

The State of Product Compliance 2025

Navigating Complexity and Driving Financial Value





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Executive Summary

Product compliance is no longer a quiet, back-office task: it's becoming a decisive factor in revenue protection, competitive advantage, and market access. In 2025, the compliance function is undergoing a pivotal transformation, as new global research with 498 compliance leaders reveals.

The findings paint a clear picture: many teams remain trapped in reactive "firefighting" mode, executives increasingly demand measurable financial ROI, and company size shapes the nature of the compliance challenge in profound ways. The shift is unmistakable; compliance is moving from simply avoiding fines to actively enabling value creation. The leaders who adapt fastest will define the competitive landscape in the years ahead.

Key Findings

Compliance Is Predominantly Reactive

- **69% of leaders** say remediating product compliance issues after they occur is their hardest task making it the single most difficult activity in the study.
- A pronounced "**Evidence Divide"** creates a last-mile challenge: 62% struggle to provide proof to external stakeholders versus just 39% for internal teams.
- This reactive stance drives hidden financial costs beyond fines, including operational overhead and lost market opportunities.

2 Financial Impact Now Drives Every Decision

- The top four metrics guiding compliance investment (**cost of compliance, cost of violations, revenue at risk, and revenue opportunities**) are all financial, each cited by ~40–50% of respondents.
- Efficiency gains like "time to compliance" matter but are secondary.
- Executives now view compliance as a financial performance lever, not just a cost center.

3 Scale Brings Distinct, Size-Dependent Struggles

- Large enterprises (>\$10B revenue) face a "complexity tax": coordinating compliance across multiple products, geographies, and teams raises task difficulty by 8–14% above average.
- Mid-market firms (\$500M-\$999M) confront tough go/no-go decisions on market participation when new regulations hit, often under resource constraints and high political pressure.

Closing Insight

This research reveals more than pain points: it identifies where compliance can shift from a reactive obligation to a proactive driver of business value. The path forward is clear: address evidence gaps, link compliance initiatives directly to financial outcomes, and tailor strategies to organizational scale. Compliance leaders who act on these insights will set the pace for their industry.

INTRODUCTION

Navigating the Complexities of Global Product Compliance



As global supply chains constantly intertwine and regulations evolve, businesses are under huge pressure to ensure their products meet internal policies, external regulations, and industry standards - all while scaling and protecting their brand's growth and reputation. Ensuring every product meets the rules in every market is no longer just a legal checkbox - it's a **strategic imperative** that directly impacts revenue, <u>market access</u>, and brand reputation. Organizations that handle compliance efficiently and transparently can unlock market opportunities and gain critical competitive advantage.

At the same time, the bar for compliance performance is rising. It's not enough to just comply; companies must be able to **demonstrate compliance quickly and credibly** to regulators, customers, and other stakeholders. This has turned compliance into a race against time and complexity - one that many organizations feel ill-equipped to win without new approaches.

Purpose of this Report

The insights in this report are designed to power compliance professionals and business leaders with a clear understanding of the market's most pressing needs and strategic opportunities.

We surveyed senior compliance leaders around the world to identify their biggest operational challenges, the priorities driving their investments in new solutions, and how these dynamics differ in companies of different sizes. Ultimately, our aim is to help compliance teams move from reactive firefighting to proactive value creation in their organizations.

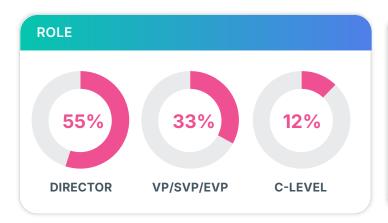


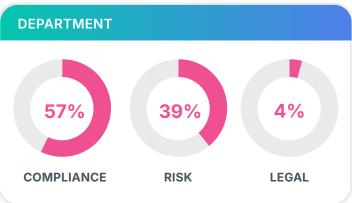
Methodology and Demographics Overview

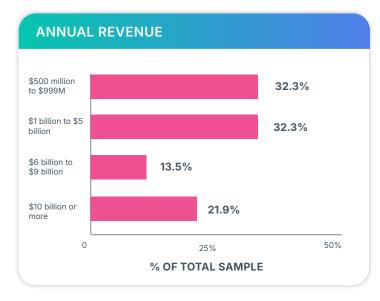
The findings presented in this report are derived from a comprehensive survey of 498 full-time directors, VPs/SVPs/EVPs, and C-Level executives. Respondents were drawn from compliance, legal, or risk departments within companies generating annual revenues of \$500 million USD or higher.

