

IQVIA Safety and Regulatory Compliance Solutions

Integrated. Connected. Complete.

The situation and impact

Life sciences companies are changing the way they stay compliant. A proliferation of regulations, products, markets and data sources — combined with intense cost pressures require innovation and interconnectedness to overcome complexity and support the needs of the business.





53% of global life sciences CEOs consider industry regulations to be a top disruptive business trend



>2000

new regulations issued by the FDA alone since 1998



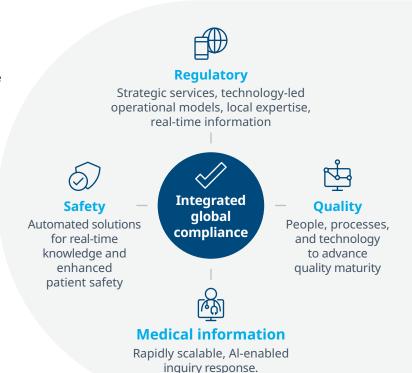
>20% annual increase in reported events

Integrated safety and regulatory compliance capabilities

Heighten performance and efficiencies. Increase value

IQVIA offers a complete approach that brings together safety, regulatory, quality, and medical information to transform how life sciences companies sustain compliance and how compliance functions perform better together.

- Fully integrated technology platforms.
- Improve compliance performance.
- Increase efficiency and reduce costs.
- · Achieve global portfolio visibility.
- · Advanced analytics leading to deep insights.
- · Unparalleled data.



AE/PQC triage

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Lower your burden. Boost operational compliance

Simplify, automate and integrate your compliance response times, accuracy, predictive planning and efficiency. Employ IQVIA's innovative technologies, decades of life sciences experience and advanced analytics — including artificial intelligence (AI) and machine learning (ML) — to glean key insights and make better decisions. Focus more resources on higher value activities.

DELIVER SAFER PRODUCTS

- Automate intake, processing and submission.
- Identify multi-sourced AEs and signals in real time.
- Glean insights for future development.

MORE INTELLIGENTLY MANAGE REGULATORY INFORMATION

- Automate high-volume tasks.
- Access regulatory intelligence for up-to-date reporting requirements.
- Improve deliverable quality.

IMPROVE QUALITY

- Reduce risk with a single enterprise platform.
- Ensure inspection readiness; address remediation.
- Promote a culture of quality.

MITIGATE COMMERCIAL COMPLIANCE RISK

- Manage on a single compliance platform.
- Automate provider engagement.
- Stay up to date with global transparency reporting regulations.

Better compliance powered by IQVIA Connected Intelligence™

Connected Intelligence is our unique capability that connects the right insights, technology, and compliance experts to go beyond following the rules and deliver more value to the business.

Safety and regulatory compliance solutions

SAFETY

- · Vigilance Platform.
- Signal detection.
- Case management.
- Reporting.
- Literature searching.
- Surveillance.
- Risk management.
- Adverse event tracking/ risk management.

REGULATORY

- RIM Smart.
- Intelligence database.
- Regulatory strategy.
- Regulatory submissions.
- Marketing authorizations and transfers.
- · Publishing.
- Tech-enabled regulatory maintenance.
- Post-market commitments.

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QUALITY

- Complete QMS suite and platform.
- GXP solutions.
- Event management.
- Document control and training.
- Inspection and auditing services.
- Supplier quality management.
- Consulting services.

MEDICAL INFORMATION

- Medical information experts.
- AI-powered intelligent agents.
- Global scale and flexibility.
- Leading technologies.
- Advanced analytics.

CONTENT MANAGEMENT SYSTEM

