QACV CONSULTING

a Quality Management Organization™

NEWSLETTER

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ANNIVERSARY EDITION

CELEBRATING 25 Years

Our Evolution into a Quality Management Organization™

A new era of Quality, Innovation and Leadership

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Celebrating 25 Years

Entering a new era of Quality, Innovation and Leadership

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

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 2026 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.

With sincere appreciation,

Chris Wubbolt
CEO I Principal Consultant

Shaping the Future of Quality as We Celebrate 25 Years of Excellence

As QACV Consulting celebrates its 25th year in business, 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.

From Quality Consulting to a Quality Management Organization™ (QMO™)

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**
- **Investigator site, vendor, CRO, and system audits**
- **Regulatory inspection readiness and mock inspections**
- **Quality system development, remediation, and oversight**

TRAINING, REGULATORY SUPPORT, AND INSPECTION READINESS

Education and preparedness are cornerstones of effective quality systems. QACV Consulting continues to expand its training initiatives, delivering tailored, regulation-driven programs for organizations of all sizes.
From executive leadership training to role-based GxP education, our programs are designed to be practical, scalable, and inspection-focused.
In parallel, we provide hands-on support for regulatory agency inspections, including preparation for and interaction with authorities such as the FDA, EMA, MHRA, and other global health authorities. Our advisory teams work closely with clients before, during, and after inspections to ensure confidence, clarity, and compliance at every stage.

ALWAYS UP TO DATE WITH GLOBAL REGULATIONS

In an ever-evolving regulatory environment, staying current is not optional—it is essential. QACV Consulting maintains continuous regulatory surveillance across global regions, ensuring that our guidance, audits, and training reflect the latest regulations, guidance, and industry best practices. This commitment allows our clients to anticipate change rather than react to it, strengthening their compliance posture and operational resilience.

STRENGTHENING OUR OWN QUALITY SYSTEM: ISO 9001 CERTIFICATION

As part of our ongoing commitment to excellence and continuous improvement, QACV Consulting is pursuing ISO 9001 certification for its own Quality Management System (QMS), with the goal of achieving certification by mid- to late 2026. This initiative reflects our dedication to operating under a formally certified quality framework and further strengthens our ability to support clients with consistency, transparency, and operational rigor.
ISO 9001-certified QMS will enhance how we deliver quality assurance, advisory services, and global oversight—reinforcing trust and alignment with internationally recognized quality principles.

QMS SUPPORT: LOOKING AHEAD TO 2026

Looking toward the mid-to-end of 2026, QACV Consulting plans to further expand its services to support clients in achieving and maintaining their Quality Management Systems (QMS). This initiative will complement our existing GxP expertise, enabling us to support clients holistically—across quality, compliance, and operational excellence. Through structured QMS assessments, gap analyses, implementation support, and ongoing oversight, QACV Consulting will help organizations build quality systems that are not only compliant, but efficient, scalable, and aligned with their strategic goals.

We are expanding our SERVICES as we evolve into A QUALITY MANAGEMENT ORGANIZATION™ (QMO™)

New I QACV Consulting 2026 Portfolio Services

AI COMPLIANCE CENTER OF EXCELLENCE

- Machine Learning-enabled Medical Devices (MLMDs), including Good Machine Learning Practice (GMLP) for Medical Devices: Guiding Principles
- Artificial Intelligence (AI) Usage in Drug & Biological Product Development & Manufacturing Processes

GxP Services & Auditing

GxP services including Auditing Services such as:

- GCP Audits, including Central Laboratories, Bioanalytical Laboratories, IRBs, CROs, Trial Master Files (TMFs), Investigator Sites, Sponsors
- GVP Audits
- GMP Audits
- GLP Audits
- QA Support
- Excipient Supplier Audits
- Computer Validation Audits
- AI/ML Compliance & Validation

Data Integrity Programs

Data Integrity Programs, Training, Assessments, and Remediation:

- Data Integrity Assessments and Gap Analysis
- Development of Data Integrity Programs, Policies, and Procedures
- Development of Data Process Flows
- Data Integrity Remediation Support
- Review of AI/ML Regulatory Submissions

CSV Support

Computer Systems Validation Support, including:

- Applicability and Risk Assessments
- Validation Plans
- User Requirements Specifications
- System Specifications
- Testing (System and Acceptance) Requirements Traceability Matrix
- Validation Summary Reports
- Machine Learning Software as a Medical Device (MLMD)
- Ethical AI & Transparency

Training Programs

Training Programs and Courses include:

- Good Manufacturing Practices
- Audit Conduct
- Data Integrity
- Product Complaint
- Computer Validation
- 21 CFR Part 11
- Good Laboratory Practices
- Good Clinical Practices
- Good Pharmacovigilance Practices
- SOP Development
- FDA Inspection Readiness Training
- AI/ML Compliance & Validation

To learn more contact us I contact@qacvconsulting.com
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INTRODUCING

New I QACV Consulting 2026 AI Program Development

AI COMPLIANCE CENTER OF EXCELLENCE

" AI/ML is transforming industry — but Compliance is falling behind "

Article by Robert J. Wherry, MSc, MS, CPIP
Vice President, AI Compliance Innovation, QACV Consulting

Artificial Intelligence (AI) and Machine Learning (ML) are now embedded across regulated industries. From predictive analytics and automation to quality monitoring and decision support, nearly every organization is leveraging AI/ML in some capacity. Innovation is moving fast. Compliance, however, is not.