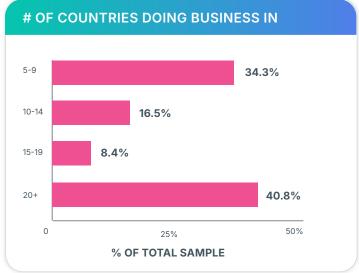
All participating companies were headquartered in the United States, United Kingdom, Germany, Denmark, Finland, Norway, or Sweden, and actively conducted business in at least five countries. A significant 40.8% of these companies operate in 20 or more countries, underscoring the global reach and applicability of the insights. The geographic focus of business and sales efforts among respondents is predominantly Europe (94.58%), North America (79.52%), and East Asia (61.24%), further emphasizing the multinational context of the challenges discussed. This robust demographic foundation ensures that the findings reflect the realities of complex, globally operating compliance operations.

To provide a quick overview of our survey participants, the following tables summarize their key demographic breakdowns:











Our first area of analysis looked at the operational pain points in product compliance. We asked leaders how difficult they find various compliance tasks (using a Customer Effort Score approach), from initial planning through to audits. The results clearly show that many compliance teams are stuck in reactive mode, struggling most with tasks that occur after problems have already surfaced. In particular, two themes stand out: a prevalence of firefighting to remediate issues, and a significant gap in providing evidence to outsiders versus insiders – what we call the evidence divide.

Firefighting Mode: Remediation as the #1 Pain Point

When we mapped the difficulty of common compliance activities, "remediate product compliance issues" emerged as the single hardest job for teams. An overwhelming **69% of surveyed leaders** rated remediation as "difficult" or "very difficult," making it the top pain point in product compliance operations.

This finding suggests that many organizations find themselves **putting out fires** - dealing with <u>compliance</u> <u>problems only after they've ignited</u>. Resources are heavily spent on crisis management, such as fixing non-compliance issues, handling recalls or stop-ships, and damage control, rather than on preventive measures. This reactive state drives up operational costs and elevates stress levels for compliance teams.



Operating in this constant firefighting mode is costly and stressful. It not only drives up operational expenses, but also diverts teams from strategic work. The prominence of remediation as a challenge indicates a clear opportunity: if companies can strategically transition - catching and addressing compliance requirements **early in the product lifecycle** - they can save significant effort and reduce the fire drills down the line.

It's worth noting that other proactive compliance tasks also scored relatively high in difficulty. For instance, "Ensuring that a product's design covers all relevant compliance requirements throughout its lifecycle" was rated difficult by about 60% of leaders.

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In short, it's clear that prioritizing compliance from the start isn't easy - when it falls short, teams pay for it with late-stage headaches.

The Evidence Divide: A Last-Mile Challenge in Compliance Reporting

Another major operational struggle revealed by the survey is the challenge of providing proof of compliance to external parties. Compliance teams frequently need to <u>demonstrate their products meet requirements</u> - to regulators, certification bodies, customers, or auditors. A staggering 23-point gap exists in the difficulty of providing evidence: 62% of leaders find it difficult to provide evidence to external stakeholders, compared to only 39% for internal stakeholders. This evidence divide is the second-most difficult task overall (just after remediation), highlighting a critical last-mile problem in compliance programs. A direct consequence of this difficulty in demonstrating compliance effectively to external bodies is an increased likelihood of non-compliance findings during audits, thereby directly contributing to the high burden of remediation.

