systems (21%, 428 findings), Human Rights (13%, 273 findings), Environment (11%, 221 findings), and Ethics (1%, 26 findings)[1]. This distribution has remained relatively stable over the five-year analysis period, with Health & Safety consistently representing approximately half of all findings, underscoring its business-critical nature and potential life-threatening implications.

Geographic Distribution and Regional Patterns

The 2024 audit portfolio reflects the global nature of pharmaceutical manufacturing, with significant representation from China (28%, 64 audits), Western Europe (27%, 61 audits),India (20%, 45 audits), United States (8%, 19 audits), and other regions including Rest of Asia, South America, Eastern Europe, and Rest of the World[1]. Each region exhibits distinct patterns in finding types and severity, reflecting differences in regulatory frameworks, industrial maturity, workforce practices, and environmental management capabilities.

China and India, representing nearly half of all audits, show elevated findings in Occupational Health & Industrial Hygiene, Process Safety, and working hours compliance. Western Europe demonstrates strong performance in severity ratings (62% Minor findings) but continues to face challenges in Worker Protection, particularly machine guarding and electrical safety. The United States recorded no Critical findings but showed concentration in Worker Protection and Process Safety topics, particularly electrical safety systems and Process Hazard Analysis completeness[1].

Five-Year Trend Analysis

The longitudinal analysis reveals several significant trends that contextualize the 2024 findings. Governance & Management Systems findings have increased substantially since 2023, overtaking Environment as a proportion of total findings. This shift reflects growing auditor focus on risk management, Business Continuity Planning, supplier due diligence against international standards, and incident investigation expectations[1].

Within Health & Safety, the number of Major findings per audit has increased since 2022, suggesting more detailed investigations and higher expectations rather than deteriorating performance. Auditor findings demonstrate increasing specificity and technical depth, encompassing more sophisticated requirements and systemic safety procedures. Topics such as Lock Out Tag Out (LOTO), toxic carcinogenic/mutagenic/reproductive (CMR) chemicals, and process hazard studies are receiving heightened attention[1].

Human Rights findings show sharper attention to contract worker treatment, with multiple critical findings in 2023-2024 related to benefits, overtime compensation, and contract completeness. Additionally, alignment with international standards such as the OECD Guidelines and UN Guiding Principles on Business and Human Rights appears more frequently after 2022, demonstrating maturing expectations for due diligence and value-chain coverage[1].

Critical Challenges Identified Across PSCI Principles

Governance & Management Systems: The Foundation of Operational Resilience

Governance & Management Systems accounted for 21% of findings in 2024, with Risk Management representing the largest subcategory (38%, 164 findings)[1]. Three themes dominate this category: Business Continuity Planning deficiencies, inadequate Risk Assessment scope and methodology, and weak Change Management processes.

Business Continuity Planning gaps represent perhaps the most consequential systemic vulnerability identified in the audit findings. Many facilities maintain plans with limited scenario coverage, unclear recovery time objectives, or weak testing and review protocols. Some suppliers were unable to evidence their plans at all, while others demonstrated plans with insufficient detail or untested mitigations[1]. Given the pharmaceutical industry's critical role in public health and the increasing frequency of supply chain disruptions, these deficiencies pose significant business interruption and reputational risks.

Risk Assessment methodology and scope findings reveal that many suppliers do not address risks beyond traditional Health, Safety & Environment topics. Business interruption, reputation, ethics, and human rights risks frequently receive inadequate attention. Moreover, many facilities rely on qualitative rather than systematic approaches, lacking traceable methodologies and documented evidence[1].

The five-year trend analysis shows GMS focus shifting from "plan exists" to "effective communication and execution," including customer notification procedures during crises. Incident investigation and root cause analysis expectations have strengthened significantly, with specific analytical methods now required by the audit protocol[1].

Health & Safety: Persistent Risks Despite Consistent Focus

Health & Safety remains the largest topic area with 1,098 findings representing 54% of the total[1]. This consistency across five years reflects both the maturity of Health & Safety as an audit discipline and the inherently high-risk nature of pharmaceutical manufacturing operations.

Worker Protection generated the most findings (29%, 318 findings), with electrical safety issues increasing across all regions. Lock Out Tag Out system deficiencies, inadequate arc- flash assessments, materials handling and warehouse safety gaps, and work-at-height protection weaknesses dominate this category[1]. The technical complexity of modern pharmaceutical facilities, combined with the potentially catastrophic consequences of electrical failures, makes this a critical focus area.

