PHARMACOVIGILANCE AND REGULATORY AFFAIRS

AT QPS WE BELIEVE IN DEVELOPING CLOSE AND LONG-LASTING RELATIONSHIPS WITH OUR CLIENTS ON THE BASIS OF TRUST AND MUTUAL RESPECT.

This mutual trust, combined with the agile approach we offer as a specialty CRO, helps improve the quality of your outsourced clinical work and reduces the degree of required oversight.

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The boundary between pharmacovigilance and regulatory affairs has never been thinner. As health authorities accelerate the digitization of safety reporting, tighten electronic submission standards, and expand expectations for real-time safety transparency, sponsors who treat these two disciplines as separate functions face compounding risks, such as missed deadlines, non-compliant submissions, and inspection findings that could have been prevented.

QPS, a global, full-service Contract Research Organization (CRO), operates at this intersection by design. Our integrated pharmacovigilance and regulatory affairs model combines clinical trial safety operations, medical oversight, electronic reporting infrastructure, and regulatory intelligence under a single governance framework. The result is a seamless, inspection-ready capability that protects participants, satisfies regulators, and gives sponsors a decisive operational advantage across all phases of clinical development.

This white paper examines the forces driving convergence between pharmacovigilance and regulatory affairs, the specific regulatory changes sponsors must now prepare for, and the QPS custom-built CRO model that transforms compliance complexity into controlled, repeatable performance.

THE CONVERGENCE OF PHARMACOVIGILANCE AND REGULATORY AFFAIRS

Pharmacovigilance and regulatory affairs have historically operated as adjacent but distinct disciplines. Safety teams processed adverse events and generated reports, while regulatory teams managed submissions, dossiers, and interactions with authorities. Each function maintained its own systems, timelines, and organizational identity.

Modern safety reporting requires regulatory expertise at every step. Determining whether an adverse event is reportable demands current knowledge of jurisdiction-specific rules. Submitting a case electronically requires validated technical infrastructure aligned to authority-specific gateway requirements. Preparing a development safety update report requires both clinical safety judgment and regulatory writing expertise. Responding to a health authority query about a submitted case requires simultaneous access to safety data, submission history, and regulatory expertise.

At the same time, regulatory affairs increasingly depends on pharmacovigilance outputs. Integrated safety summaries, risk management plans, benefit-risk evaluations, and post-authorization safety commitments all draw directly from the safety surveillance infrastructure. A regulatory submission is only as strong as the safety data and analysis behind it.

For sponsors working with a global, full-service CRO, this convergence is an opportunity. When pharmacovigilance and regulatory affairs share governance, systems, processes, and institutional knowledge, the combined capability is materially stronger than either function operating independently. QPS has designed its custom-built global service model around this principle.

THE REGULATORY LANDSCAPE IS CHANGING AND THE TIMELINE IS NOW

Three interconnected developments are reshaping what sponsors must deliver and when: FDA's electronic reporting mandate taking effect in 2026, evolving annual and aggregate reporting expectations, and the EMA's expanding pharmacovigilance framework. Each development demands a coordinated response from both pharmacovigilance and regulatory affairs.

FDA Electronic Reporting Requirements: The 2026 Mandate

The FDA's requirement for electronic submission of individual case safety reports using the E2B(R3) standard represents one of the most operationally significant changes to clinical trial safety reporting in recent years. Under the updated requirements, sponsors submitting IND safety reports must do so electronically in ICH E2B(R3) XML format through the FDA's Electronic Submissions Gateway, replacing legacy paper-based and older electronic formats. This is not simply a technology

upgrade. It is a fundamental change to how safety data is structured, validated, transmitted, and received. The implications are substantial:

- System Validation Requirements: Safety databases must be configured and validated to produce E2B(R3)-compliant XML outputs. Oracle Argus Safety, QPS's core safety platform, supports E2B(R3) generation, but configuration, testing, and validation must be completed and documented in advance of the effective date.
- Gateway Connectivity: Sponsors must establish and test transmission pathways through the FDA Electronic Submissions Gateway. This requires technical setup, account management, test submissions, and acknowledgment verification — all of which take time and require regulatory and technical coordination.
- Data Quality Standards: E2B(R3) transmissions are subject to automated validation checks at the receiving gateway. Submissions with missing required fields, invalid code values, or structural errors will be rejected. This places new emphasis on upstream data quality in case processing, MedDRA coding, and narrative completeness.
- Timeline Preservation: Regulatory reporting clocks do not pause for technical failures. A rejected electronic submission does not extend a seven- or fifteen-day reporting deadline. Sponsors must have contingency procedures, resubmission workflows, and technical support available to prevent compliance gaps when transmission issues arise.