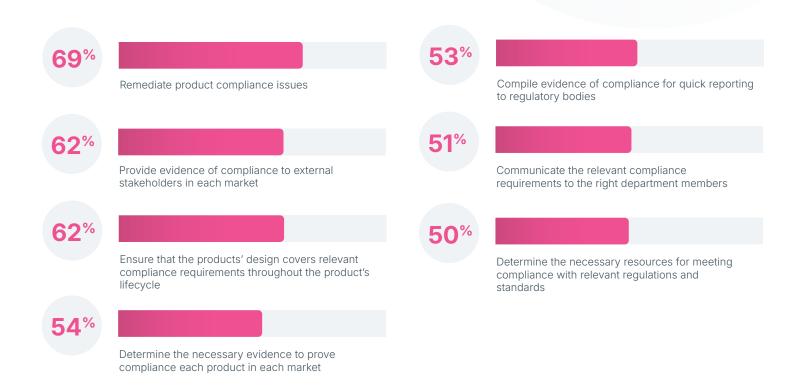


Why is external evidence provision so painful? Leaders tell us that preparing compliance reports or audit packages for outside entities often involves chasing down documentation, translating technical data into regulator-friendly formats, and navigating different jurisdictions' requirements. Many organizations have siloed data and manual processes, making it labor-intensive to compile the exact evidence each regulator expects. It's one thing to internally know you're compliant; it's another to quickly prove it to an external authority. This gap points to a trust and communication challenge – compliance teams might have the data, but delivering it in a credible, streamlined way is a hurdle.

Multiple survey data points reinforce this struggle:

- Determining what evidence is necessary to prove compliance for each product/market is a significant pain (54% find this difficult). Deciding "what do we need to show to whom?" is a complex task in itself.
- Compiling that evidence **quickly for regulatory audits or inquiries** is similarly tough (53% difficult). Even if you know what you need, pulling it together under time pressure is often an ordeal.

KEY PRIORITIES RESPONDENTS FOUND DIFFICULT



Together with the external reporting challenge (62%), these figures underscore that documentation and reporting are pervasive stress points. Compliance is not just about doing the right things; it's about being able to demonstrate those things on demand.

The evidence divide suggests many teams lack efficient systems for tracking compliance actions, aggregating proof, and delivering it externally – a clear area where better tools or practices are needed.

What Compliance Leaders Want: Financial Outcomes Over Efficiency

If the previous section outlined the challenges, this one addresses the **solutions and improvements** compliance leaders are looking for. We shifted from "What hurts?" to "What do you value most in a new compliance solution?"

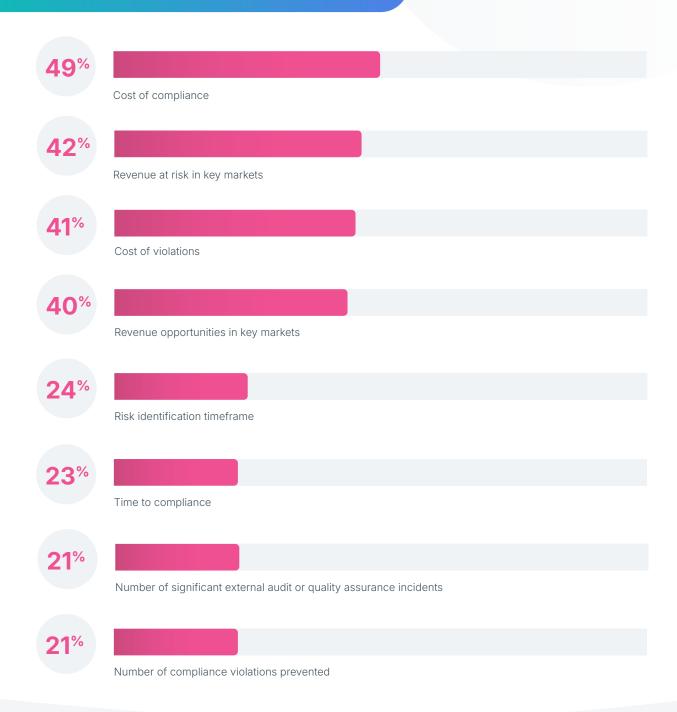
The results are striking: when compliance executives consider <u>investing in new tools or programs</u>, their top priorities are firmly rooted in **financial impact**. They want solutions that will save money, protect revenue, or even boost revenue. While operational efficiencies (including speeding up processes) are appreciated, they clearly take a back seat to metrics that move the bottom line. In short, **ROI is the North Star** for compliance investments today.



