NOVEMBER 2026 | ISSUE 8

QACV CONSULTING
a Quality Management Organization™

NEWSLETTER



AICCoE 2026 PROGRAM DEVELOPMENT

QACV Delivers First-of-its-Kind AI & Data Integrity Training to FDA (OSI)

The evolving role of AI in GCP-regulated clinical trials



QACV Consulting Delivers First-of-Its-Kind **AI & Data Integrity Training** to FDA Office of Scientific Investigations (OSI)

ARTICLE BY **ROBERT J. WHERRY**, QACV CONSULTING VP OF AI COMPLIANCE CENTER OF EXCELLENCE

September marked a major milestone for QACV Consulting as Chris Wubbolt, CEO and Principal Consultant, and Robert (Bob) Wherry, Vice President of AI Compliance, delivered a two-part training series on AI and Data Integrity to the FDA's Office of Scientific Investigations (OSI). This marks the first time FDA OSI has received a dedicated training program focused on the rapidly evolving role of artificial intelligence in GCP-regulated clinical trials—an area where clarity, rigor, and governance are becoming increasingly essential.

The training, developed specifically for FDA investigators, centers on the **current state of AI adoption, the challenges sponsors and vendors face, and the regulatory expectations emerging under ICH E6(R3)**. As noted in the training materials, the sessions will emphasize "risk-proportionate oversight", "data reliability/integrity," and the growing need for the **qualified verification of AI-generated outputs**, especially as innovation accelerates and information volume expands.

Across two sessions—held in September—participants explored:

- **Real-world AI use cases** in clinical research and the practical obstacles encountered by sponsors, CROs, investigator sites, and vendors.
- **Inspectional considerations**, including sponsor oversight responsibilities, controls on AI tools, vendor management, and data integrity risks.
- **Governance frameworks**, covering processes, procedures, and human-in-the-loop oversight models needed to ensure trustworthy AI deployment.
- **Validation approaches** tailored to AI-driven applications, where traditional software validation must adapt to probabilistic outputs and model drift.
- **Case studies** from industry, academic research groups, and AI technology providers.

For QACV Consulting, this engagement reflects both industry leadership and growing recognition of the firm's expertise in AI compliance. As organizations navigate the intersection of innovation and regulation, QACV's structured, risk-based approach is helping shape how the life sciences sector—and now FDA OSI—evaluates and governs AI technologies.

This landmark training underscores QACV's commitment to advancing safe, reliable, and compliant AI use across the clinical research ecosystem and all GxP Compliance areas.

AI COMPLIANCE CENTER OF EXCELLENCE

Services include:

If you are interested in learning more about the training provided to the FDA or what you may need to ensure compliance in the AI landscape, contact us at **contact@QACVconsulting.com**

1 Trainings

- Strategic training, to help understand the emerging regulatory expectations
- Historical context to explain the "Why?" behind regulatory requirements.
- Tactical training with introduction to AI/ML and the appropriate compliance controls specifics for Quality and Compliance experts

2 Audits

- Performed for companies that are using AI/ML vendors
- Targeted specifically for vendors who develop or use AI/ML

3 Systems / SOPs

- Align AI/ML development into current best practices
- Avoid a force-fit of AI/ML development into inadequate systems

4 Submissions

- Built for companies that need clear guidance on how to properly position and document AI/ML systems within medical device and pharmaceutical filings

5 Expert Consultation & Advice

- Consultation for companies that require practical, experience-based guidance to implement compliant and scalable AI/ML governance models

6 AI Compliance Corner

- Case studies
- Monthly meetings
- Articles
- Evaluations



"I just wanted to send a personal thank you to all of you for taking the time to lead the **two training sessions on AI in GCP-regulated clinical trials**. We really appreciate the time and effort you put into preparing for both sessions and, especially, your willingness to share your knowledge and experience with us. The discussions were timely, practical, and very helpful in thinking through some of the important questions around AI, including **data integrity, validation, human oversight, and governance**. I also really appreciated the discussion. Thank you again for your time and partnership. We truly enjoyed the sessions and are grateful for your support."