Occupational Health & Industrial Hygiene represented 22% of Health & Safety findings (240 total)[1]. Suppliers frequently lack robust exposure monitoring strategies for Active Pharmaceutical Ingredients and hazardous substances. The systematic identification of CMR chemicals, along with relevant exposure assessments, is not consistently implemented. Respiratory protection programs show particular weaknesses, with inconsistent fit testing being especially problematic[1].

Process Safety findings (17%, 193 findings) identified gaps in suppliers' ability to identify, assess, and control hazards involving combustible materials and chemicals. Electrical classification and explosion protection gaps persist, alongside preventive maintenance and safety-critical device management deficiencies[1]. From 2022 onward, the number of major findings per audit increased, and findings related to Personal Protective Equipment and Respiratory Protective Equipment saw the greatest increase in severity classification[1].

Human Rights: Growing Scrutiny on Labor Practices

Human Rights accounted for 13% of findings in 2024, with Wages, Benefits & Working Hours representing the dominant theme (47%, 129 findings)[1]. Findings concentrated on overtime limit violations, insufficient rest days, and delayed payment processes. The report identifies multiple Critical findings related to excessive working hours, restrictions on audit access preventing worker interviews, and contract worker treatment issues[1].

Policy and implementation gaps frequently appear, with facility-level procedures not matching corporate commitments. Contract and migrant worker protections show particular vulnerabilities, including incomplete contracts and insufficient onboarding transparency[1]. The five-year trend reveals contract worker treatment rising significantly as an area of concern, with multiple Critical findings in 2023-2024 related to benefits and overtime compensation[1].

The increased emphasis on alignment with international standards such as the OECD Guidelines and UN Guiding Principles reflects evolving regulatory landscapes and stakeholder expectations. Human Rights findings show that increased auditor focus on these frameworks after 2022 demonstrates maturing expectations for due diligence and value-chain coverage[1].

Environment: Technical Complexity and Evolving Standards

Environment findings represented 11% of the total (221 findings), with Waste & Emissions comprising the largest subcategory (50%, 111 findings)[1]. The audit findings reveal particular challenges in three areas: Pharmaceuticals in the Environment management, secondary containment systems, and hazardous waste handling.

Pharmaceuticals in the Environment findings reflect auditors' focus on this critical topic, extending beyond generic wastewater treatment to API-specific risk assessment and measurement. Many sites have not yet implemented quantitative assessments, treatment effectiveness verification, or integrated API management programs. Examples include missing or outdated risk assessments for API discharge and outdated Predicted No-Effect Concentration evaluations despite changes in discharge profiles[1].

Secondary containment system findings reflect gaps for both tank and bulk storage facilities as well as laboratory and small containers. Specific issues include unloading areas not meeting containment capacity requirements, high-performance liquid chromatography waste management risks, and insufficient protection for storage devices[1].

The five-year trend shows environmental audits becoming more granular, with hazardous waste handling, environmental risk assessment for storage, and PiE-specific controls appearing more frequently. This indicates higher expectations and enhanced auditor capability rather than deteriorating supplier performance[1].

Ethics: Small Volume, Systemic Implications

Ethics remains the smallest share of findings in 2024 (less than 1%, 26 findings)[1]. However, the systemic nature of ethics failures means that even small numbers of findings can have disproportionate consequences. Findings cluster around ethics training completeness, policy integration into operational procedures, and privacy or data protection adequacy.

The findings indicate incomplete system coverage, such as codes of conduct not fully embedded in procedures and downstream supplier engagement, alongside documentation shortfalls including inconsistent training records and missing refresher cadence[1]. While no major structural shifts occurred across the five-year period, audit commentary indicates increasingly clear expectations for policies to extend beyond corporate statements to operational controls[1].

How the Right PSCI Auditing Firm Transforms Challenges into Solutions

Technical Expertise and Industry-Specific Knowledge

The complexity and technical depth of findings identified in the PSCI report underscore a fundamental reality: pharmaceutical supply chain auditing requires specialized expertise that extends far beyond generic compliance checking. The right auditing firm brings deep pharmaceutical industry knowledge, understanding not only regulatory requirements but also the practical operational challenges of API manufacturing, controlled environments, specialized equipment, and process safety management.

Expert PSCI auditors possess the technical background to identify nuanced risks that less specialized auditors might overlook. For example, the report's findings on Occupational Exposure Banding implementation, Process Hazard Analysis methodologies including Layer of Protection Analysis and Safety Integrity Level studies, and API-specific wastewater treatment effectiveness require auditors with chemical engineering, industrial hygiene, or pharmaceutical manufacturing backgrounds[1]. A firm staffing audits with personnel holding these qualifications ensures findings are technically accurate, practically actionable, and appropriately contextualized.

