MARCH 2025 | ISSUE 4

QACV CONSULTING NEWSLETTER

Celebrating 24 Years !

ONE STEP AHEAD

in Security & Data Integrity

Committed to excellence, contributing to the advancement of QUALITY STANDARDS in the healthcare industry WORLDWIDE.

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Special Celebration!

QACV Consulting is thrilled to celebrate **24 years** of delivering top-tier solutions in Compliance, and Quality Assurance. We want to extend our thanks and gratitude to all of **our clients, industry colleagues, and partners** that we have worked and collaborated with over these past **24 years** building strong relationships through our guiding philosophy that centers around what we call the **"Five C's + R".**

We also want to extend our gratitude to our dedicated team members that have helped us to grow from a small group to **over 70 consultants worldwide. Thank you for trusting QACV Consulting for 24 remarkable years! There will be many more to come.**

Erika Reátegui, VP, Operations and Compliance & **Chris Wubbolt**, CEO, Principal Consultant

We believe that success is built on a foundation of strong relationships, shared understanding, and aligned goals. Our guiding philosophy centers around the **Five C's + R: Culture, Communication, Cooperation, Collaboration and Confidentiality plus Responsiveness** which are integral to delivering excellence in every project.

QACV's Five C's Philosophy

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.

"

I have always said that QACV Consulting is here to help, whether it's a little or a lot, depending on our clients' needs.

If client priorities shift or resources change, QACV Consulting can easily adjust to provide the right level of scalable support.

Whatever the situation, we're always happy to assist and ensure everything runs smoothly.

Chris Wubbolt | CEO, Principal Consultant

QACV CONSULTING

5 + n

STRENGTHENING CYBERSECURITY FOR A SAFER ORGANIZATION

FORTIFYING OUR FUTURE. In an ongoing effort to strengthen our organization's cybersecurity, **QACV Consulting** has successfully implemented **Microsoft Defender for Office 365** to provide enhanced email protection. This new security service, which was introduced in our Microsoft computing environment, analyzes incoming emails for harmful attachments and suspicious links, helping to safeguard our systems against potential threats. We have also brought on IT support to assist in administration of Defender and monitor our computing environments.

Microsoft

Microsoft Defender for Office 365 works by quarantining any emails that exhibit signs of malicious intent.

Whether it's a harmful attachment or a link that leads to a phishing site, this tool ensures that these potentially dangerous emails do not reach users' inboxes.

By scanning and isolating suspicious emails, the service effectively prevents various types of cyberattacks, including phishing and malware distribution.

This enhanced email protection feature plays a crucial role in our broader efforts to fortify our IT security framework.

With cyber threats continually evolving, it is essential to stay one step ahead by utilizing advanced security measures such as **Microsoft Defender for Office 365.**

We encourage all users to remain vigilant and report any unusual activity they encounter, as cybersecurity is a shared responsibility. This upgrade marks another step in our commitment to maintaining a secure and protected digital environment for everyone in the organization.

For more details on how the service works or to learn about additional security tips, refer to the **Microsoft Defender for Office 365 service description**.

Welcome

WILLIAM DRUMMOND
eSystems CLIENT LEAD I SR COMPLIANCE CONSULTANT

Managing **QACV** consultants' projects for computer systems validation (CSV), eSystems audits, QA support, data integrity training, and data integrity assessments.

Bill joins **QACV Consulting** with over 20 years experience, most recently at Charles River Laboratories. Bill is also heavily involved with the SQA CVIC group. Bill adds to our deep bench of **QACV** eSystems consultants.

Business News

LATEST INDUSTRY HIGHLIGHTS & REGULATION UPDATES

GUIDELINE ON COMPUTERISED SYSTEMS AND ELECTRONIC DATA IN CLINICAL TRIALS

The EMA's **Guideline on Computerised Systems and Electronic Data in Clinical Trials - Search** provides comprehensive recommendations for the use of computerized systems and electronic data in clinical trials, ensuring their integrity, reliability, and compliance with regulatory requirements.

> **This guideline is designed to help sponsors, investigators, and other stakeholders in clinical trials understand best practices for using computerized systems and managing electronic data to ensure the trials' success, reliability, and regulatory compliance.**

Erika Reátegui, VP, Operations and Compliance

The guideline focuses on:

1. Validation:
Ensuring that computerized systems are appropriately validated for their intended use, maintaining the accuracy, consistency, and reliability of data throughout the clinical trial process.

2. Data Integrity:
Establishing measures to prevent unauthorized access or alterations to data. The guideline emphasizes maintaining the integrity of electronic records and ensuring that data can be accurately reconstructed and audited.

3. Security and Confidentiality:
Recommending proper controls to safeguard patient data, ensuring that systems are secure from data breaches and that confidentiality is maintained at all stages of the trial.

4. Audit Trails:
Implementing systems that create reliable audit trails to track all changes made to electronic records, allowing for transparency and traceability.

5. Compliance:
Ensuring that electronic systems and data management practices comply with regulatory standards, including GxP (Good Clinical Practice), and are aligned with applicable laws and industry standards.

