# QACV CONSULTING NEWSLETTER

New Edition

# Globalization Initiative

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

# GLOBALIZATION INITIATIVE

**QACV Consulting** combines industry knowledge, regional focus, and relationship-building to attract top-notch consultants globally.

**QACV Consulting** commitment to excellence, ensures that we significantly contribute to the advancement of **QUALITY STANDARDS** in the healthcare industry worldwide.

As part of our globalization strategy, **QACV Consulting** actively collaborates with compliance professionals who possess extensive knowledge of regional regulations.

By leveraging these experts' insights, we gain a deeper understanding of specific compliance challenges and requirements in different parts of the world.

We seek consultants who are well-versed in local regulations and can provide valuable insights to our clients.

This approach not only strengthens our ability to navigate complex regulatory landscapes but also enhances our clients' confidence in our ability to deliver tailored solutions that meet their unique needs across diverse markets.

QACV Consultants

## KEY PERFORMANCE INDICATORS

- COMMITMENT TO EXCELLENCE
- KNOWLEDGE OF REGIONAL REGULATIONS
- UNDERSTANDING OF SPECIFIC COMPLIANCE CHALLENGES
- PROVIDING VALUABLE INSIGHTS

Our consultants come from various regions in the EU, India, APAC, North America and South America.

**QACV Consulting** strong reputation for QUALITY and EXPERTISE further attracts consultants from around the world. Our rigorous selection process ensures that we onboard professionals who not only meet but exceed industry standards, bringing with them a wealth of specialized knowledge and practical experience.

> **We firmly established our global presence by engaging highly qualified consultants.**

Erika Reátegui, VP of Compliance

This global network of consultants enriches our capability to address diverse regulatory challenges with precision and agility, enhancing our clients' confidence in navigating complex compliance landscapes effectively.

This diverse team enables **QACV Consulting** to offer comprehensive support tailored to the specific requirements of each market we serve.

By harnessing their local knowledge and understanding of regional nuances, we not only ensure compliance but also facilitate smoother market entry and sustainable growth for our clients worldwide.

**QACV's** commitment to excellence is reinforced by our consultants' collective dedication to upholding the highest standards of quality and regulatory adherence across borders.

Additionally, **QACV Consulting** taps into its existing network of satisfied clients and consultants by leveraging established relationships.

Referrals from trusted sources often lead to successful recruitment.

# Consultant Recruitment Process

At the beginning of 2024, we have successfully identified, hired and onboarded 10 highly-skilled US-, EU-, and India- based TOP-Notch consultants, with average 15 years of experience in the GCP, GLP, GMP, PV and monitoring areas.

## 1 RECRUITMENT & SELECTION

**QACV Consulting** identifies potential consultants through various channels, including referrals, industry networks, and direct applications.

The selection process involves evaluating candidates' qualifications, experience, and alignment with **QACV's** values and mission.

## 2 ONBOARDING & ORIENTATION

During orientation, consultants learn about **QACV's** history, services, and organizational culture.

They receive an overview of the company's structure, policies, and expectations.

## 3 TRAINING & SKILL DEVELOPMENT

New consultants participate in training sessions specific to their areas of expertise (e.g., GCP, GVP, GMP, GLP, data integrity, computer validation).

**QACV Consulting** provides access to resources, tools and documentation needed for successful consulting engagements.

## 4 PROJECT ASSIGNMENT

Consultants are assigned to projects based on their skills and client needs.

They collaborate with experienced team members to gain practical insights and contribute to ongoing projects.

## 5 MENTORING & SUPPORT

**QACV Consulting** assigns mentors to guide new consultants.

Mentors provide advice, answer questions, and help integrate consultants into the team.

## 6 PERFORMANCE EVALUATION & FEEDBACK

Regular performance evaluations assess consultants' progress.

Feedback sessions help identify areas for improvement and recognize achievements.