Furthermore, experienced PSCI auditing firms understand regional variations in regulatory frameworks, industrial practices, and workforce dynamics. The report demonstrates that China, India, Western Europe, and the United States each present distinct challenge profiles[1]. Auditors familiar with local contexts can better assess whether practices meet not only PSCI standards but also local regulatory requirements, enabling suppliers to address compliance holistically rather than treating PSCI audits as isolated exercises.

Constructive, Development-Oriented Audit Approach

The PSCI report emphasizes that increases in findings do not necessarily indicate worsening performance; they may reflect growing auditor expertise, evolving regulations, or heightened expectations[1]. This insight reveals a critical distinction between auditing firms: those that approach audits as fault-finding exercises versus those that view audits as capability-building opportunities.

The right PSCI auditing firm adopts a constructive, development-oriented approach that balances rigorous assessment with practical guidance. Rather than simply documenting deficiencies, expert auditors provide context for findings, explain the underlying risks, reference relevant industry best practices, and suggest feasible remediation pathways. This approach transforms audit findings from burdensome compliance obligations into valuable improvement roadmaps.

For example, when identifying Business Continuity Planning gaps—one of the most common findings in the GMS category[1]—a skilled auditor does not simply note the absence of a plan. Instead, they explain recovery time objective concepts, provide examples of scenario coverage appropriate for pharmaceutical manufacturing, and reference industry frameworks such asISO 22301 or NIST guidelines. This educational component helps suppliers understand not just what to fix, but why it matters and how to build sustainable systems.

Moreover, constructive auditors recognize that many suppliers face resource constraints, competing priorities, and technical knowledge gaps. By prioritizing findings based on risk severity and feasibility, expert auditing firms help suppliers develop phased improvement plans that deliver meaningful risk reduction without overwhelming operational capacity.

Consistency and Reliability in Assessment

One of the pharmaceutical industry's most significant audit challenges is variability—different auditors interpreting standards differently, applying inconsistent severity classifications, or focusing on different aspects of the same requirement. This inconsistency frustrates suppliers, complicates benchmarking, and undermines confidence in audit findings.

The right PSCI auditing firm addresses this challenge through robust internal quality systems, standardized assessment methodologies, calibrated auditor training, and systematic peer review processes. These firms invest in auditor development programs that ensure consistent application of PSCI Principles across different auditors, geographies, and facility types.

The PSCI report's five-year trend analysis reveals that severity classifications have evolved over time, with Major findings increasing as a proportion of total findings[1]. While this partly reflects heightened expectations, it also underscores the importance of auditor calibration. A reliable auditing firm maintains clear, documented severity classification criteria and regularly calibrates auditor judgments through case study reviews, ensuring that a major finding in one audit represents the same level of risk as a major finding in another.

Consistency also extends to follow-up audits and corrective action verification. The right auditing firm maintains detailed records of previous findings, tracks remediation progress, and verifies effectiveness of corrective actions rather than simply checking whether actions were completed. This longitudinal perspective enables true continuous improvement rather than cyclical firefighting.

Data-Driven Insights and Benchmarking

The PSCI Audit Findings Report demonstrates the power of aggregated data to identify systemic patterns, regional variations, and emerging trends[1]. Individual suppliers and pharmaceutical companies benefit immensely when their auditing firm can provide similar benchmarking insights tailored to their specific supply chains.

The right PSCI auditing firm collects, analyzes, and synthesizes audit data across their portfolio to generate actionable intelligence. They can inform suppliers how their performance compares to regional or sector peers, identify which finding types are trending upward or downward in their industry segment, and highlight emerging regulatory or stakeholder expectations before they become widespread audit issues.

For pharmaceutical companies managing large supplier networks, data-driven auditing firms provide portfolio-level analytics that enable risk-based supplier management. Rather than treating all suppliers identically, companies can use audit data to segment suppliers by risk profile, target capacity-building resources where they will have the greatest impact, and make informed decisions about supplier relationships.

The report's regional analysis provides a model for this approach, showing how finding patterns vary significantly between China, India, Western Europe, and the United States[1]. An auditing firm that can deliver similar granular analysis for a company's specific supplier base enables much more sophisticated supply chain risk management than firms that simply produce individual audit reports without broader context.

Proactive Risk Identification and Forward-Looking Assessment

Effective auditing extends beyond documenting current compliance status to identifying emerging risks and assessing future resilience. The right PSCI auditing firm brings a forward-looking perspective, considering how regulatory trends, technological changes, stakeholder expectations, and business model evolution might affect supplier performance.