The Dominance of Financial Impact

We asked respondents to select up to three top metrics or outcomes they hoped a new compliance solution would improve. The clear front-runners were all **financial metrics** - indicating that budgets for compliance initiatives hinge on delivering dollar value. The ranked improvement areas were:

% OF OUTCOMES RESPONDENTS HOPE TO IMPROVE



The top four metrics were chosen by **40% or more** of respondents, forming a distinct cluster of financial priorities. It sends an unequivocal signal: compliance is increasingly viewed through a <u>business-value lens</u>. Senior management is asking, "How does our compliance spend contribute to the bottom line?" and compliance leaders are responding by seeking tools that can either cut costs or drive revenue (or ideally both). This represents a maturation of the compliance function - from a pure cost center focused only on avoiding trouble, to a strategic function that must justify itself in ROI terms.

How does compliance spend contribute to the bottom line?

Will this solution meaningfully impact our costs or revenue?

This doesn't mean operational pain points have vanished from concern - but it does mean that when push comes to shove, the deciding factor for investment is "Will this solution meaningfully impact our costs or revenue?" If not, it's likely to be deprioritized.

Efficiency: Important, but a Means to a Financial End

Interestingly, **operational efficiency metrics ranked noticeably lower** than the financial ones. For example, Time to compliance - essentially the speed of getting products compliant and market-ready - was selected by only 23% of leaders as a top improvement area, substantially fewer than those who chose cost or revenue metrics. This indicates that while slow processes and delays are frustrating (as seen in our earlier section), they are not in themselves the primary justification for new investments. Rather, efficiency is valued when it **leads to financial gains**.

This finding suggests a pragmatic mindset: compliance teams care about speeding up and smoothing out workflows, but mostly because those improvements can reduce costs (e.g. less labor hours per project) or protect revenue (e.g. avoid launch delays). If a tool makes the team 20% more efficient but doesn't clearly tie to dollars saved or earned, it may be a tough sell in budget meetings. Leaders have to prioritize, and right now they prioritize the **metrics their CEOs and CFOs care about** - which are financial outcomes.

That said, the fact that nearly a quarter of respondents did highlight time to compliance shows that efficiency is still on the radar. They do want solutions that streamline work - but ideally those solutions will prioritize both speed and money. For example, cutting regulatory research time by 30% means teams can handle more strategic projects to reach markets faster. Efficiency for efficiency's sake isn't the winning argument; **efficiency for the sake of ROI** is.

Expectations for Impact: Transformation vs. Reliability

Our research also uncovered a fascinating nuance in what leaders expect from solutions. When it comes to efficiency improvements, leaders are actually quite bold - their highest expectation is for transformational gains. For cost improvements, however, they tend to be more conservative and focused on certainty. In other words, leaders need a major leap forward in speed but for costs, they're looking for more reliable, predictable savings rather than a complete financial overhaul.

For each key metric, we asked leaders what minimum improvement they would expect from a new solution. The **average expected improvements** give a sense of the bar solutions need to clear:

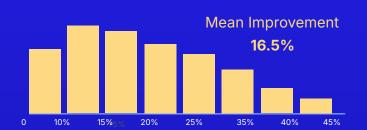


Frequency of Answer

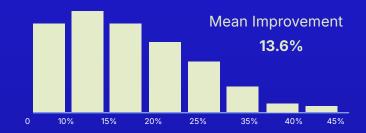
NUMBER OF COMPLIANCE VIOLATIONS PREVENTED

Mean Improvement 14.0% 0 10% 15% 20% 25% 35% 40% 45%

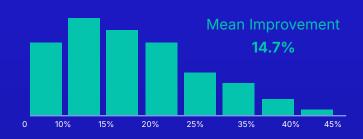
TIME TO COMPLIANCE



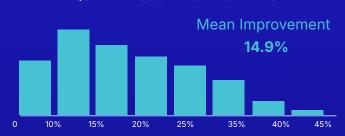
COST OF COMPLIANCE



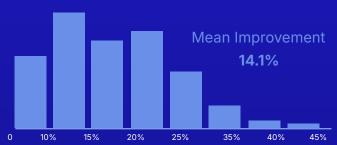
RISK IDENTIFICATION TIMEFRAME



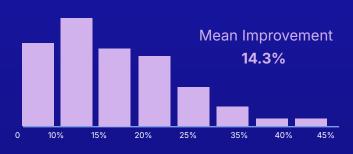
NUMBER OF SIGNIFICANT EXTERNAL AUDIT OR QUALITY ASSURANCE INCIDENTS



REVENUE AT RISK IN KEY MARKETS



REVENUE OPPORTUNITIES IN KEY MARKETS





Alongside the ranking in the table on the previous page, what's even more telling is the distribution of responses behind these averages:



For **speed/efficiency metrics**, such as time to compliance, the distribution curve was relatively flat and wide. Many respondents weren't clustered around 15% - instead, a good number aimed higher (20%, 25% or more improvement).

