

# QACV

CONSULTING  
NEWSLETTER



Special Edition

# Celebrating 23 Years!

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

Empowering Excellence in  
Quality Assurance & Compliance.

# Special Celebration!

## 23 YEARS

**“PROVIDING  
QUALITY ASSURANCE,  
COMPLIANCE AND COMPUTER  
VALIDATION SERVICES  
TO THE LIFE SCIENCES INDUSTRY  
FOR OVER 23 YEARS”**

**QACV was founded in 2001** and has provided GxP quality assurance, compliance, data integrity, and computer validation services to the life sciences industry for over 23 years.

We are a team of over **60 experienced consultants** in all GxP areas, including GLP, GCP, GCLP, pharmacovigilance, GMP, and QSR.

**We are proud to share** that **QACV's growth** has occurred primarily by **word-of-mouth referrals and repeat work from satisfied customers.**

**QACV** is well-respected within the industry and has provided training in many industry meetings.

**QACV** has also provided data integrity training to the Food and Drug Administration (FDA).

**We are successful when our customers are successful,** and we strive to provide personalized services that are professional, effective, efficient, and value-added.

Our team has extensive project and audit management tools that allow us to provide transparency to our clients as to the status of projects. **Project management principles are applied to our projects, large or small.** Our consulting team is professional, responsive, and highly qualified to meet our client's needs.

With skill sets in all areas of compliance, project management, Six Sigma, and validation, we have provided a combination of unique services and solutions for over **23 years** to meet your quality and compliance challenges.

*We provide*



- AUDIT MANAGEMENT AND CONDUCT.
- DATA INTEGRITY ASSESSMENT SERVICES.
- MOCK INSPECTION AND INSPECTION READINESS SUPPORT.
- QUALITY AND COMPLIANCE TRAINING, INCLUDING DATA INTEGRITY TRAINING.
- COMPUTER VALIDATION SERVICES.
- REMEDIATION SERVICES TO ADDRESS REGULATORY OR AUDIT OBSERVATIONS.



# Business News

LATEST TRENDS & DEVELOPMENTS IN QUALITY ASSURANCE AND COMPLIANCE

NEWS HIGHLIGHTS | Celebrating Recent Achievements and Client Success Stories



## QACV attended the CDER SBIA Training Symposium

FDA, MHRA and Health Canada GCP and Pharmacovigilance

Our team had the privilege of engaging with industry experts, regulatory authorities, and fellow stakeholders in an enriching exchange of insights and best practices.

The February symposium is instrumental in enhancing industries understanding of regulatory expectations and industry trends in GCP and Pharmacovigilance compliance. QACV is committed to utilizing this knowledge when supporting our clients compliance initiatives.

For more information on how QACV Consulting can support your pharmacovigilance needs, please contact us at [contact@qacvconsulting.com](mailto:contact@qacvconsulting.com)



## QACV team is Growing !

**Russell Wilson, Ph.D.**, Client Lead/Sr. Compliance Consultant  
**Jayvin Amigo**, Manager, QA Compliance/Project Manager

**Russell's** background, spans the full breadth of GxP through every phase of drug development (from preclinical to commercial). With expertise in GMP, he has worked on projects supporting the manufacturing of therapies, including cell and gene therapies, in vitro diagnostics (IVD), RNA therapeutics, medical devices, combination and over-the-counter (OTC) products.

**Jayvin** is a highly skilled Supplier Quality/Quality Compliance professional with over 12 years combined experience in ensuring the quality and compliance of both internal and external processes in various industries. with an Industrial Engineering background, she will bring a wealth of skills and expertise in process optimization, systems integration, and driving continuous improvement initiatives.

## CLIENTS FEEDBACK



WE ARE SUCCESSFUL WHEN OUR CUSTOMERS ARE SUCCESSFUL

## "Exceptional FDA Inspection Support from QACV" CLIENT TESTIMONIALS

**"We recently had the privilege of partnering with QACV Consulting for FDA inspection support during our latest regulatory assessment.**

It was nothing short of exemplary.

From meticulous preparation to expert guidance throughout the inspection process, **QACV's team demonstrated unparalleled professionalism and dedication.**

The support provided instilled confidence in our team and significantly **alleviated the stress associated with regulatory scrutiny.**

QACV commitment to excellence and unwavering support make them a trusted partner in navigating complex regulatory challenges."

SHARE YOUR STORY OR GET TO KNOW MORE ABOUT US, SUBSCRIBING ON THE LINK BELOW TO RECEIVE OUR QUARTERLY NEWSLETTER <https://qacvconsulting.com/newsletter-sign-up/>

Empowering Excellence in Quality Assurance & Compliance

# EXPERTS CORNER

EXCLUSIVE INSIGHTS FROM OUR QACV CONSULTING LEADERS ON EMERGING CHALLENGES & BEST PRACTICES

“We **EMPOWER** our clients to navigate the **COMPLEX REGULATORY LANDSCAPE** with **CONFIDENCE**, ensuring the safety, efficacy, and quality of clinical research and healthcare products for the betterment of **patients worldwide.**”

“I envision QACV Consulting as a beacon of excellence, known for our unwavering commitment to delivering innovative and tailored services that exceed our clients’ expectations, through collaborative partnerships, exceptional service delivery, and a relentless pursuit of excellence.”

## ERIKA REATEGUI

**VP of Compliance  
QACV Consulting**

With a strong academic foundation and years of hands-on experience in the industry, throughout her career, **Erika** held various roles in research compliance; progressively expanding her responsibilities and honing her expertise.

Our VP experience encompasses:

- Developing and implementing compliance programs and policies tailored to the unique needs of clinical research organizations.

- Conducting comprehensive compliance audits and assessments to identify areas for improvement and ensure adherence to regulatory requirements.

- Providing expert guidance and training to research teams on compliance obligations, ethical considerations, and best practices in clinical research.



- Collaborating with cross-functional teams, including legal, regulatory affairs, and quality assurance, to address compliance-related issues and drive continuous improvement initiatives.

Erika is deeply committed to upholding the highest standards of integrity, ethics, and compliance in clinical research. She approaches her role with a proactive and solution-oriented mindset, viewing compliance as an essential component of ensuring the safety, integrity, and ethical conduct of research activities.

Save the Date for Webinars, Workshops & Industry Conferences

## UPCOMING EVENT

### 40TH SQA ANNUAL MEETING & QUALITY COLLEGE 2024

Aurora, Colorado, USA  
6-11 April 2024

We are delighted to announce that QACV Consulting will be in attendance at **Booth 204-206** during the forthcoming **40th Annual Conference in SQA.**

We extend a sincere invitation to all participants to join us, where our seasoned team will be available to discuss our cutting-edge solutions and their application in meeting your quality assurance and compliance requirements.

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

**SQA<sup>TM</sup> Society of Quality Assurance**  
**40th Annual Meeting & Quality College**  
6-11 April 2024 📍 Aurora, Colorado, USA  
#SQA2024 SQA.ORG/SQA2024

**SQA<sup>TM</sup> 2024**