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Together makes progress

AI with purpose

Reimagining regulatory intelligence

Contents

Executive summary

Regulatory compliance is now a strategic priority for life sciences, as global regulators rapidly raise expectations driven by scientific advances and transparency demands.

Traditional, reactive compliance systems expose organizations to costly risks and operational disruptions. To stay resilient and competitive, companies should consider investing in modern data-driven, predictive compliance models that enable proactive risk management and continuous readiness.

Intelligence-enabled compliance is essential for operational confidence in today's evolving regulatory landscape and life sciences should reimagine compliance by leveraging data and AI and make compliance a competitive advantage.

The rising burden of noncompliance

$11.2B+ in fines[1]

A 2025 analysis of "pharma fines" reports that pharmaceutical companies paid roughly US$11.2 billion in global regulatory fines in 2024 alone.

$50B+ annual spend[3]

Biopharmaceutical companies invested more than $50 billion in compliance-related activities in 2023, with costs rising more than 7% year over year.

$10M–$100M risk[5]

In severe cases, global manufacturers have faced penalties ranging from $10 million to $100 million from a single compliance incident.

Regulatory advances

Regulatory bodies are now using AI and building risk-based models to flag compliance issues, making the call to action more pertinent.

72% of professionals[2]

Highlighting the operational burden created by constant updates in Good Manufacturing Practices (GMP), 72% of pharmaceutical quality professionals say they have difficulty keeping pace with changing regulatory expectations.

$15M average impact[4]

A single major noncompliance event can cost nearly $15 million per facility when accounting for downtime, delayed filings, and supply disruptions.

Multiple cost drivers

Validation, quality system maintenance, GMP certification, audits, and supplier oversight remain persistent and compounding cost centers.

Hidden inefficiencies

Contract manufacturing organization (CMO) dependencies across geographies quietly inflate cost and risks through disconnected data flows and manual oversight gaps.

Compliance as the backbone of modern pharmaceutical manufacturing

Supply chain and manufacturing compliance in pharmaceuticals is a **complex interconnected discipline encompassing regulatory, industry, and internal standards across quality, safety, environmental stewardship, labor, and ethical sourcing**. Compliance is not a one-time event, but a continuous process requiring ongoing risk assessments, audits, policy updates, workforce training, and process improvements. **Treating compliance as a living system, rather than a static checklist**, builds operational reliability, enables confident scaling, and sustains trust in global markets.

Eight specialized compliance domains (listed below as operational and enterprise domains) underpin compliance with regulatory, industry, and internal standards across the manufacturing value chain

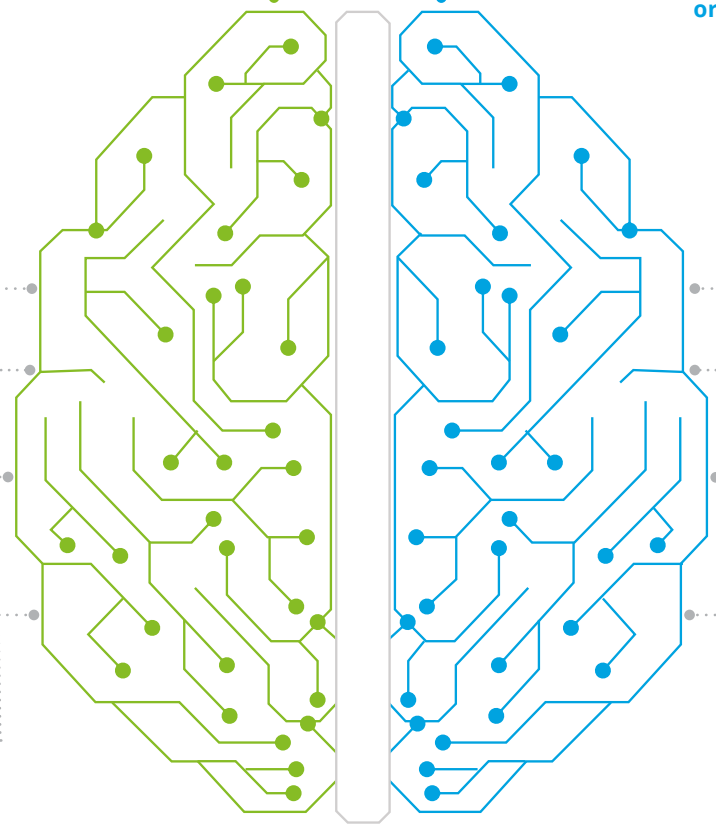
Operational domains drive safe, ethical, and efficient day-to-day execution