Testimonial I FDA training attendee

FDA

BUILDING

ARTICLE BY **MIKE SOBCZYK,** QACV CONSULTING GCP ADVISER | SR. COMPLIANCE CONSULTANT



A CULTURE OF QUALITY: QA AND COMPLIANCE AS STRATEGIC BUSINESS PARTNERS

In today's highly regulated life sciences environment, quality assurance and compliance are no longer simply functions responsible for reviewing documents, conducting audits, and addressing regulatory requirements. When integrated effectively across an organization, they become strategic business partners that support operational excellence, protect patients, reduce risk, and enable sustainable growth.

At **QACV Consulting**, we believe that a strong quality culture begins with a shared understanding that quality is everyone's responsibility. Policies and procedures provide an essential framework, but lasting compliance depends on how consistently quality principles are applied in day-to-day decision-making. Leadership commitment, clear accountability, effective communication, and practical training are all critical to transforming written requirements into meaningful and sustainable practices.

MOVING

FROM REACTIVE TO PROACTIVE COMPLIANCE

Organizations often focus on quality and compliance after an issue has occurred—for example, following an audit observation, inspection finding, deviation, or procedural gap. Although corrective and preventive actions are essential, a mature quality system should also help identify and address risks before they become significant problems.

A proactive approach may include periodic reviews of quality systems, risk-based audits, meaningful performance indicators, effective vendor oversight, and regular assessments of procedures and training programs. These activities provide organizations with greater visibility into emerging risks and opportunities for improvement.

Early identification of potential compliance gaps can also reduce operational disruption, prevent repeated issues, and strengthen inspection readiness. Rather than preparing only when an audit or inspection is approaching, organizations should maintain a continuous state of readiness supported by reliable processes and accurate documentation.

CREATING

PRACTICAL AND SUSTAINABLE QUALITY SYSTEMS

An effective quality management system must be both compliant and practical. Procedures that are overly complex, unclear, or disconnected from actual business operations can create confusion and increase the likelihood of noncompliance. Quality systems should therefore be designed around applicable regulatory requirements while remaining proportionate to the organization's size, activities, and risk profile.

Well-designed standard operating procedures establish clear responsibilities, provide consistent instructions, and support efficient execution. However, procedures alone are not enough.

Organizations must also ensure that employees understand how the requirements apply to their roles and feel comfortable raising concerns, reporting errors, and recommending improvements.

This is where training, communication, and leadership engagement become especially important.
A healthy quality culture encourages transparency and treats issues as opportunities to learn and improve rather than occasions to assign blame.

THE VALUE

OF INDEPENDENT QUALITY EXPERTISE

Independent quality and compliance support can provide an objective perspective on existing processes, identify areas that internal teams may overlook, and offer specialized expertise during periods of growth or organizational change. External consultants can also help organizations manage temporary resource constraints, prepare for audits and inspections, develop or strengthen procedures, and implement risk-based quality strategies.

QACV Consulting works collaboratively with clients to develop solutions that are tailored, practical, and sustainable. Our goal is not simply to identify gaps, but to help organizations understand the underlying risks and implement improvements that support both compliance and business objectives.

As regulatory expectations continue to evolve, organizations that embed quality into their strategy and operations will be better positioned to respond confidently. A strong quality culture does more than demonstrate compliance—it protects patients, supports reliable data, strengthens stakeholder trust, and creates a foundation for long-term success.

ARTICLE BY **ERIKA REATEGUI**, QACV CONSULTING CHIEF COMPLIANCE OFFICER (CCO)





SPONSOR OVERSIGHT OF CMOs AND CDMOs

MOVING BEYOND QUALITY AGREEMENTS

As pharmaceutical and biotech companies adopt virtual or highly outsourced operating models, **Sponsor oversight of Contract Manufacturing Organizations (CMOs) and Contract Development and Manufacturing Organizations (CDMOs)** has become one of the most important Quality responsibilities. Outsourcing manufacturing does not reduce regulatory accountability, it often increases the complexity of maintaining it.