This suggests a significant cohort of compliance leaders feel their current processes are fundamentally broken and would love to see a **major leap forward in efficiency**. In essence, the market is giving solution providers permission to be bold - can they dramatically accelerate their compliance workflows? The appetite for disruptive change is there when it comes to speed and ease of compliance management.



For **financial metrics**, including cost of violations, the pattern was the opposite. The distribution was sharp and peaked around a specific modest improvement. In our data, a large proportion of leaders agreed on needing approximately a 10-12% reduction in violation costs from a new solution. This indicates that when it comes to money, what they want is reliability and predictability. Leaders appear to favor solutions that deliver steady, proven and specific savings.

This dual finding reveals a sophisticated market psychology:

For efficiency gains, think big:

Compliance teams are so frustrated with slow, manual processes that they're open to big changes. They know speeding up compliance management could transform their effectiveness, with the data suggesting leaders won't be scared off by ambitious efficiency claims - many are hoping for them.

For financial outcomes, think certain:

When it comes to budgets and hard savings, these same leaders turn cautious. They need to forecast and justify ROI to the higher-ups, so they value solutions that can demonstrate measurable, guaranteed cost impact. The emphasis should be on precise claims, trust and proof - backing up financial benefit claims with data, case studies, or even guarantees, to show that the savings will materialize.

For compliance teams building a business case, the takeaway is clear: tailor the message. When pitching how a potential compliance management solution improves operations, don't undervalue the transformation. But when pitching the financial benefits, err on the side of concrete and dependable improvements.



Compliance Challenges by Company Size: A Segmented View

While many compliance struggles are universal, our research reveals that a company's scale introduces its own twists on these challenges. We segmented responses by company revenue band and found that the nature of **compliance pain points can shift as organizations grow**. In particular, the largest enterprises and the mid-market firms stand out for having distinctive issues. The biggest players wrestle with complexity and coordination at scale, whereas mid-sized companies feel acute pressure in strategic decision-making. Understanding these differences is crucial - it means a one-size-fits-all approach to compliance management or solutions will likely fall short.

The Enterprise Complexity Tax at \$10B+

For the largest companies in our sample (those with annual revenues over \$10 billion), compliance challenges are amplified by sheer scale and complexity. These organizations operate vast product portfolios across many regions, involving large teams and intricate processes. Our data shows that these giants struggle significantly more than average on several critical compliance tasks – a consequence of what we term the complexity tax.



Key pain points for enterprises:

Ensuring lifecycle compliance in product design

74% of leaders at \$10B+ companies rated "ensuring the product's design covers relevant compliance requirements throughout its lifecycle" as difficult, compared to 60% average.

+14% higher difficulty

This indicates how hard it is for large firms to maintain oversight from initial design through end-of-life across numerous products and markets.

Remediating compliance issues

77% difficult for large enterprises (vs. 69% average).

This indicates how hard it is for large firms to maintain oversight from initial design through end-of-life across numerous products and markets.

+8%
difference

Gaining stakeholder agreement on compliance changes:

55% difficult (vs. 48% average) - +7%.

In large enterprises, aligning all internal stakeholders on how to implement compliance changes is a heavier lift due to organizational silos and scale.

Providing evidence to external stakeholders

75% of large enterprise respondents find this difficult (vs. 62% average).

With dozens of regulatory bodies to satisfy and mountains of documentation, the last-mile evidence problem is even more acute at scale.

+13%

Determining necessary compliance resources

58% difficult (vs. 50% average).

+8%
difference

Planning budgets and staffing for compliance is harder when operations are spread globally and involve so many moving parts.

Interestingly, our study also found that some things are easier for large enterprises. For example, "making a recommendation on how to comply with relevant policies and regulations" was significantly less difficult for \$10B+ companies: only 31% rated this as difficult, compared to 45% on average (a -14% difference). This suggests that expertise and knowledge aren't the issue - these organizations often have excellent compliance professionals and robust internal frameworks for formulating compliance plans or policies. They know what needs to be done - the challenge is in the doing.