GLP AND GCLP

Common Compliance Issues

While there have been no changes to the GLP regulations in recent years, proposed revisions and comments are still under review with no expectation for issuance. **However, we may see the FDA issue or revise guidelines to better align with international standards, such as those from the OECD.**

Compliance to GCLP is often focused on compliance with international standards and harmonization with other regulatory bodies (such as FDA, EMA, and ICH and industry best practices).

Common compliance issues impacting GLP and GCLP laboratories include emphasis on Data Integrity, effectiveness of the Quality Management System, Technological Integration, Continuous staff training, Adoption of Risk-Based Approaches, Global Harmonization Efforts, and Adaption to Emerging Technologies.

1. Emphasis on Data Integrity:

Regulatory bodies are increasingly prioritizing data integrity.
Laboratories must ensure that all data generated is accurate, reliable, and traceable. This includes stringent documentation practices and audit trails.

2. Effectiveness of Quality Management System:

Inspections of GLP and GCLP laboratories are becoming more thorough, with regulators emphasizing compliance with standards and the effectiveness of Quality Management Systems (QMS).

3. Technological Integration:

There is a growing trend towards integrating digital solutions, such as electronic lab notebooks and automated data management systems, to improve efficiency and ensure compliance with regulatory standards.

4. Continuous Staff Training:

There is a strong emphasis on the ongoing training of laboratory personnel. Regulatory bodies require that staff remain updated on GLP and GCLP practices to ensure that staff are knowledgeable and compliant with current practices.

5. Risk-Based Approaches:

A trend toward risk-based approaches is evident, allowing laboratories to focus resources on critical aspects of studies that significantly impact outcomes.

6. Global Harmonization Efforts:

Regulatory agencies are collaborating to harmonize GLP and GCLP guidelines across regions. This initiative aims to streamline processes for international studies and foster a consistent regulatory environment.

7. Adaptation to Emerging Technologies:

As scientific advancements, particularly in personalized medicine and genomics, emerge, regulatory bodies are updating guidelines to address the implications and challenges these technologies present for GLP and GCLP compliance.

For more information, we recommend checking the **FDA's website** for the latest guidance documents and regulatory changes and webinars related to GLP and GCLP.

READ MORE

READ MORE

For more information, we recommend checking **ICH official website** or subscribing to their newsletters for the latest guidance documents and regulatory changes and webinars related to GLP and GCLP.

Summary of Trends in FDA 483 warning letters for GLP and GCLP Laboratories

Training and Competency:
Several warning letters pointed out deficiencies in training protocols, emphasizing the need for comprehensive training for staff to ensure compliance with GLP and GCLP standards.

Equipment Calibration and Maintenance:
Many laboratories failed to adhere to proper calibration and maintenance schedules for critical equipment, which could compromise the reliability of results.

Data Integrity Concerns:
Numerous laboratories were cited for issues related to data integrity, including inadequate documentation practices and failure to maintain complete records.

Quality Control Measures:
Non-compliance with quality control procedures was a recurrent theme, with labs being found lacking in proper validation of analytical methods and controls.

Protocol Deviations:
Instances of unreported deviations from approved protocols were noted, raising concerns about adherence to study plans.

FDA NESA- FDA WARNING LETTER

READ MORE

A warning letter issued by the FDA to Applied Therapeutics, Inc. on December 3, 2024.
*The letter details violations related to the company's clinical investigations and compliance with **FDA** regulations.*

*The **FDA** raised concerns about the company's inadequate oversight of clinical trial procedures, failure to properly monitor study sites, and deficiencies in reporting adverse events.*

*The **FDA** demands that Applied Therapeutics take corrective actions to address these issues, including ensuring compliance with GCP standards and submitting a detailed plan for remediation. Failure to address these violations may result in further enforcement actions.*

BUILDING STRONG RELATIONSHIPS / CLIENT'S TESTIMONIALS

*" It has been an absolute pleasure working with you (Chris Wubbolt) and Victoria – your team exemplifies integrity, transparency, and attention to detail, and I will consider/refer your services in the future. Thanks again! "— **CLIENT TESTIMONIAL / US-based GMP Client***

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

Events

SUMMITS, WEBINARS, WORKSHOPS & CONFERENCES

APRIL 2025

LATEST EVENTS

The Annual QACV Consulting Meeting - QACV Leaders

San Diego, California, USA | 4-5 February 2025

The Annual QACV Meeting proved to be an unforgettable and highly productive event, bringing together QACV leaders.

This annual meeting is designed to address the current Company and Industry challenges, opportunities, and innovations in the Life Science field. The meeting provided invaluable insights and set the stage for key advancements in the coming year.

Key Themes and Discussions
This annual meeting covered topics from technology integration to best practices for maintaining compliance in a rapidly evolving regulatory environment.

1. Technological Advancements in Quality Assurance
2. Navigating the Evolving Regulatory Landscape
3. The Role of Data Security and Privacy in Compliance
4. Collaborative Approaches to QACV Partners

Key Takeaways from the Event

- **Technological Innovation is Key**
- **Proactive Compliance is Critical**
- **Collaboration Drives Success**
- **Data Security Remains a Top Priority**

The 2025 QACV Annual Meeting provided a unique opportunity for professionals in quality assurance and compliance verification to connect, share insights, and explore new opportunities for collaboration.

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.

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

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

Empowering Excellence in
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