Quality Control
Ensure products consistently meet customer expectations

Safety Standards
Ensure product safety for employees and customers

Environmental Compliance
Manage waste, emissions, resource consumption in accordance with EPA

Supply Chain Transparency
Compliance for upstream suppliers on ethical sourcing, responsible production, traceability



Enterprise domains protect the organization through governance and strategic risk management

Trade Compliance
Manage international trade requirements, following sanctions lists and embargoes

Product Liability
Ensure products conform to regulatory standards to avoid harm, recalls, and litigation

Intellectual Property
Protect legal use of patents, trademarks, copyrights to avoid counterfeit goods

Data Security and Privacy
Adhere to data protection laws with rise of digitization

Why manufacturers should adapt their compliance models

The growing sophistication of regulatory oversight introduces a new set of implications for pharmaceutical organizations. As inspections become more targeted and AI-driven, companies will likely face greater scrutiny of how reliably their data reflects actual operations.

Routine cycles tend to matter less; the **patterns within the data tend to matter more.** For many manufacturers, this shift can elevate the importance of data integrity, harmonized quality processes, and the ability to generate clear, defensible insights from their operational systems. Organizations that strengthen these foundations early will likely be better equipped to operate with confidence in a more transparent regulatory environment.

At the same time, the **financial burden of maintaining compliance continues to rise.**[6] Expanding manufacturing networks, diverse product portfolios, and global regulatory expectations all contribute to growing cost pressures. For many large pharmaceutical companies, compliance activities account for **5% to 9% of annual revenue,**[7] with annual spending frequently reaching several million dollars. Global manufacturers may invest anywhere from **$10 million to $200 million**[8] each year to support quality systems, maintain documentation, train personnel, and sustain monitoring programs across sites.

Proactive investment remains the most cost-effective strategy. The cost of noncompliance can be more than double the investment required to maintain a strong program, especially once remediation, downtime, and supply disruptions are factored in.[9] Companies that modernize their regulatory intelligence, automate routine reporting, and integrate quality data across systems reduce the likelihood of findings and limit the operational instability that typically follows.

Beyond direct expense, the operational and reputational risks associated with noncompliance are substantial. A single issue can result in lost batches, extended investigations, production delays, and downstream supply chain impacts that quickly escalate into multimillion-dollar consequences. Remediation often requires significant staffing, sustained oversight, and diverted resources, slowing innovation and placing strain on teams already managing complex production environments. These events can also carry **reputational weight: They can erode trust among regulators, partners, and the broader health care ecosystem.**

Modern quality and compliance excellence

The four pillars of excellence

1 Integrated quality and regulatory systems

Modern manufacturing requires unified systems that connect quality, regulatory, operations, and supply chain data. Fragmented processes increase risk, slow inspections, and obscure visibility. Integrated environments enable faster decisions, stronger compliance oversight, and real-time transparency across the enterprise.

2 Stronger oversight of external partners

As reliance on CMOs, suppliers, and contract labs grows, so does the need for consistent compliance oversight. Organizations must implement standardized governance, documentation, and monitoring frameworks to reduce supplier risk, enable accountability, and improve inspection outcomes across extended networks.

3 Evolving workforce requirements

Compliance today demands new capabilities, including regulatory intelligence, data governance, digital validation, and automated quality systems. Closing talent gaps and investing in skill development are essential to managing regulatory change while maintaining operational continuity and resilience.

4 Enhanced focus on compliance culture

A strong compliance culture drives inspection readiness, reduces variability, and strengthens organizational alignment. Effective governance leads to fewer deviations, better documentation, and greater stakeholder confidence. Compliance excellence is a hallmark of operational maturity.

Global trends

The shift toward intelligent compliant networks

At the heart of every improvement initiative is data and AI. As production environments become more digitized, the line between everyday operations and compliance oversight grows increasingly interconnected. Data shifts from being a historical record to becoming a real-time indicator of process health, revealing where variation emerges and where controls may be drifting. AI builds on this by interpreting those signals, identifying patterns that point to early compliance risks, and guiding site teams toward intervention.

