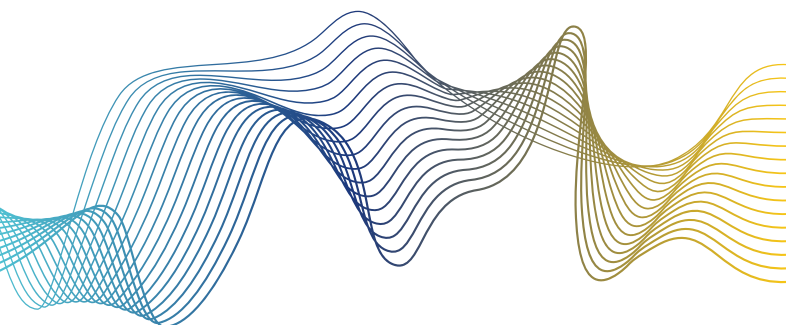




QACV Consulting - Providing Quality Assurance, Compliance, and Validation Service to Pharmaceutical, Biotech, and Medical Device Industries for over 24 years.



Expert Guidance Strategically & Globally

Our vision is to be a trusted global leader & partner, empowering organizations to achieve regulatory excellence and drive innovation.

OUR SERVICES |

Aim to provide high-quality, personalized compliant solutions empowering our partners to achieve excellence and maintain the highest standards in their Quality Assurance programs.

✓ GxP AUDITS

✓ DATA INTEGRITY

✓ CSV COMPUTER SYSTEM VALIDATION

✓ TRAINING PROGRAMS



GxP services including auditing services such as:

- GCP Audits, Including Central Laboratories, Bioanalytical Laboratories, IRBs, CROs, Trial Master Files, Investigator Sites, Sponsors
- GVP Audits
- GMP Audits
- GLP Audits
- QA Support
- Excipient Supplier Audits
- Computer Validation Audits



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



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



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

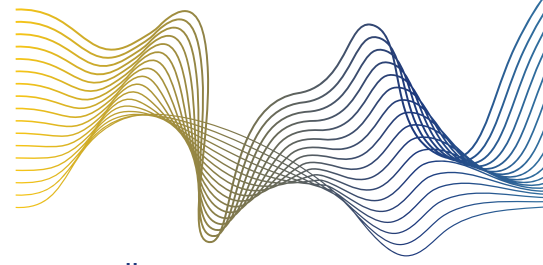
We are committed to helping organizations navigate complex regulatory environments,

while optimizing operational efficiency and ensuring high-level of regulatory compliance.

Founded in 2001, we have been delivering Quality Assurance, Compliance, and Computer System Validation services to the life sciences industry for 24 years and continue to grow, expanding our expertise and capabilities to meet evolving industry needs. We strategically built our business primarily through strong word-of-mouth referrals and repeat clientele, driven by a track record of delivering exceptional service and customer satisfaction.

We are committed to delivering tailored solutions that are not only effective and efficient but also add significant value to their businesses. There are numerous paths to achieving compliance, and with QACV's expertise and experience, we provide tailored recommendations that align perfectly with your organization's specific needs.

With unique global expertise in compliance, project management, Six Sigma, and validation, QACV Consulting delivers a comprehensive suite of services and solutions designed to effectively address your regulatory challenges.



Our Five C's + R Philosophy

Empowering Excellence in Quality Assurance, Compliance, and Validation Services

1

Culture: Building a Foundation of Integrity and Respect

A strong culture is the backbone of any organization. At QACV Consulting, we safeguard our values and principles, knowing that culture shapes our identity and guides our actions. When nurtured with integrity and respect, it fosters excellence; when neglected, it risks eroding the very foundation of who we are.

2

Communication: Clear, Transparent, and Consistent

We prioritize open and honest communication with our clients, partners, and team members. By ensuring clarity in every interaction, we minimize misunderstandings and foster trust. Our approach to communication is proactive, timely, and tailored to meet the unique needs of each client.

