



NEWSLETTER



Holiday Edition

A BRIGHT FUTURE

Our commitment to EXCELLENCE
contributing to the advancement
of QUALITY STANDARDS in the
healthcare industry WORLDWIDE.

A BRIGHT FUTURE AHEAD

QACV's MISSION is to deliver expert guidance **GLOBALLY** and **STRATEGICALLY** combining innovative solutions and practical, scalable approaches to quality assurance, compliance, and validation.

QACV is committed to helping organizations successfully navigate complex regulatory environments while optimizing operational efficiency and ensuring high-level of regulatory compliance. Through personalized, high-quality consulting services, we empower partners to achieve excellence and maintain the highest standards in their Quality Assurance programs.

QACV's GLOBALIZATION STRATEGY was initiated at the end of 2023 to expand our resources in key regions globally, offering our clients local, regional consulting support, when necessary, to reduce travel costs, conduct audits in local languages, and enhance the overall consulting process. The globalization initiative will continue to expand to pave the way for a brighter future for our clients, where high standards and compliance drives success on a global level.

The key elements of our strategy include:

1. Comprehensive Service Offering:

QACV Consulting provides a wide range of services, including regulatory compliance, quality system implementation, GxP auditing, data integrity initiatives, inspection support, and computer system validation (CSV) enabling QACV to meet diverse regulatory requirements and industry standards globally.

2. Tailored Solutions:

QACV Consulting specializes in creating customized, practical and scalable solutions to fit the unique needs of each client.

This flexibility helps us address specific regulatory challenges in different countries and regions, ensuring compliance with local and international standards, regardless of company size or phase of research or commercialization.

3. Experienced Team:

QACV Consulting team brings decades of combined experience in quality assurance and compliance, enhancing our ability to provide expert guidance and support to our clients worldwide.

Our team is trained and qualified to handle projects across various global environments, including pharmaceutical, biotech, gene & cell therapy and medical device.



Our VISION at **QACV Consulting** is **to be a trusted global leader in quality assurance, compliance, and validation services, empowering organizations to achieve regulatory excellence and drive innovation.**





USA, CANADA, EU, UK, AFRICA, ISRAEL, INDIA, AUSTRALIA AND MORE TO COME IN 2025.

QACV's extensive background enables them to navigate complex regulatory landscapes with confidence and precision. QACV personnel are not only trained and qualified but also continually engage in professional development to stay updated on the latest industry standards and best practices.

“
We aim to provide high-quality, compliant solutions to our clients, enabling them to succeed in the international life sciences market.

Erika Reátegui, VP Operations and Compliance

4. Proactive and Responsive Approach:

QACV Consulting emphasizes proactive identification and elimination of potential project issues. We are highly responsive to client needs, expectations, schedules, and timelines. This ensures timely and efficient project execution, which is crucial for maintaining compliance in a global market.

5. Scalable Support:

QACV Consulting offers scalable consulting support that can adapt to the size and needs of any organization, from small startups and virtual companies to large multinational corporations.

QACV's ability to scale our support to meet client expectations is essential for addressing the varying regulatory landscapes and market demands globally.

By integrating these elements into our **globalization strategy**, **QACV** aims to provide high-quality, compliant solutions to our clients, enabling them to succeed in the international life sciences market.

Business News

LATEST INDUSTRY HIGHLIGHTS & REGULATION UPDATES

What's New ? FDA REGULATORY UPDATES 2024

Some areas of focus from the FDA (FDA.GOV) closing 2024.

1 ARTIFICIAL INTELLIGENCE IN HEALTHCARE

The FDA is expected to release further guidance on the use of artificial intelligence (AI) in medical devices, focusing on safety, effectiveness, and post-market surveillance. "CBER, CDER, CDRH, and OCP plan to tailor their regulatory approaches for the use of AI in medical products to protect patients and health care workers and ensure the cybersecurity of medical products in a manner that promotes innovation." [AI Medical Products Paper](#). In addition, the strategy for adoption (2024-2027) is described in [FDA Information Technology Strategy](#). Strategic goals include creation of a shared FDA Ecosystem, strengthen IT infrastructure, modernize enterprise services and capabilities, share data for mission outcomes, adopt AI and mission-driven innovations and cultivate talent and leadership.



2 REGULATING DEVICES

On May 6, 2024, 21 CFR Part 809 was issued to ensure the safety and effectiveness of laboratory developed tests (LDTs). The rule makes it explicit that in-vitro diagnostic tests (IVTs) are devices and require to be regulated as such. The FDA will provide greater oversight of IVDs. This will have significant impact for laboratories that perform these tests. However, litigation (from Association for Molecular Pathology and American Clinical Laboratory Association) may impact the timelines, the regulation is expected to be adopted in 5 stages over 4 years. [Laboratory Developed Tests I FDA](#) and final rule: [Federal Register :: Medical Devices; Laboratory Developed Tests](#).



3 CANNABIS & CBD PRODUCTS

There is an ongoing discussion about establishing clearer guidelines for the regulation of cannabis and CBD products, particularly concerning safety and efficacy. This includes potential regulations and guidance on IND and regulatory pathways. The FDA has only approved one cannabis-derived and three cannabis-related drug products.

For more information:
[FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol \(CBD\) I FDA](#)



4 DRUG APPROVALS

The FDA may streamline the approval process for certain types of medications, particularly in response to public health needs or emerging diseases, including updates to existing pathways like the Fast Track and Breakthrough Therapy designations.