Agentic AI adds an additional layer of coordination by enabling autonomous systems to communicate with one another, validate information across platforms, and maintain alignment between procedures and actual execution. This collaborative intelligence supports a more stable inspection readiness posture. Instead of preparing after the fact, manufacturers can benefit from continuous verification of data integrity, document completeness, and decision traceability. Compliance becomes a sustained operational state, strengthened by ongoing data-driven insight rather than episodic review.

Post intelligent compliance networks

Emerging advancements in agent-based AI architecture are reshaping how life sciences organizations approach inspection readiness, regulatory monitoring, and ongoing compliance execution. Instead of operating through traditional linear workflows, intelligent compliance networks use **specialized agents** that collaborate to assess site conditions, surface risks, automate documentation review, and guide teams through inspection preparation. These systems work continuously and support a more proactive and resilient compliance environment, answering key gaps and questions traditionally faces by regulatory stakeholders and roles.

Coordinated intelligence across the compliance life cycle

In an agent-based ecosystem, inspection readiness is supported by the **coordinated actions of multiple digital agents** that each contribute specialized insights. Instead of manual monitoring or isolated functional reviews, these agents create a collaborative intelligence network that evaluates site readiness from multiple perspectives at once.

In this model, the **Regulatory Intelligence Agent** monitors external laws, guidelines, and inspection trends and identifies changes that may affect site operations. Its insights feed directly into the **Audit Readiness Agent**, which evaluates QMS data, audit trails, deviations, CAPAs, and open tasks to detect inconsistencies or preparation gaps.

The **Inspector Intelligence Agent** adds another layer by analyzing historical inspector behavior, focus areas, and recurring themes, helping teams anticipate where scrutiny is likely to occur. Bringing these insights together, the **Orchestration Agent** consolidates all inputs into a unified readiness view, prioritizes issues, and routes actions to responsible teams.

Together, the agents form a connected intelligence network that increases the speed and consistency of readiness activities. Organizations using this model see meaningful performance gains, including a **15% to 18% improvement in identifying risks and addressing readiness gaps, and a 20% to 25% reduction in manual work**[10] associated with pre-audit preparation and document review.

This approach creates a continuous readiness environment that integrates regulatory expectations, internal quality performance, and predicted inspector focus areas. Through coordinated agent workflows, companies can maintain a more stable and proactive compliance posture and reduce the operational burden of inspection preparation.

Regulatory Intelligence Agent

Monitors external regulatory sources for new laws, guidelines, and best practices

Audit Readiness Agent

Delivers automated, real-time monitoring of unresolved inspection events and CAPA gaps

Inspector Intelligence Agent

Validates GxP and regulatory criteria across business processes, analyzes historical audit outcomes

Orchestration Agent

Prioritizes compliance actions based on risk and deadlines

Pre-Audit Management Dashboard

A unified dashboard displaying key parameters provides near real-time insight into site inspection readiness

Turning compliance into a competitive advantage

The regulatory landscape for global biopharma companies is becoming more complex, faster moving, and more interconnected. Compliance excellence is no longer optional; it is a core strategic imperative. Future-proofing compliance requires immediate action, coordinated leadership, and investment in a modern regulatory intelligence ecosystem capable of meeting the challenges of 2025 and beyond.

Benefits through investment in compliance

Reduced time to compliance

- Up to 30% to 50% faster interpretation of global regulations
- Shorter change control cycles
- Faster adoption of ICH, EMA, and FDA expectations

Accelerated approvals

- Faster variation submissions
- More streamlined PAS and CBE 30 packages
- Improved readiness for post-approval commitments

Improved success

- Higher first-time right performance
- Fewer observations and warning letters
- Stronger confidence from global regulators

Lower cost of compliance

- Automation and harmonization reduce manual work
- Redundant interpretations decrease
- Rework decreases due to consistent application
- Documentation variability decreases

Supply chain stability

- Better control of API sourcing and raw materials
- Faster responses to deviations and shortages
- Reduced risk of product recalls
- Improved decision-making across internal and external networks

Strengthened reputation

- Transparent and consistent regulatory execution builds confidence
- Increased regulatory trust
- Stronger credibility among partners
- Greater confidence among regulators, HCPs, and patients

Endnotes

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Continue the conversation

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