3

Cooperation: Combined Effort Toward Shared Goals

Cooperation is about working together with respect and understanding. At QACV Consulting, we value diverse perspectives and recognize the importance of aligning our efforts with our clients' objectives. This ensures that every project is executed seamlessly and with a shared vision for success.

4

Collaboration: Leveraging Expertise for Innovation

Collaboration is at the heart of improvement. By combining our expertise with that of our clients and partners, we co-create solutions that deliver outstanding results. At QACV Consulting, collaboration is not just about working together, it is about achieving more, together.

5

Confidentiality: Protecting Trust and Integrity

Confidentiality is fundamental to our commitment to clients. At QACV Consulting, we safeguard sensitive information with the highest level of integrity, ensuring compliance and discretion in every interaction. Trust is earned through diligence, and we take every measure to protect it.

Plus, Responsiveness: Adapting Swiftly to Client Needs

Responsiveness is key to delivering exceptional service. At QACV Consulting, we act with agility and efficiency, ensuring our clients receive timely support and solutions tailored to their evolving needs. We understand that success depends on being proactive and adaptable.





CLIENT TESTIMONIAL I

Success is built on a foundation of strong relationships, shared understanding, and aligned goals to deliver excellence in every project.

Client: Chimerix

Project: Mock Inspection Readiness Support

"As our team wraps up our sponsor FDA Inspection, we want to take a moment to express our heartfelt gratitude for your support in helping us reach this point. It was an active inspection week, and thanks to your unwavering assistance, we were able to address the Inspectors' requests and questions with confidence.

Your insights, shared during the mock inspection and practice interviews, truly amplified our level of preparedness. Your expertise proved to be indispensable in navigating the numerous inquiries and challenges posed by the inspectors. We are grateful for the tremendous amount of time, knowledge, and support you have offered us and you've been instrumental in our success this week."

QACV Consulting - Your Global Regulatory Partner

Why work with QACV Consulting in Asia-Pacific?

- Reduce costs associated with overseas consulting and compliance programs.
- Minimize travel time with localized 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



QACV 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

Israel

South Africa

India

Singapore

South Korea

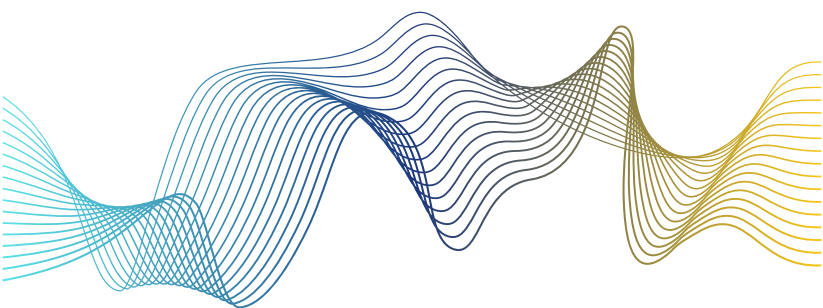
Japan

Australia





We strive to be key partners in supporting our clients' compliance journey and objectives.



Our success is directly tied to the success of our clients around the world.

Our extensive background enables us to navigate complex regulatory landscapes with confidence and precision in the Pharmaceutical, Biotech, and Medical Device Industries.

Providing high-quality cost-efficient, professional, and personable consulting services.

Providing right-sized and scalable support to help organizations of any size meet their objectives.

Meeting and exceeding client expectations by proactively identifying and eliminating potential project issues.

Being responsive to client needs, expectations, schedules and timelines, while providing appropriately trained and qualified personnel.

Together with our team of over **70 consultants worldwide**, 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.



CHRIS WUBBOLT

CEO | PRINCIPAL CONSULTANT

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VICE PRESIDENT | OPERATIONS AND COMPLIANCE

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Specializing in Data Integrity, GxP Audits, Training, Validation, GCP, GMP, GLP, PV QA Support and Compliance Services.

Empowering Excellence in Quality Assurance, Compliance, and Validation Services