While manufacturing, testing, packaging, storage, and distribution activities may be delegated to CMOs and CDMOs, regulatory responsibility does not transfer. Ultimate regulatory responsibility remains with the Sponsor / Marketing Authorization Holder (MAH) / application holder. This expectation is clearly established and is consistent across global regulatory frameworks, including **21 CFR Part 211, ICH Q10 Pharmaceutical Quality System, ICH Q9(R1) Quality Risk Management, and EU GMP Chapter 7 – Outsourced Activities.**

For example, 21 CFR 211.22 requires the Quality Unit to maintain responsibility for approving or rejecting procedures, specifications, investigations, and other activities that may impact product quality. Similarly, ICH Q10 Section 2.7 makes clear that responsibility for outsourced activities remains with the sponsor, regardless of where those activities are performed.

For most Sponsors, oversight starts with supplier qualification, which may include a supplier audit, technical due diligence, and execution of a Quality Agreement. Those are critical first steps, but they are only the beginning. Regulators expect ongoing oversight, governance, and monitoring, not just initial qualification.

In practice, oversight typically includes **routine review of key quality and operational indicators** such as:

- Batch disposition oversight
- Validation status
- Data integrity controls
- Deviations and investigations, consistent with 21 CFR 211.192
- Product, packaging, labeling or performance Complaints
- CAPAs and effectiveness checks for significant quality events
- Change controls impacting validated processes, analytical methods, materials, suppliers, or regulatory filings
- Production process review, including, as applicable, environmental monitoring trends, media fills, and other critical process indicators
- Annual Product Quality Reviews (APQRs/PQRs), aligned with 21 CFR 211.180(e) and EU GMP expectations
- Supply chain risks
- Stability program performance, including expiry support and regulatory commitments
- Analytical performance, including OOS/OOT investigations and laboratory trends
- Audit outcomes, regulatory inspections, and post-inspection commitments
- Quality metrics and KPIs, such as deviation closure timelines, right-first-time batch release, and CAPA effectiveness



> Sponsor oversight is not about reviewing more documents. It is about reviewing the right information, at the right frequency, with enough technical and quality oversight to identify risk before it becomes a compliance issue.

One area where I commonly see Sponsors struggle is determining how involved they need to be in routine quality events, particularly minor deviations generated within a CMO or CDMO quality system.

A common reaction is to open a duplicate deviation within the Sponsor's own eQMS for every event received. While this may create the appearance of control, in practice, it often creates administrative burden without adding meaningful oversight. Duplicate systems also may reduce resources for other critical quality related activities or cause discrepancies or inconsistencies in quality records.

A more effective and scalable approach, and one that aligns well with ICH Q9(R1), is a **risk-based oversight model**. Using this approach, the CMO or CDMO remains responsible for owning, investigating, and closing deviations within its quality system, while the Sponsor focuses on what matters most:

- **Reviewing the adequacy of the investigation,**
- **Assessing product and regulatory impact,**
- **Identifying recurring trends, and**
- **Escalating events that require Sponsor review or approval**

The same thinking applies well beyond deviations. An APQR may identify emerging process drift. Stability data may raise questions around shelf life or expiry commitments. A change control may introduce filing, validation, or supply chain risk. In each case, the Sponsor's role is not to recreate the work of the CMO or CDMO, it is to ensure the work was appropriately executed, scientifically justified, and aligned with regulatory commitments.

Ultimately, Sponsor oversight is not about reviewing more documents. It is about reviewing the right information, at the right frequency, with enough technical and quality oversight to identify risk before it becomes a compliance issue. To support sponsor oversight activities, periodic governance meetings, escalation mechanisms, and clear and constant communication are key.

Manufacturing and GxP activities may be outsourced, but product quality, patient safety, regulatory compliance, and quality accountability must remain with the Sponsor.

> To support sponsor oversight activities, periodic governance meetings, escalation mechanisms, and clear and constant communication are key.



Risk-based oversight model

- **Reviewing the adequacy of the investigation**
- **Assessing product and regulatory impact**
- **Identifying recurring trends**
- **Escalating events that require sponsor review or approval**

Latest News

GUIDANCE - PUBLISHED OCTOBER 2026

MHRA STRATEGY TO 2030:

What it means for you - GOV.UK

LEARN MORE >

A series of explainers to help you understand the parts of the MHRA Strategy to 2030 most relevant to you, and what they mean in practice. The strategy appears to demonstrate the MHRAs desire to enable innovation, rather than gatekeep compliance. Key aspects of note:

1. Continuation of emphasis on risk-based approaches.
2. Encouragement of earlier regulatory engagement, e.g., scientific advice meetings.
3. Quality functions to be more strategically involved in a sense that quality and risk-based thinking needs to be designed in from the start to ensure proportionate effort as well as safe and compliant outcomes.
4. Development of an MHRA AI Med Dev action plan. They also notably are continuing to emphasize NAMs and their desire to support innovation as we continue the shift away from animal models.