## 7 CLIENT INTERACTION & RELATIONSHIP BUILDING

Consultants engage with clients, understand their requirements and deliver high-quality services. Building strong client relationships is essential for successful consulting. This process aligns with **QACV Consulting** values of quality compliance, data integrity, and patient safety and emphasizes personalized services, professionalism, and client success overall.

# ISO 13485 CERTIFICATION EXPERTISE

**QACV Consulting** is one of the TOP few consulting firms with **ISO 13485 (Medical Device)** experience, which will provide the support that many clients need around medical device inspections and audits.

## Why ISO 13485 ?

**ISO 13485** is the QMS standard for the medical device industry and **QACV Consulting** recently provided expert support for our client's successful implementation and certification of **ISO 13485.**

Based on the ISO 9001:2015 series, **ISO 13485** uses a process-based approach to ensure the quality of the medical device design, manufacturing, installation and service, and is applicable for all stages of the product life cycle.

It supports medical device manufacturers by demonstrating compliance with regulatory requirements in the following areas:

- Management responsibility
- Resource management
- Product realization
- Measurement, analysis and improvement

**ISO 13485** is also at the core of the Medical Device Single Audit Program (MDSAP).

ISO 13485 MEDICAL DEVICES
ISO
13485

**ISO 13485 certification represents commitment to prioritize both patient safety and product quality.**

**Our deep understanding of regulatory requirements and commitment to excellence ensures that your path to ISO 13485 certification is smooth and efficient.**

The medical device industry operates within a complex regulatory landscape where adherence to quality standards is paramount.

**ISO 13485,** specifically designed for medical devices, provides a framework for organizations to establish effective quality management systems (QMS).

## QACV Consulting plays a crucial role in supporting your ISO 13485 journey

1

**Customized QMS Implementation:**
**QACV Consulting** collaborates closely with medical device companies to tailor QMS processes to their unique needs. Ensuring alignment with ISO 13485 requirements from document control to risk management.

2

**Gap Analysis and Remediation:**
**QACV Consulting** can help you identify areas where existing practices fall short of **ISO 13485** standards and assist in remediation efforts.

3

**Training and Education:**
**QACV Consulting** conducts training sessions emphasizing ISO 13485 principles.
These sessions empower your staff to understand their roles in maintaining compliance and fostering a culture of quality.

4

**Internal Audits:**
As we all know, periodic internal audits are essential. **QACV Consulting** assesses processes, identifies non-compliance areas, and recommends corrective actions.
This proactive approach ensures continuous improvement.

**You can confidently navigate the complexities of ISO 13485, knowing that you have a dedicated trusted consulting partner committed to your success.**

Erika Reátegui, VP of Compliance

# Business News

LATEST INDUSTRY HIGHLIGHTS & REGULATION UPDATES

## What's New ?

**In March 2024,** the FDA has issued a draft guidance document on the handling and retention of Bioavailability (BA) and Bioequivalence (BE) testing samples.

This guidance provides recommendations for study sponsors, drug manufacturers, contract research organizations (CROs), site management organizations (SMOs), clinical investigators, and independent third parties regarding the procedure for handling reserve samples from relevant BA and BE studies, as required by 21 CFR 320.38 and 320.63.

## FDA guidance on BE/BA retention samples

### Key points from the guidance include:

1. **Distribution of Test Article and Reference Standard:**
The test article and reference standard for BA and BE studies should be distributed to the testing facilities.

2. **Random Selection of Samples:**
Testing facilities should randomly select samples for testing and maintain the materials as reserve samples.