For sponsors who have not yet begun preparing for the 2026 mandate, the window for orderly implementation is narrowing. QPS recommends that sponsors assess their current IND safety reporting infrastructure now, identify gaps against E2B(R3) and gateway requirements, and execute a structured readiness program with sufficient time for validation, testing, and staff training.

Evolving Annual and Aggregate Reporting Expectations

Annual safety reporting in the clinical development setting has grown substantially more complex. The Development Safety Update Report, or DSUR, remains the primary periodic safety report for investigational products under ICH E2F, but the expectations surrounding its preparation, content, and integration with other safety documents have intensified.

Health authorities increasingly expect DSURs to reflect genuine benefit-risk analysis rather than descriptive data summaries. Reviewers look for evidence that safety signals identified during the reporting period have been assessed, contextualized, and acted upon. A DSUR that catalogues events without analytical depth, or that fails to connect safety findings to protocol amendments, informed consent updates, or risk mitigation actions, is unlikely to satisfy modern review standards. Several specific expectations are shaping current practice:

- Alignment Across Safety Documents: Development Safety Update Reports (DSURs) must be consistent with risk management plans, investigator brochures, informed consent forms, and any safety-related regulatory correspondence. Inconsistencies across documents are a frequent inspection finding and a signal to reviewers that safety oversight is fragmented.
- Signal Integration: Any signal identified through aggregate review, literature surveillance, or spontaneous reporting during the DSUR period should be addressed explicitly. The DSUR is increasingly viewed as evidence of a functioning pharmacovigilance system, not merely a reporting obligation.
- Multi-Regional Harmonization: For global programs, a single DSUR prepared to ICH E2F standards should serve as the foundation for country-specific periodic reports. Managing the differences between DSUR requirements, US annual IND reports, and other local periodic reports requires close coordination between regulatory affairs and the safety team.
- QPS medical writers, safety physicians, and regulatory strategists collaborate on DSUR preparation from data extraction through final review, ensuring that each report reflects the analytical depth and cross-document consistency that modern health authorities expect.

European Medicines Agency (EMA) Pharmacovigilance Requirements: Expanding Expectations

The EMA operates one of the world's most demanding pharmacovigilance frameworks, and its requirements for clinical trial sponsors continue to evolve. Several areas warrant particular attention.

- EudraVigilance Suspected Unexpected Serious Adverse Reaction (SUSAR) Reporting: This remains a critical operational requirement for sponsors conducting clinical trials in the EU and EEA. SUSARs must be

submitted electronically through EudraVigilance in E2B format, and sponsors must complete prerequisite steps, including system registration, role configuration, training certification, and reporting mode selection, before any submission can be made. These prerequisites are frequently underestimated in study start-up planning, creating avoidable delays and compliance risk.

- The Clinical Trials Regulation (EU CTR 536/2014): Now in full effect through the Clinical Trials Information System (CTIS), this has changed how sponsors manage safety reporting obligations across EU member states. CTIS centralizes trial management and safety reporting, but it also introduces new complexity around document submission, multi-member state coordination, and inspection readiness. Regulatory affairs and pharmacovigilance teams must work together to manage CTIS obligations effectively.
- Risk Management Plans (RMPs): These are increasingly required not only at the time of marketing authorization but as living documents throughout clinical development for products with significant safety profiles. The EMA expects RMPs to reflect current safety knowledge, evolving signal assessments, and proportionate risk minimization measures. Keeping an RMP current requires continuous input from pharmacovigilance surveillance and regulatory strategy simultaneously.
- Good Pharmacovigilance Practice (GVP) Modules provide the operational framework for EU pharmacovigilance compliance. Sponsors and their CRO partners must demonstrate adherence to GVP expectations across case processing, signal management, periodic reporting, risk management, and audit readiness. QPS maintains current GVP expertise as a core organizational competency, updated continuously through regulatory intelligence monitoring.