Final rule for assessments of drug-drug interactions (DDI), intended to harmonize the regional recommendations for designing, conducting, and interpreting in vitro and clinical evaluations of drug-drug interactions while developing investigational drugs. Interdisciplinary guidance document M12 Drug Interaction studies, 89 FR 630205, issued August 2, 2024 ([Federal Register :: M12 Drug Interaction Studies; M12 Drug Interaction Studies: Questions and Answers; International Council for Harmonisation; Guidance; Guidances for Industry; Availability](#)).



“

We aim to create a future, where our clients thrive in ever-evolving regulatory landscapes, maintaining the highest standards of quality and integrity while continuously improving their operations.

Erika Reategui, VP Operations and Compliance



Business Newsletter

QACV CONSULTING | DECEMBER 2024 | ISSUE 3

Business News

LATEST INDUSTRY HIGHLIGHTS & REGULATION UPDATES

5 TOBACCO CONTROL

Additional regulations regarding flavored tobacco products and e-cigarettes could be anticipated to address youth usage and public health concerns.

On August 30 2024, 21CFR Part 1140 was issued to establish a new minimum age for the sale of tobacco products as 21 years. Final rule [Federal Register :: Prohibition of Sale of Tobacco Products to Persons Younger Than 21 Years of Age.](#)



6 OTHERS

The FDA may implement updated regulations regarding nutrition labeling, especially for added sugars and front-of-package labeling to help consumers make healthier choices.

There may be new rules regarding the safety and labeling of cosmetics, especially concerning harmful ingredients.



BUILDING TRUSTED RELATIONSHIPS

OUR CLIENTS TESTIMONIALS

"Working with **QACV Consulting** elevated our experience. Their team went above and beyond to make us feel valued and understood, providing that personal touch that distinguishes them from the rest. It was clear that is not just about delivering results; they genuinely care about building relationships. This visit showcased their commitment to quality and client satisfaction, leaving us confident that we made the right choice in partnering with them."



WE ARE SUCCESSFUL WHEN OUR CLIENTS ARE SUCCESSFUL

"I am thrilled to share my exceptional experience with **QACV Consulting**. Our **QACV consultant's** abilities, thoroughness, and attention to detail were truly impressive. Her extensive experience and meticulous approach ensured a flawless audit process. She was an absolute pleasure to work with, and I would not hesitate to engage her and **QACV Consulting** services again in the future. Your commitment to quality assurance and compliance is unmatched."

Share your testimonial or get to know more about us, subscribing to receive our newsletter.

[CLICK HERE](#)

Empowering Excellence in Quality Assurance & Compliance

Events

SUMMITS, WEBINARS, WORKSHOPS & CONFERENCES

APRIL 2025

UPCOMING EVENT

Society of Quality Assurance (SQA) 41st Annual Meeting & Quality College

Orlando, Florida, USA | 06-11 April 2025

Join us in Sunny Florida!

This event is a key gathering for quality assurance professionals, filled with quality ideas, inspiring conversations, and networking opportunities.

 Society of Quality Assurance
41st Annual Meeting & Quality College
6-11 April 2025 🌞 Orlando, Florida, USA

Spotlight on Quality Assurance: The Future is Bright

The week will kick off with SQA's Quality College, offering in-depth courses (4 to 8 hours) before and after the main event.

The two-and-a-half-day conference will feature plenary sessions and five (5) concurrent tracks, covering a wide range of GXP topics, insights into the latest regulations and best practices, and updates from regulatory agencies like the FDA and EPA.

Visit us at our booth in the exhibit hall, where industry partners like QACV Consulting will be on hand. Swing by to say hi, explore new collaborations, or just talk shop!

The evenings will include special networking events, giving you a chance to connect with peers, experts, and thought leaders in quality assurance.

Don't miss this enriching experience designed to enhance your knowledge and professional journey.

We look forward to sharing this exciting week with you in Orlando!

READ MORE >>



OCTOBER 2024



GMP University Conference

RTP, North Carolina, USA | 22-24 October 2024

QACV Consulting participated in the **KENX GMP University Conference**, which took place in Chapel Hill, NC from 22-24 October 2024.

QACV's team showcased its GMP consulting services and presented sessions titled, *Assessing the Effectiveness of Your Quality Management System* and *Developing a Site Preparation Strategy for a Successful FDA Inspection*.

The event, which was co-sponsored by **Temple University's Quality Assurance & Regulatory Affairs Master's Degree program**, was attended by representatives from the FDA and industry.

Attendees were provided with a glimpse into the latest trends and current thinking in GMP compliance.

QACV Consulting provides comprehensive GMP consulting services to a wide range of clients. Our GMP consultants have expertise in conducting audits, mock inspections, validating equipment, processes and computer systems, and reviewing quality agreements, and batch record review.

Our consultants are well-versed in the regulations, which govern the manufacturing of pharmaceuticals, biologics, medical devices, combination products, cell and gene therapies, radiopharmaceuticals, in-vitro diagnostics and 503B regulated products.

**QACV
Consulting**
wishes everyone
happy holidays
and a happy
new year !

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

Empowering Excellence in
Quality Assurance & Compliance.



Contact Us



610-442-2250

Thank you for reading. Get to know more about us;
subscribe to receive our **QACV Consulting Newsletter**.

CLICK HERE