Most companies are attempting to force-fit AI/ML systems into traditional Computer System Validation (CSV) or Software as a Medical Device (SaMD) frameworks. These legacy approaches were designed for static, deterministic software — not data-driven models that are capable of adapting to new data. Paradigms are changing and the compliance approach must also change to prevent regulatory risks.

Documentation is often the weakest link. AI/ML development is typically iterative and agile, yet records are frequently scattered across slide decks, informal project notes, and disconnected files. Critical elements such as model assumptions, risk assessments, data governance decisions, and performance monitoring plans are rarely structured in a way that is inspection-ready. In a regulated environment, this creates significant exposure.

Until recently, regulatory agencies provided limited oversight specific to AI/ML systems. Now, authorities are developing clearer expectations around lifecycle management, transparency, risk controls, and ongoing performance oversight of AI-driven systems. Organizations that continue to rely on outdated compliance and validation models will struggle as scrutiny increases.

Likewise, current industry guidance is often written for AI specialists and data scientists. It lacks of holistic view of how AI/ML impacts the broader quality system. This makes it difficult for QA, RA, and CSV professionals to interpret and apply effectively.

Organizations that build structured AI/ML governance today will not only reduce regulatory exposure — they will accelerate innovation with confidence, strengthen audit readiness, and gain a measurable competitive advantage. The future belongs to companies that innovate boldly — and govern responsibly. Our newly launched QACV's AI Compliance Center of Excellence (AI CCoE), stands at the intersection of innovation and regulatory rigor, enabling organizations to unlock AI's full potential while maintaining the highest standards of compliance and accountability.

AI CCoE SERVICES INCLUDE

Access for registered users only

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

AUDITS

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

SYSTEMS/SOPS

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

SUBMISSIONS

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

EXPERT CONSULTATION & ADVICE

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

AI COMPLIANCE CORNER

- Case studies
- Monthly meetings
- Articles
- Evaluations

REGISTER TODAY

Access* exclusive content on AI/ML. Gain insights into the current and emerging regulatory requirements, learn best practices for validating machine learning algorithms, data governance, case studies, specialty trainings and more.

*Access for registered users only

Latest News

QACV ANNUAL QUALITY MEETING

February 10-12, 2026 | Houston, Tx

QACV Consulting successfully conducted its Annual Quality Meeting on February 10–12 at our Texas Medical Center office in Houston, bringing our team together to align on strategic quality priorities, enhance internal processes, and reinforce our commitment to excellence as a compliance-driven organization.

The meeting provided a valuable opportunity to strengthen collaboration across teams while supporting our continued growth. During the week, we were also pleased to present QACV's capabilities and key compliance focus areas at the Wednesday Lunch & Learn session, fostering meaningful dialogue and engaging discussions with attendees.

Announcing our Partnership with SeerPharma- leading APAC-focused provider of Quality and GMP Consulting

SeerPharma clients now gain direct access to QACV's experienced Quality and GxP professionals based in the U.S.

- **Global Synergy:** QACV Consulting, in turn, can leverage SeerPharma's expertise for support in the Asia-Pacific region—ensuring compliance across FDA, EMA, PMDA, and other global frameworks QACV Consulting.
- **Shared Mission:** Jointly committed to "Advancing Quality and GMP best practices" across regions and accelerating client success.

DIA 22ND TOKYO, JAPAN

October 19–21, 2025 | Big Sight Tokyo

We made a meaningful impact in Asia as we engaged in dynamic conversations around cross-border compliance, regulatory strategies, digital health innovation, and patient safety across the Asia-Pacific region.

As proud participants in the 22nd DIA Japan Annual Meeting, we connected with global and regional stakeholders to discuss how to deliver **"Tomorrow's Normal"**—a future of healthcare that is safer, more efficient, and driven by innovation and collaboration. This year's meeting underscored the importance of strong international partnerships—especially between Japan, the wider Asian market, and the global healthcare community—in shaping the future of medical product development and post-marketing surveillance. The introduction of an English-language track enriched the global exchange of ideas and perspectives.

It was a tremendous experience connecting with the Asian market, yielding remarkable results and forging valuable relationships. We returned inspired, informed, and more committed than ever to advancing global healthcare systems that support vibrant and healthy lives for all.

