



Evolving from Quality Consulting to a Quality Management Organization™ (QMO™)

Celebrating 25 Years!



Overview by Chris Wubbolt, M.S. QACV Consulting CEO | Principal Consultant

Entering a New Era of Quality, Innovation and Leadership

On January 22, 2026, QACV Consulting celebrated our 25th anniversary. It's been quite the journey—from starting as a single consultant to building an outstanding team and becoming a globally recognized consulting organization with over 80 highly qualified and experienced consultants supporting clients, large and small. QACV Consulting has never had a business development plan or a sales team; instead, we have remained focused on providing practical, personable, high-quality consulting services. This was our approach in 2001 and remains our approach today—shaped by our culture, our internal team, and the processes and methodologies we have built. Our growth has been the result of consistently doing the best job we can, maintaining collaborative partnerships with our clients, and earning trust through the quality and integrity of our services.

QACV Consulting is a different organization today than we were 25 years ago. As we have expanded our global consultant and partner network, we have developed a strong onboarding program that reinforces our culture, processes, and expectations for how we conduct ourselves professionally with clients, partners, and associates. These onboarding and management processes ensure that our clients continue to receive the same high-quality consulting support that has defined QACV for the past 25 years.

We have also implemented tools that provide greater transparency to our clients regarding the status of projects and activities. As we continue to evolve, we are marking our 25th anniversary by transitioning from a traditional consulting firm to a **Quality Management Organization™**, partnering more closely with our clients to align with their values, expectations, priorities, and strategic initiatives.

Over the past 25 years, we have had the opportunity to support a wide range of life science organizations across the globe and throughout all phases of development and commercialization.

QACV Consulting has steadily expanded its services across GCP, GMP, GLP, GVP, and eSystems, as well as data integrity and quality system development. In addition, QACV Consulting is expanding its service offerings to include our **Artificial Intelligence Compliance Center of Excellence** and our new **eQMS-as-a-Service solution**, designed to provide scalable, compliant support for smaller organizations. We have also established global partnerships to further enhance our capabilities, including providing Qualified Person support within the EU. QACV Consulting is also on track to achieve **ISO 9001 certification** in early 2027, through continued enhancement of our internal Quality Management System.

I would personally like to thank all of our clients and partners we have had the privilege to meet, collaborate with, and support over the years. It is truly one of the most rewarding aspects of consulting to help organizations grow, advance their clinical programs, achieve successful regulatory approvals, and overcome complex regulatory and compliance challenges. I also want to thank our exceptional and dedicated management team and consultants, who consistently go the extra mile to meet and exceed client expectations. While QACV Consulting has implemented and supported many robust systems, processes, and methodologies, I often remind our team that “we can always get better.” This commitment to continuous improvement is fundamental to who we are. We have achieved a great deal over the past 25 years, but we are not done yet—we will continue to grow, evolve, and strengthen our capabilities in the years ahead.

SHAPING THE FUTURE OF QUALITY

We reflect with pride on a journey defined by integrity, expertise, and an unwavering commitment to quality and compliance across the life sciences industry.

What began as a focused quality consultancy has grown into a globally recognized **Quality Management Organization™ (QMO™)**—one that supports clients not only in meeting regulatory requirements, but in building sustainable, inspection-ready quality systems for the future.

The next phase of QACV's evolution is firmly rooted in our transition toward a QMO™ model. This approach goes beyond traditional auditing and advisory services, positioning QACV Consulting as a long-term quality partner that integrates seamlessly with client organizations. Our QMO™ framework emphasizes proactive quality oversight, risk-based decision-making, continuous improvement, and regulatory intelligence—ensuring our clients are prepared not just for today's inspections, but for tomorrow's regulatory expectations. As a QMO™, QACV Consulting becomes a trusted Quality Partner—supporting strategy, execution, and continuous compliance across regions and functions.

Embracing Innovation: AI AND THE FUTURE OF QUALITY

Innovation is central to QACV's vision. As part of our forward strategy, we are actively developing AI-enabled initiatives to enhance quality management, audit efficiency, data review, and compliance oversight. These tools are designed to support smarter risk identification, trend analysis, and documentation review—while maintaining the human expertise and regulatory judgment that remain essential in quality assurance.

Our AI initiatives are being developed responsibly, with a clear focus on regulatory compliance, data integrity, and transparency, ensuring alignment with global expectations as technology continues to reshape the quality landscape.

A TRULY GLOBAL FOOTPRINT

Today, QACV Consulting operates across all major continents, with an active footprint in over 20 countries and a global network of nearly 80 highly qualified consultants. Our team brings deep regional and cultural expertise while operating under a unified quality framework—allowing us to support global programs with consistency, agility, and local insight. Our consultants cover the full spectrum of Quality Assurance needs, including:

- ☒ GCP, GMP, GLP, GCLP, PV, CSV and Data Integrity
- ☒ Regulatory inspection readiness and mock inspections
- ☒ Investigator site, vendor, CRO, and system audits
- ☒ Quality system development, remediation, and oversight



INTRODUCING

New | QACV Consulting
2026 AI Program DevelopmentAI COMPLIANCE CENTER
OF EXCELLENCEQACV Consulting Delivers
First-of-Its-Kind AI & Data Integrity
Training to FDA Office of Scientific
InvestigationsRobert J. Wherry, MSc, MS, CPIP
VP of AI Compliance Center of Excellence

This September marks a major milestone for QACV Consulting as Chris Wubbolt, CEO / 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 is the first time FDA OSI received a dedicated 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.

QACV Consulting
AI Compliance
Center of
Excellence
Services Include:



Audits

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



Submissions

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

AI Compliance Corner

- Case studies
- Monthly meetings
- Articles
- Evaluations



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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



3

Systems / SOPS

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



5

Expert Consultation & Advice

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



INTRODUCING

eQMS-as-a-Service
for small to mid-size
companiesEnsuring 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 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 | contact@qacvconsulting.com

QACV Consulting - Your Trusted Global Regulatory Partner
in Asia-Pacific

Regulatory Expertise. Global Reach. AI-Driven Innovation

- 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 | contact@qacvconsulting.com

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.

Scan the QR Code and Connect with our Team

- Discover our NEW 2026 AI Compliance Center of Excellence Program—designed to support innovation in regulated environments
- Discuss with us your Quality, Compliance and Validation needs



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Providing Tailored Global Consulting Services in Quality Assurance, AI/ML Compliance, Data Integrity and Validation Services in the Pharmaceutical, Biotech, and Medical Device Industries for over 25 years.