China/NMPA - China's Revised Good Clinical Practice Requirements: What Sponsors and Quality Professionals Need to Know

China issued a revised version of its Good Clinical Practice for Drugs requirements in June 2026, replacing the 2020 version. A guideline designed to ensure the ethical and scientific conduct of clinical studies, aiming to enhance the nation's research ecosystem and support innovation in biotechnology.

Key updates include enhanced expectations for data governance, use of new technologies and methods, principal Investigator responsibility, participant protection, ethics committee oversight, and quality management throughout the clinical trial lifecycle. The revised GCP became effective September 1, 2026.

- **Stronger alignment with modern, risk-based GCP principles and ICH E6(R3) concepts**
- **Increased sponsor and investigator accountability for trial quality and oversight**
- **Greater emphasis on participant rights, safety, and well-being**
- **Enhanced expectations for data governance, data reliability, traceability, and computerized systems**
- **Increased focus on quality management throughout the clinical trial lifecycle**
- **Recognition of evolving technologies and methods used in clinical research**
- **Strengthened expectations for ethics committee oversight and principal investigator responsibilities**

GLOBAL REGULATORY UPDATES II SEMESTER OF 2026

01 DRAFT GUIDELINES FOR GOOD CLINICAL PRACTICES FOR TRIALS ON PHARMACEUTICAL PRODUCTS

WHO made draft revised GCP materials available for public consultation, including the Main Principles, Annex 1, and Annex 2, reflecting continued international efforts to modernize GCP expectations and accommodate evolving clinical trial designs and technologies.
Source: Health products policy and standards

02 ETHICAL CRITERIA FOR CONTROLLED HUMAN INFECTION STUDIES

On August 6, 2026, WHO opened public consultation on draft ethical criteria for controlled human infection studies conducted in emergency preparedness settings. **Source:** Public consultation on the draft key ethical criteria for controlled human infection studies in emergency preparedness

03 ICH E6 (R3) GOOD CLINICAL PRACTICE ANNEX 2 - STEP 5

EMA published the finalized ICH E6(R3) Annex 2 at Step 5 on July 15, 2026. Annex 2 addresses GCP considerations for trials incorporating decentralized elements, real-world data, pragmatic designs, and other non-traditional trial approaches. The EU legal effective date is January 15, 2027. **Source:** ICH E6 Good clinical practice - Scientific guideline | European Medicines Agency (EMA)

04 MHRA-CLINICAL TRIALS ROLES AND RESPONSIBILITIES GUIDANCE

MHRA updated its guidance on July 7, 2026. The guidance addresses investigator eligibility and responsibilities, training and experience, delegation, medical oversight, safety reporting, and pharmacy supervision under the amended UK Clinical Trials Regulations. **Source:** Clinical trials for medicines: roles and responsibilities - GOV.UK

05 MHRA-CLINICAL TRIALS REGULATIONS TRANSITIONAL ARRANGEMENTS

MHRA updated its transitional arrangements guidance on July 15, 2026, covering the transition between the previous and amended UK Clinical Trials Regulations, including GCP, pharmacovigilance, trial approvals, modifications, labeling, and record retention. **Source:** Clinical trials for medicines: Clinical Trials Regulations transitional arrangements - GOV.UK

06 MHRA-COLLECTION, VERIFICATION AND REPORTING OF SAFETY EVENTS

MHRA updated its clinical trial safety reporting guidance on July 15, 2026, including clarification related to SUSAR reporting requirements under the amended Clinical Trials Regulations. **Source:** Clinical trials for medicines: collection, verification and reporting of safety events - GOV.UK

07 TGA-FIRST-IN-HUMAN AND EARLY CLINICAL TRIALS GUIDELINE

The TGA published its adopted guideline on July 2, 2026, providing updated expectations for identifying and mitigating risks in first-in-human and early-phase clinical trials. **Source:** Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products | Therapeutic Goods Administration (TGA)