# Business News

## LATEST INDUSTRY HIGHLIGHTS & REGULATION UPDATES

3

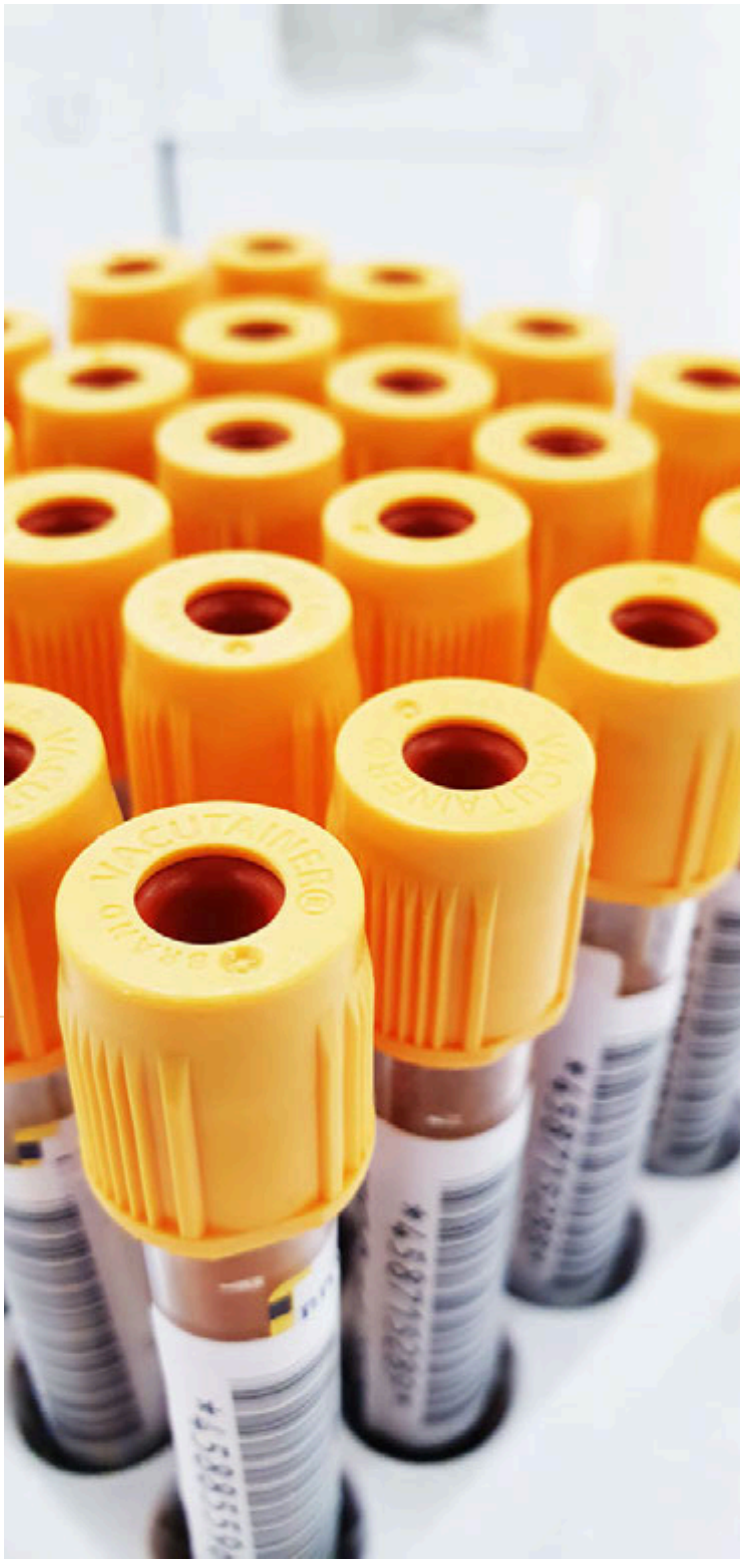
**Retention of Reserve Samples:**
Reserve samples should be retained according to the specified guidelines.

The guidance clarifies and emphasizes points addressed in §§ 320.38 and 320.63.

Additionally, the FDA has a compliance policy related to the retention of reserve samples for BA and BE studies.

This policy applies to the requirements for retention of reserve samples contained in 21 CFR 320.38(c).

The finalized portion of the guidance specifies that sponsors and CROs must set aside 30 single-dose or 3 multi-dose units for each test and reference product in the original container across all testing sites, with at least one (1) unit in the original container.