The PSCI report's discussion of Governance & Management Systems findings illustrates this dimension. Risk assessments that only address traditional Health, Safety & Environment topics miss critical business interruption, reputation, ethics, and human rights risks[1]. Expert auditors probe whether suppliers' risk assessment methodologies are sufficiently comprehensive and forward-looking to anticipate rather than merely react to challenges.

Similarly, in the Environment category, the increasing emphasis on Pharmaceuticals in the Environment reflects evolving scientific understanding and regulatory attention to API environmental fate and toxicity[1]. Auditing firms at the forefront of these developments help suppliers prepare for tightening standards before they become compliance requirements, avoiding costly reactive remediation.

Proactive auditing firms also assess suppliers' management systems for adaptability and continuous improvement capability. Rather than simply verifying that current practices meet current standards, they evaluate whether suppliers have the organizational learning mechanisms, leadership commitment, and technical competency to respond effectively as expectations evolve.

Strong Stakeholder Communication and Transparency

Audit findings only create value when effectively communicated to relevant stakeholders and translated into action. The right PSCI auditing firm excels at stakeholder communication, producing clear, well-organized audit reports that balance technical detail with executive-level synthesis.

Effective audit reports move beyond compliance checklists to tell the story of a supplier's performance: strengths to leverage, critical vulnerabilities requiring immediate attention, systemic gaps indicating process or culture issues, and opportunities for competitive differentiation through excellence. They use risk-based prioritization, visual data presentation, and clear remediation recommendations to make findings accessible and actionable for diverse audiences.

The right auditing firm also facilitates productive dialogue between pharmaceutical companies and their suppliers. Rather than positioning auditors as adversarial inspectors, expert firms foster collaborative problem-solving relationships. Closing meetings focus on shared understanding of findings, realistic remediation timelines, and available support resources rather than defensive posturing or blame assignment.

Transparency extends to audit methodology and decision-making processes. The right auditing firm clearly explains how they interpret PSCI Principles, what evidence they require for different compliance levels, and how they determine severity classifications. This transparency builds trust and enables suppliers to prepare effectively for audits rather than treating them as unpredictable ordeals.

Capability Building and Supplier Development

The PSCI report emphasizes that the organization translates audit evidence into actionable insights used to prioritize supplier capability-building training, practical guidance, and collaboration with regional partners[1]. While PSCI provides valuable industry-level resources, individual auditing firms play an equally critical role in supplier development at the relationship level.

The right PSCI auditing firm does not limit their engagement to audit events. They offer training programs, guidance documents, webinars, and consultation services that help suppliers build the knowledge and capabilities needed to address common findings. For example, an auditing firm might provide training modules on Business Continuity Planning development, electrical safety program implementation, or exposure monitoring strategy design—directly addressing the most common finding categories identified in the PSCI report[1].

These capability-building services are most effective when tailored to suppliers' specific contexts, maturity levels, and resource constraints. Generic training rarely translates into sustained improvement; contextually relevant guidance that acknowledges suppliers' operational realities and provides practical implementation pathways drives actual change.

Moreover, expert auditing firms connect suppliers with industry best practices, reference materials, and case studies that illustrate successful approaches to common challenges. They serve as knowledge brokers, helping suppliers learn from peers' experiences and avoid reinventing solutions to well-understood problems.

Technology-Enabled Audit Excellence

Modern pharmaceutical supply chain auditing increasingly leverages technology to enhance efficiency, consistency, and insight generation. The right PSCI auditing firm invests in audit management platforms, data analytics tools, and digital collaboration systems that elevate audit quality beyond what paper-based or basic documentation systems can achieve.

Technology enables several important capabilities: standardized data collection that facilitates benchmarking and trend analysis; automated severity classification guidance that promotes consistency; visual evidence capture that provides richer context for findings; real-time collaboration between auditors and technical specialists; and integrated corrective action tracking that ensures remediation accountability[1].

The PSCI platform itself demonstrates the value of digital audit management, enabling member companies to share audits efficiently and generate the rich analytical insights documented in the Audit Findings Report[1]. Individual auditing firms that similarly embrace technology can deliver analogous benefits at the company and supplier relationship level.

Furthermore, technology enables more efficient audit processes that reduce burden on suppliers while maintaining or enhancing audit thoroughness. Pre-audit questionnaires, document repositories, and remote interviews can accomplish significant assessment work before on-site visits, allowing auditors to focus their limited on-site time on physical observations and deep-dive investigations that truly require in-person presence.