08 CONDUCTING REMOTE REGULATORY ASSESSMENTS: QUESTIONS AND ANSWERS-FINAL GUIDANCE

FDA issued final guidance addressing its approach to Remote Regulatory Assessments and expectations for records, information, and interactions conducted remotely.
Source: Conducting Remote Regulatory Assessments Questions and Answers | FDA

09 M11 CLINICAL ELECTRONIC STRUCTURED HARMONISED PROTOCOL (CeSHarP)- FINAL GUIDANCE, TEMPLATE AND TECHNICAL SPECIFICATION

FDA finalized the ICH M11 guidance establishing a harmonized structure and standardized data fields for clinical trial protocols to facilitate electronic exchange and regulatory review.
Source: M11 Clinical Electronic Structured Harmonised Protocol | FDA

10 SUBMITTING CONTINUOUS GLUCOSE MONITORING DATA IN CLINICAL TRIALS- FINAL GUIDANCE

FDA issued final technical guidance describing specifications for submitting continuous glucose monitoring data from clinical trials in support of drug and biological product marketing applications. **Source:** Submitting Continuous Glucose Monitoring Data in Clinical Trials | FDA

11 GUIDELINE ON STRATEGIES TO INDENTIFY AND MITIGATE RISKS FOR FIRST-IN-HUMAN AND EARLY CLINICAL TRIALS

The TGA adopted the international guideline on May 24, 2026, addressing risk identification and mitigation for first-in-human and early-phase clinical trials involving investigational medicinal products.Guideline on strategies to identify and mitigate risks for first-in-human and early clinical trials with investigational medicinal products. **Source:** Therapeutic Goods Administration (TGA)



INTRODUCING

eQMS-as-a-Service for small-to mid-size companies

Ensuring compliance with all applicable regulations



Smaller companies often lack the resources to implement a compliant eQMS and rely on tools like SharePoint or network folders for their Quality Management System (QMS). QACV's eQMS-as-a-Service provides a scalable, cost-effective, and compliant alternative.

QACV Consulting partners with Simploud to deliver clients the **eQMS-as-a-Service** offering.
QACV's clients can securely access the **eQMS-as-a Service** platform as part of their quality and compliance services, enabling real-time visibility into quality processes, controlled access to relevant documentation, improved oversight, and enhanced audit readiness.

Learn more about how we can support your organization. Partner with QACV Consulting to strengthen your quality systems and ensure regulatory compliance.
Contact us for a free demonstration I contact@QACVconsulting.com

LEARN MORE

Welcoming our Global Team Members

We are pleased to welcome the newest members of QACV Consulting.
Their expertise, experience, and contributions will further strengthen our team and support our continued commitment to delivering excellence to our clients.

Regulatory Expertise. Global Reach. AI-Driven Innovation

- **ROBERT J. WHERRY** VP of AI Compliance Center of Excellence (AICCoE)
- **ORLAITH GREENAN** EU/UK Lead | Executive Director
- **RACHEL NARINO** QA Lead | Sr. Compliance Consultant
- **MAIKO NAKAZATO** ASIA/PACIFIC, Project Management Administrator

Together, we are paving the way for a brighter future in the industry, where high standards and compliance drive success on a global level, being key partners in supporting our clients' compliance journey.



ISO 9001 Certification

As a QMO™, QACV Consulting is working toward becoming ISO 9001 certified in early 2027, to strengthen internal processes, promote continuous improvement, manage risk, and consistently meet the needs and expectations of our clients and other interested parties.

As part of this effort, QACV Consulting will continue to review and enhance its quality processes, conduct internal audits, and monitor the effectiveness of the QMS. This initiative reflects QACV's ongoing commitment to quality, consistency, accountability, and client satisfaction.



CLIENT TESTIMONIALS

AUDIT CERTIFICATE

"An audit certificate and close-out letter were successfully delivered to the client, concluding the audit of our newest CRO. The entire process was managed seamlessly from start to finish, demonstrating excellent ownership, organization, and communication throughout. The audit was completed smoothly and efficiently, leaving a very positive impression of the overall experience."