**For more detailed information, refer to FDA's official guidance document on Handling and Retention of BA and BE Testing Samples.**

It provides comprehensive insights into the procedures and requirements for sample handling and retention in BA and BE studies.

READ MORE


# QACV Consulting supports the successful FDA inspection of GLP client

Having worked with our client for over **10 years**, we played a key role in creating and implementing their Quality System and SOPs, which were essential during the **FDA inspection**.

Our dedicated team ensured all regulatory requirements were met, demonstrating our commitment to quality and compliance.

## CLIENT TESTIMONIAL

*"As a long-time client of **QACV Consulting,** I am thoroughly impressed with their exceptional support during our recent **FDA inspection.** Their dedicated team went above and beyond to ensure every regulatory requirement was not just met but exceeded, showcasing their unwavering commitment to quality and compliance.*

*Thanks to their expertise and diligence, we sailed through the inspection smoothly, reinforcing our confidence in them as a trusted partner in our GLP endeavors. Their proactive approach and attention to detail truly set them apart. I highly recommend **QACV Consulting** to any organization seeking reliable regulatory support."*

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

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# Events

SUMMITS, WEBINARS, WORKSHOPS & CONFERENCES

JULY 2024

## QACV Consulting attended the 4th Annual mRNA-Based Therapeutics Summit

**Westin Boston Seaport District Hotel | July 29-31 2024**

At the **QACV Consulting** booth we engaged with potential partners to explore how our services, may be able to assist their Quality, Compliance and Validation needs, including compliance audits, data integrity support, QA/compliance staffing, CMC, and validation services.

Additionally, we presented a poster which featured **QACV's risk-based approach to data integrity, using data mapping processes** to ensure data integrity in the development and manufacture of mRNA-based therapies.

- The event featured sessions and panel discussions from experts in the field including representatives from the FDA, EMA and leaders from industry showcasing mRNA technology.
- This technology has come to the forefront of drug development since the adoption of mRNA-based COVID-19 vaccines just over three years ago.
- **QACV Consulting** is eager to help accelerate these novel therapies into clinical trials and eventually to the market by offering its GxP consulting services to companies with a footprint in this exciting field.

**QACV Consulting** has helped to support several clients in the mRNA therapeutics space in recent years, onboarding consultants who have considerable background working with mRNA therapies.

# Events

SUMMITS, WEBINARS, WORKSHOPS & CONFERENCES


## QACV Consulting attended the 40th SQA Annual meeting & Quality College 2024

**Aurora, Colorado, USA | 6-11 April 2024**

**QACV Consulting's** seasoned team was available at the conference to discuss their cutting-edge solutions, designed to meet quality assurance and compliance requirements, making them valuable resources for attendees.

SQA conference provided an invaluable opportunity for **QACV Consulting** to connect with outstanding professionals. These interactions allowed for enriching discussions and the exchange of expertise in areas such as GCP (Good Clinical Practice), GLP (Good Laboratory Practice), and various systems.

We were delighted to reunite with our colleagues and engage in enriching discussions about our capabilities, highlighting our commitment to excellence and innovation in the field.

By participating actively, they demonstrated their dedication to staying at the forefront of quality assurance practices.

Overall, **QACV Consulting's** engagement during the conference was impactful, and we look forward to leveraging the insights gained to enhance our services to support our clients' needs.

Thank you to everyone who contributed to making this event memorable and impactful.

# UPCOMING EVENT

KENX
KNOWLEDGE EXCHANGE NETWORK

## GMP University Conference

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

Join us in October on an enriching 3-day conference and training program at Research Triangle Park for the latest insights and best practices in change control, risk management, audits/inspections, quality metrics, quality management systems, data integrity, impact of AI on GMP practices, and more !

We look forward to the opportunity to engage with you and explore potential collaborations.

READ MORE

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

Empowering Excellence in
**Quality Assurance & Compliance.**

QACV CONSULTING

**Contact Us** 610-442-2250

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