Regulatory Alignment and Compliance Integration

Pharmaceutical suppliers face complex, overlapping regulatory requirements from multiple jurisdictions, industry standards, and customer-specific expectations. The right PSCI auditing firm helps suppliers navigate this complexity by explicitly addressing how PSCI Principles align with and complement other requirements.

For example, many PSCI findings related to Process Safety, electrical safety, and hazardous material management intersect with OSHA regulations in the United States, REACH in Europe, or analogous national frameworks in China and India[1]. Expert auditors identify these intersections, helping suppliers understand how PSCI compliance contributes to broader regulatory compliance rather than representing an additional, separate burden.

Similarly, pharmaceutical companies increasingly face corporate social responsibility reporting requirements, supply chain due diligence legislation such as the German Supply Chain Act or proposed EU Corporate Sustainability Due Diligence Directive, and stakeholder pressure regarding environmental, social, and governance performance. PSCI audits conducted by firms that understand these broader contexts provide valuable documentation and assurance for these additional compliance needs.

The right auditing firm also stays current with evolving regulatory landscapes and proactively advises clients about emerging requirements. The PSCI report's discussion of increasing alignment with international standards such as the OECD Guidelines and UN Guiding Principles on Business and Human Rights exemplifies this dynamic regulatory environment[1]. Auditing firms that monitor these developments and adapt their assessment approaches accordingly provide clients with early warning and preparation time rather than reactive scrambling when new requirements take effect.

Long-Term Partnership and Continuous Improvement

Sustainable supply chain excellence emerges from long-term commitment and continuous improvement rather than transactional audit events. The right PSCI auditing firm approaches client relationships as partnerships, investing in deep understanding of specific supply chains, building trust through consistent performance, and demonstrating genuine commitment to shared success.

Partnership-oriented auditing firms maintain stable audit teams that develop familiarity with suppliers' operations, personnel, and improvement journeys. This continuity enables more nuanced assessment—auditors can distinguish between longstanding systemic issues and temporary implementation gaps, recognize genuine progress even when findings persist, and provide coaching that builds on previous conversations rather than starting from scratch each audit cycle.

Long-term partnerships also enable collaborative priority-setting. Rather than dictating audit scope and focus unilaterally, expert auditing firms engage pharmaceutical company clients in strategic discussions about supply chain risk profiles, business priorities, and resource allocation. This collaborative approach ensures audits generate insights that align with clients' actual decision-making needs rather than generic compliance data.

Moreover, partnership-oriented firms demonstrate flexibility and responsiveness as client needs evolve. They scale audit programs up or down as supplier portfolios change, adapt assessment approaches when business models shift, and customize deliverables as organizational maturity develops. This adaptability sustains value creation across long time horizons rather than providing one-size-fits-all services that become obsolete as contexts change.

Conclusion: The Transformative Power of Expert PSCI Auditing

The PSCI Audit Findings 2025 report provides an invaluable snapshot of pharmaceutical supply chain performance, documenting 2,046 findings across Health & Safety, Governance & Management Systems, Human Rights, Environment, and Ethics[1]. These findings reveal persistent challenges: inadequate Business Continuity Planning, electrical safety system deficiencies, contract worker protection gaps, Pharmaceuticals in the Environment management weaknesses, and insufficient integration of ethical requirements into operational procedures.

However, the existence of these findings does not predetermine outcomes. The quality, expertise, and approach of the auditing firm fundamentally shape whether audit observations catalyze genuine improvement or simply generate compliance paperwork. The right PSCI auditing firm transforms challenges into solutions through technical expertise that ensures accurate and relevant findings, constructive approaches that balance rigor with practical guidance, consistency that builds confidence and enables benchmarking, data-driven insights that illuminate patterns and trends, proactive risk identification that prepares suppliers for future expectations, strong stakeholder communication that facilitates collaborative problem-solving, capability building that addresses root causes rather than symptoms, technology enablement that enhances efficiency and insight, regulatory alignment that integrates compliance activities, and long-term partnership that sustains continuous improvement.

For pharmaceutical companies committed to responsible, resilient supply chains, selecting the right PSCI auditing firm represents a strategic investment rather than a procurement commodity decision. The report's emphasis on translating audit evidence into actionable insights, prioritizing capability-building, and fostering collaboration underscores that auditing's ultimate purpose is improvement, not mere documentation[1]. Firms that share this philosophy and possess the capabilities outlined in this paper enable pharmaceutical companies to realize auditing's full transformative potential, advancing from compliance- driven reactive management toward proactive, data-informed supply chain excellence that protects patients, workers, communities, and business value.

References

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