GCP TRAINING

"The session was highly impactful and well received by the team. Participants appreciated the clear, direct, and insightful answers provided, as well as the practical guidance shared throughout the session that left a strong positive impression on the clinical operations team. The experience built confidence in the consultant's expertise and established a strong foundation for future collaboration on inspection preparation and mock inspections."

TMF AUDIT

"The TMF audit received very positive feedback from the client team. The auditor was recognized for being a clear communicator and explaining the audit process thoroughly and effectively. The team appreciated the collaborative approach and the smooth working relationship throughout the audit, resulting in a positive overall experience and strong client satisfaction."

AUDIT REPORT

"Exceptional Quality Report. The client had prepared several pages of notes to summarize their observations, but ultimately needed only a small portion of their original content, as the report had already captured the key points and presented them in a clearer, more concise, and effective manner. This reflects the high standard of reporting and the ability to communicate findings accurately and professionally."



QACV Consulting Chief Compliance Officer Publishes Article in **RQA's Quasar Magazine**



We are proud to announce that **Erika Reategui, Chief Compliance Officer** at QACV Consulting, is the author of an article published in the May 2026 edition of QUASAR magazine (Issue #175), a publication of the Research Quality Association (RQA). Her article, **"Archiving with Integrity: Turning 'Storage' into a Compliance Asset",** explores the critical role of archiving in maintaining data integrity, regulatory compliance, and inspection readiness across regulated industries.

Too often, archiving is viewed simply as a storage function. In her article, Erika emphasizes that effective archiving goes far beyond storing records. It is a fundamental component of a robust compliance framework, helping organizations protect critical information, maintain accessibility, support business continuity, and meet evolving regulatory expectations.

Through her published work, Erika shares valuable insights into how organizations can transform traditional archiving practices into strategic compliance assets that strengthen quality systems, improve operational efficiency, and support long-term regulatory success.

At QACV Consulting, we are proud of Erika's contribution to the industry's ongoing dialogue on quality, data integrity, and compliance. Congratulations, Erika, on this publication and your continued commitment to advancing excellence in regulatory compliance!.

NOVEMBER 2026

Upcoming Events

8th GLOBAL QA CONFERENCE
November 4-6, 2026 | Novotel London West

Held every three (3) years, the global QA conference (GQAC) will take place in London for 2026. Run in conjunction with SQA, JSQA and RQA, this global event is THE place for quality professionals to network, learn and discuss current hot topics in the world of QA. Join us in London!

Register Now





































Latest Events

Every event brings new opportunities to reconnect with industry friends, strengthen client relationships, and build meaningful partnerships that move the life sciences industry forward.

- **MARSQA MID Atlantic Region Society of Quality Assurance**
  October 01, 2026 | Lahaska, PA

- **QACV presents at MWSQA Annual Meeting and Quality College**
  July 27–30, 2026 | Madison, WI

  Featured sessions:

  - **eClinical Systems and Data Integrity** : Define how technology-enabled clinical data flows create data integrity risks and identify the controls needed to manage them, including risk scenario assessment, vendor and SaaS oversight, validation evidence for intended use, and data migration safeguards
  - **Regulatory Inspection and Audit Considerations:** A practical framework for readiness, conduct, response, and sustainable remediation.

- **DIA 2026**
  June 14–18, 2026 | Philadelphia, PA

- **42nd SQA Annual Meeting**
  April 11-16, 2026 | National Harbor, MD

DIA 23RD TOKYO, JAPAN

October 18–20, 2026 | Big Sight Tokyo

QACV Consulting continues to strengthen its presence across Asia-Pacific.
Our return this year marked an important step forward in our regional engagement, creating new opportunities for collaboration, deepening relationships with key industry stakeholders, and reinforcing our position as a trusted global regulatory partner.

At the 23rd DIA Japan Annual Meeting, we engaged with industry leaders and regional and global stakeholders on critical topics shaping the future of life sciences, including cross-border compliance, regulatory strategy and digital health innovation.
The discussions highlighted the growing importance of international collaboration, regulatory alignment, and innovative approaches to medical product development and post-marketing surveillance across Japan, Asia-Pacific, and global markets.