Mid-Market: Securing High-Stakes Buy-In at \$500M-\$1B



Mid-sized companies (in our study, those roughly in the \$500 million to \$1 billion annual revenue range) exhibit a different profile of challenges. They often have global reach similar to the bigger organizations, but with smaller teams and tighter budgets. Their most pronounced compliance
pain point is less about day-to-day task difficulty and more about **strategic decision-making**under resource constraints. Specifically, the data shows mid-market leaders struggle disproportionately with deciding where to do business given compliance costs.

One survey item asked about gaining agreement on whether it's worthwhile to continue selling products in each market given new compliance requirements. For the mid-market segment, 52% rated this decision-making step as difficult, compared to 47% on average - about a +5% higher difficulty, and notably higher than what larger companies reported. These companies can't easily absorb the cost of heavy new regulations in a market. The go/no-go decision of staying in a particular market is a more painful and difficult conversation. Our data shows that making that call - and getting stakeholder alignment - is often a difficult process for midsized organizations.



Other compliance tasks for mid-market companies generally tracked close to the overall average, indicating they face many of the same operational painpoints, but not drastically more so than others. What does this imply for solutions and management strategies? Mid-market compliance leaders would benefit from tools that provide **clear cost-benefit analysis and horizon scanning**. Additionally, as resources are more limited, mid-market teams often wear multiple hats. Compliance might be a team of a few people coordinating with many departments. They benefit from efficient, user-friendly tools that don't require large dedicated staff to run.



For compliance professionals and executives responsible for these functions, the data in this report highlights a clear mandate to evolve practices. Here are several strategic moves to consider in response to the findings:

Shift from Reactive to Proactive Compliance:

Make it a priority to move your team out of constant firefighting mode. This means actively seeking and implementing tools that automate compliance monitoring and evidence collection, provide real-time visibility into compliance status, and flag potential issues before they escalate. By catching problems early (or preventing them altogether), you'll reduce the burden of costly remediation later.

Quantify Compliance Value in Financial Terms:

When you advocate for compliance initiatives - be it hiring staff, purchasing software, or launching a new program - frame the value in clear business terms. Tie everything back to cost, revenue, and risk. Wherever possible, use specific numbers or ranges to demonstrate ROI. This approach aligns with what top executives need to hear and will significantly increase your success in securing budget and buy-in. Essentially, speak the language of the CFO: show how compliance improvements will pay off financially, not just operationally.

Tailor Your Strategy to Your Organization's Scale:

Recognize that compliance solutions and approaches are not one-size-fits-all. Consider the specific needs of your organization's size and complexity:

If you're in a large enterprise, prioritize <u>integrated</u>, <u>scalable platforms</u> that can manage complex compliance lifecycles and facilitate cross-functional coordination.

If you're in a mid-market firm, look for tools that help with strategic decision support - for instance, software that can model the financial impact of complying with a new regulation versus exiting a market. Also favor tools that are easy to deploy and use (since teams are smaller) and that produce executive-friendly reports to help you make the case for compliance investments or strategic choices.



Embrace Global Intelligence and Localization:

Over 40% of surveyed companies operate in 20+ countries, and more than two-thirds of leaders said they frequently or constantly need professional translations of regulations. This linguistic and regional complexity is a hidden source of friction - a true complexity tax on compliance. By integrating global compliance management solutions, you can significantly reduce the operational drag of dealing with multiple languages and legal systems. The result will be faster, more accurate compliance work and less reliance on ad-hoc human translation or external consultants for every new update. In short, think global in building your compliance infrastructure - it will pay off in reduced effort and improved consistency.

Over 40% of surveyed companies operate in 20+ countries



Crucially, the future will see compliance become more of a **strategic partner in business**. As companies realize that strong compliance can be a competitive advantage – enabling faster market entry, building customer trust, and protecting revenue streams – compliance teams will get a louder voice in the boardroom. The expectation (and opportunity) is that compliance not only keeps the company out of trouble, but also actively contributes to business objectives.



About Compliance & Risks

<u>Compliance & Risks</u> empowers global enterprises to unlock market access and confidently navigate regulatory complexity. With a 20-year legacy in regulatory intelligence, we help beloved global brands manage product and corporate sustainability obligations, transforming compliance into a force multiplier for enterprise growth.