RQA INTERNATIONAL QA CONFERENCE

November 5–7, 2025 | ICC, Belfast

We are proud to announce that Erika Reátegui, VP of Operations and Compliance at QACV Consulting, presented at the RQA 2025 International QA Conference in Belfast, Northern Ireland. The event gathered global quality professionals addressing the most pressing challenges in regulatory science and quality assurance.

Presentation Title: **"One World, One Quality: Streamlining Sustainable QA Across Borders"**
Erika's session explored the evolving role of Quality Assurance in the face of Environmental, Social, and Governance (ESG) pressures, and the rapid globalization of clinical trials. As trial sponsors and regulators increasingly emphasize sustainability and harmonization, her talk provided practical insights on:

- Minimizing travel-related emissions through hybrid and remote QA models
- Adapting quality oversight frameworks to support ESG goals
- Addressing regulatory fragmentation that slows approvals—such as varying submission formats required by the FDA (US), EMA (EU), and PMDA (Japan)
- Embedding sustainability into trial design, vendor oversight, and QA governance

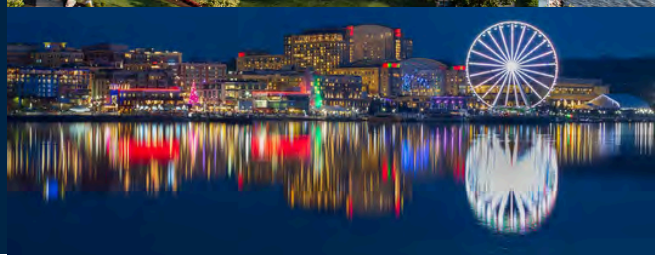
Drawing from QACV Consulting's cross-border audit expertise, Erika shared tools and strategies for harmonizing global QA processes while maintaining data integrity and compliance. Attendees left with actionable ideas to reduce redundancy, increase operational efficiency, and align quality practices with global ESG expectations.
We appreciate your attendance. Contact us to receive a copy of her presentation **contact@qacvconsulting.com**

#SQA2026 Meet us at Booth # 112-114

SQA 42nd Annual Meeting and Quality College
April 11-16 , 2026 | National Harbor, MD

Join us to discuss your quality, compliance, and validation needs, and discover our NEW 2026 AI Compliance Center of Excellence Program — designed to support innovation in regulated environments

Register Now



Upcoming Events

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

The DIA 2026 Global Annual Meeting is evolving, just like the life sciences community it serves. Join global innovators, regulators, academics, patient advocates, and industry leaders for an all-new experience designed to inspire, engage, and connect.

Register Now

MWSQA Annual Meeting and Quality College 2026, July 27–30, 2026 | Madison, WI

Join Chris Wubbolt, CEO, Principal Consultant (QACV Consulting), as he delivers a special presentation entitled: “Intro to GxPs.”

Register Now

23rd DIA JAPAN 2026, October*2026 | Tokyo

*Dates TBC / Join QACV Consulting in Asia as we continue the conversation on cross-border compliance, regulatory strategies, digital health innovation, and patient safety across the Asia-Pacific region.

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.

Register Now

CLIENTS TESTIMONIALS

OUR GLOBAL PRESENCE I PARTNERSHIPS BUILT ON TRUST

JPN

"Penny Jegede, you are the best. Working with you is a breath of fresh air. Professional, incredibly intelligent, and always prepared for the DS teams. I can't thank you enough as you make my job easier, which, as I'm sure Erika can attest to, can be challenging at times. I really appreciate your support! Thank you."

NJ

Amy Lou Mummert success with internal eTMF audit.
"We value the collaborative relationship we've built with QACV Consulting and would welcome the opportunity to partner with you again on future projects of similar scope."

CH

"It has been a privilege working with Erika and Mugdha. While we recognize that the project timeline extended beyond our original proposal, I want to express our sincere appreciation for their exceptional professionalism and adaptability throughout the process."

JPN

"Working with Beth Rayworth is a breath of fresh air. She is excellent; by the way she presents herself, the questions she presents to the team, clarifies any responses. Her professionalism is unmatched. She clearly understands the regulations, the requirements, and is clearly prepared for each meeting. It's a pleasure working with her and QACV Consulting."

LOOKING FORWARD

LEADING THE FUTURE OF PROACTIVE, INTELLIGENT, AND GLOBAL QUALITY

QACV CONSULTING
a Quality Management Organization™

As we move into our 25th year as a Quality Management Organization™ (QMO™), QACV Consulting reaffirms its commitment to what has always defined us:

- **QUALITY WITHOUT COMPROMISE**
- **EXPERTISE WITH PURPOSE**
- **PARTNERSHIPS BUILT ON TRUST**

With a global footprint, an expanding QMO™ model, innovative AI solutions, and a clear vision for the future, we are excited to continue supporting our clients as they navigate the evolving world of quality and compliance. The future of quality is proactive, intelligent, and global— and QACV Consulting is proud to help lead the way.

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

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A new era of Quality, Innovation and Leadership

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