Building on the connections established during our initial participation, this year's experience delivered even greater value, strengthening existing relationships and opening doors to new opportunities. These continued engagements reflect QACV Consulting's growing regional presence and our commitment to bringing global expertise, regulatory excellence, and practical solutions closer to the organizations we serve across Asia-Pacific.

As we continue to expand our international reach, we remain focused on fostering strategic partnerships, supporting regulatory advancement, and helping life sciences organizations navigate an increasingly interconnected global landscape.





QACV Consulting — Strengthening Our Presence in Asia-Pacific, Your Trusted Global Regulatory Partner

- Reduce costs associated with overseas consulting and compliance programs.
- Minimize travel time with localized QACV's consultants support across the region.
- Communicate in your own language — our multilingual team speaks your language.
- Navigate regional regulations with confidence — we bring experience across PMDA (Japan), HSA (Singapore), TGA (Australia), NMPA (China), and more.
- Ensure global alignment with FDA, EMA, and other key international agencies.

Expanding Compliance, Reducing Barriers:
We believe regulatory excellence should be accessible and localized.
Let's talk about how QACV Consulting can support your team—right where you are.

Learn more about our services and contact us today I contact@QACVconsulting.com





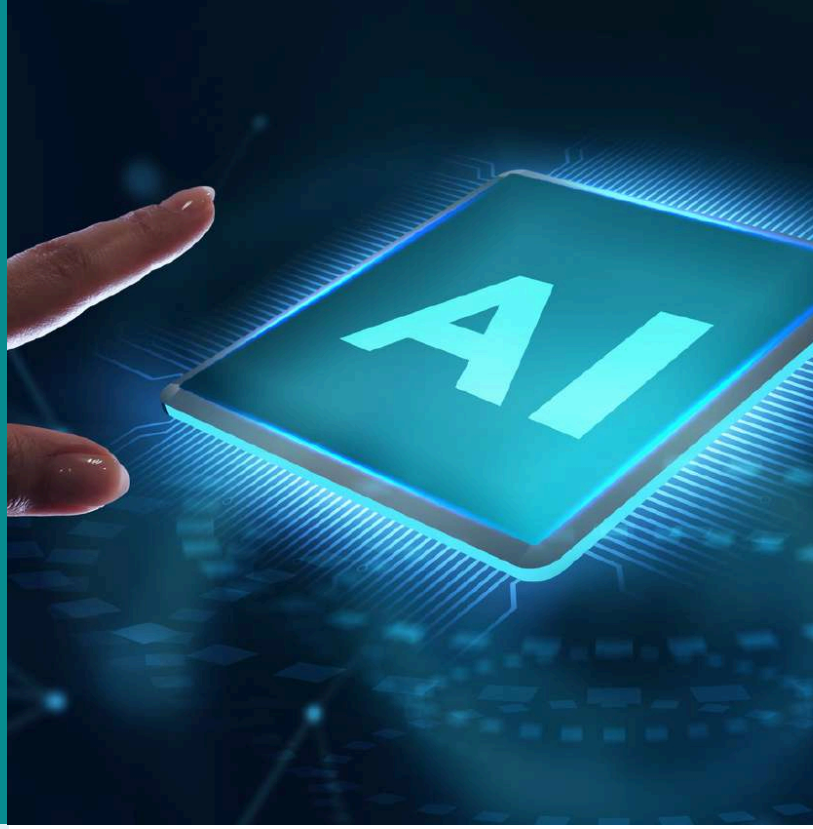
QACV Consulting Global Presence

Since 2023, our Globalization Strategy leverages extensive expertise in Quality Assurance, Compliance, and Computer System Validation (CSV), to provide world-class services for the life sciences industry on a global scale.

Canada
United States
Central America
South America

UK & EU
South Africa
Israel
India

Singapore
China
South Korea
Japan
Australia



A Quality Management Organization Company™ (QMO™) specializing in Data Integrity, GxP Audits, Training, Validation, GCP, GMP, GLP, PV QA Support, Compliance and AI/ML Compliance & Validation Services

Empowering Excellence in Quality Assurance & Compliance

QACV CONSULTING
a Quality Management Organization™

A new era of Quality, Innovation and Leadership

Contact Us **610-442-2250**

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