THE QPS INTEGRATED MODEL: PHARMACOVIGILANCE AND REGULATORY AFFAIRS AS ONE CAPABILITY

QPS has designed its global CRO service model to eliminate the organizational gap between pharmacovigilance and regulatory affairs. This integration is not a coordination arrangement between two separate departments; it is a unified operating model with shared governance, shared technology infrastructure, shared quality systems, and shared accountability for sponsor outcomes.

How Integration Works in Practice at QPS

- Single Safety and Regulatory Strategy: At study start-up, QPS develops a unified safety and regulatory strategy that covers the safety management plan, reporting responsibility matrix, electronic submission infrastructure, country-specific reporting requirements, and periodic reporting schedule. Pharmacovigilance and regulatory affairs contribute to and own this strategy jointly.
- Oracle Argus as Shared Infrastructure: QPS uses Oracle Argus as the core safety database across all clinical trial phases. Argus is configured to support E2B(R3) electronic submissions, regulatory reporting rule tracking, MedDRA coding, narrative generation, audit trails, and aggregate report data extraction. Regulatory affairs teams access the same system for submission tracking, compliance monitoring, and authority interaction documentation.
- Integrated Case Review: When a case requires a reportability determination that involves regulatory interpretation, an unusual jurisdiction, a novel reporting pathway, a question about applicable law, QPS safety physicians and regulatory affairs specialists review the case together. This eliminates the handoff delays and interpretive inconsistencies that arise when these functions operate separately.
- Electronic Submission Readiness: QPS maintains validated E2B(R3) transmission capability through established gateway connections to FDA, EudraVigilance, and other major health authorities. Our regulatory affairs team manages gateway accounts, monitors transmission acknowledgments, manages rejection handling, and maintains the technical documentation required for inspection readiness.
- Aggregate Report Collaboration: DSURs, Periodic Safety Update Reports (PSURs), and other periodic reports are prepared by integrated teams that include safety physicians, medical writers with regulatory expertise, and regulatory strategists. Each report undergoes cross-functional review before submission to ensure analytical depth, cross-document consistency, and alignment with current authority expectations.
- Regulatory Intelligence as a Shared Service: QPS regulatory intelligence specialists monitor FDA, EMA, ICH, and national competent authority guidance continuously.

When new requirements emerge, such as the FDA's 2026 electronic reporting mandate, QPS assesses the impact on active programs, communicates proactively to sponsors, and executes implementation plans before effective dates.

QUALITY, INSPECTION READINESS, AND THE AUDIT TRAIL

Pharmacovigilance and regulatory affairs share a common inspection risk profile. Health authority inspectors evaluate not only whether reports were submitted on time, but also whether the underlying system—processes, people, technology, and governance—is capable of sustained compliance.

QPS embeds inspection readiness as an operating discipline rather than a pre-inspection exercise. Our quality system covers validated systems, controlled procedures, role-based training, case-level quality control, submission compliance monitoring, deviation management, corrective and preventive action tracking, and periodic management review. Mock inspections test the integrated pharmacovigilance and regulatory affairs capability together, because that is how real inspections unfold.

The audit trail maintained in Oracle Argus provides the evidentiary foundation for inspection defense, documenting every case action, every reporting decision, every submission, and every system change with user attribution and timestamp. This level of traceability is not optional in a regulated environment; it is the difference between a successful inspection and a critical finding.

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CONCLUSION: PHARMACOVIGILANCE AND REGULATORY AFFAIRS INTEGRATION IS IMPERATIVE FOR SUCCESSFUL DRUG DEVELOPMENT

The 2026 FDA electronic reporting mandate, the EMA's expanding pharmacovigilance framework, and the increasing analytical expectations for aggregate safety reports all point in the same direction: sponsors need a partner who combines deep pharmacovigilance expertise with current regulatory affairs capability, operating as one team under one governance structure.

QPS delivers that capability. Our integrated model reduces compliance risk, eliminates handoff delays, accelerates safety decision-making, and provides sponsors with a single accountable partner for the full spectrum of clinical trial safety and regulatory obligations.

As reporting requirements grow more complex and electronic submission standards become universal, the value of true integration—not just coordination, but full integration—will only increase. The QPS custom-built organization is designed for exactly this environment.

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