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QACV CONSULTING

NEWSLETTER

WHAT'S NEW ON REGULATORY UPDATES

AND LATEST INNOVATIONS

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

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Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment

Enhancing Post-Marketing Drug Safety Monitoring

The FDA's Guidance for Industry on Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment continues to serve as a cornerstone for ensuring the safety of marketed pharmaceutical products. The guidance outlines critical recommendations for identifying, evaluating, and mitigating risks associated with drug and biological product use in the post-marketing setting.

Key Highlights of the Guidance

1

Adverse Event Reporting

Emphasizes timely, accurate, and complete adverse event reporting. Sponsors are encouraged to implement robust systems to ensure compliance with 21 CFR 314.80 and 600.80 regulations.

2

Risk Assesment

Recommends systematic approaches for signal detection and risk evaluation, including active surveillance and periodic aggregate data analysis.

3

Pharmacoepidemiologic Studies

Encourages the use of real-world data, registries, and observational studies to understand adverse event trends and rare outcomes, supporting proactive risk management decisions.

4

Risk Minimization Action Plans (RiskMAPs)

Describes strategies to communicate and mitigate identified risks—ranging from labeling changes to more complex interventions such as restricted distribution programs.

5

Periodic Safety Update Reporting

Aligns safety reporting practices with international standards (e.g., ICH E2E), enabling greater harmonization for global sponsors

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PERSPECTIVE

As pharmacovigilance practices evolve in complexity, **QACV Consulting** supports clients by strengthening their safety surveillance systems and ensuring inspection readiness. From designing signal detection frameworks to conducting pharmacovigilance audits and compliance training, our team delivers scalable solutions tailored to regulatory expectations.

Our commitment is to help sponsors integrate pharmacovigilance with real-time data monitoring and analytics to safeguard patient safety and ensure regulatory alignment throughout the product lifecycle.

You can access the full FDA guidance here:

Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment | FDA

Business News

LATEST INDUSTRY HIGHLIGHTS & REGULATION UPDATES

FDA ANNOUNCES PLAN TO PHASE OUT ANIMAL TESTING REQUIREMENT FOR MONOCLONAL ANTIBODIES AND OTHER DRUGS

On April 10, 2025, the U.S. Food and Drug Administration (FDA) announced a significant shift in drug development practices by initiating a phase-out of traditional animal testing requirements for monoclonal antibodies and other drugs. This move aims to enhance drug safety, reduce research and development costs, and ultimately lower drug prices.

The FDA plans to replace **Animal Testing** with **New Approach Methodologies (NAMs),** which include:

AI-Based Computational Models:

Utilizing Artificial Intelligence to predict a drug's behavior and potential side effects.

Human-Based Lab Models:

Employing lab-grown human organoids and organ-on-a-chip systems that mimic human organs to test drug safety.

To facilitate this transition, the FDA will launch a pilot program allowing select developers of monoclonal antibodies to use primarily **non-animal-based testing strategies**. Companies that submit strong safety data from these alternative methods may receive streamlined reviews, incentivizing investment in modern testing platforms.

This initiative aligns with the **FDA Modernization Act 2.0**, **signed into law in December 2022,** which removed the requirement for animal testing in drug development, making it optional. The Act enables the use of alternative testing methods such as computer models and cell-based assessments.

While this marks a transformative change in drug evaluation, the FDA acknowledges that further development and validation of these alternative methods are necessary to ensure they can effectively replace animal testing across all areas of drug development.

READ MORE »

What You Need to Know About ICH E6(R3)

What is ICH E6(R3)?

ICH E6(R3) is the latest revision of the GCP guideline originally adopted in 1996. This third revision reflects over two decades of advancements in clinical trial design, technology, and regulatory expectations. It aims to:

- Modernize the GCP principles
- Embrace a risk-based, flexible, and proportional approach
- Support innovations such as decentralized trials and real-world data.

The Future of GCP Is Here

As of January 6, 2025, the ICH E6(R3) Good Clinical Practice (GCP) guideline has been finalized and adopted by the ICH Assembly at Step 4 of the ICH process.

This significant update reflects the culmination of extensive collaboration among global regulatory authorities and industry stakeholders to modernize and enhance the standards for clinical trial conduct.

At **QACV Consulting**, we believe staying ahead of regulatory changes is essential to achieving compliance, quality, and patient safety. This edition of our newsletter brings you key insights and practical takeaways on ICH E6(R3).

Key Updates in R3:
ICH E6(R3) is structured into two major sections.

1. Principles Section:

- Introduces 12 GCP principles (revised from the original 13).
- Emphasizes participant safety, data integrity, and proportionality.
- Promotes risk-based approaches and quality by design (QbD).

2. Annexes:

- Annex 1: GCP expectations for traditional interventional trials.
- Annex 2 (in development): Will address non-traditional designs such as decentralized, pragmatic, or real-world evidence-based trials.

What This Means for Sponsors, CROs, and Investigators:

- Early Integration of Quality by Design (QbD): Focus on identifying critical-to-quality factors early in trial design.
- Risk-Based Monitoring (RBM): Continued emphasis on centralized monitoring, data analytics, and remote oversight.
- Fit-for-Purpose Documentation: Encourage lean documentation practices aligned with the complexity and risk of the trial.
- Technology and Innovation: Supports electronic systems, digital health technologies, and decentralized trial models while ensuring validation, security, and data integrity.

Implications for Quality and Compliance

- Organizations must reassess SOPs, training, and vendor oversight strategies.
- Quality teams should prepare for regulatory scrutiny on risk assessment practices and critical data/process documentation.
- Auditors will need to adjust checklists and risk models to evaluate compliance with the new principles and approaches.

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ICH harmonisation for better health

For detailed information, you can access the final **ICH E6(R3) Good Clinical Practice (GCP) Final Guideline** READ MORE

How **QACV Consulting** Can Help

As global experts in quality and compliance, **QACV Consulting** offers:

- **Gap Assesments against ICH E6(R3) principles and Annex 1.**
- **Customized training programs for QA teams, clinical operations, and vendor partners.**
- **Audit tools and checklists aligned with the new guidelines.**
- **Strategic consulting to align QbD and RBM with your organizational practices**

The transition to **ICH E6(R3)** represents a pivotal shift in clinical research—one that emphasizes agility, innovation, and a renewed focus on what matters most: **PARTICIPANT SAFETY and RELIABLE DATA.** Now is the time to get ready. **QACV Consulting** is here to help you lead the change.

The finalized guideline is scheduled to become effective in **July 2025**, providing a transitional period for sponsors, investigators, and regulatory bodies to align their practices with the updated standards. This period allows for necessary adjustments in trial design, conduct, oversight, and documentation to ensure compliance with the new requirements.

Additionally, the FDA has provided resources and guidance to facilitate the implementation of ICH E6(R3) within the United States. These resources offer insights into the FDA's expectations and recommendations for adopting the updated GCP standards.

BUILDING STRONG RELATIONSHIPS / CLIENT'S TESTIMONIALS

*"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."*

— CLIENT TESTIMONIAL / CHIMERIX Thank You Note For The Mock Inspection Readiness Support.

" I want to say thank you for going extra miles in the GCP audit. It was a tough audit from the initial planning phase, audit, and post audit. You were excellent in handling the meeting today."
— CLIENT TESTIMONIAL / GCP Client recognition to Beth Rayworth, Sr. Compliance Consultant.

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

Empowering Excellence in Quality Assurance & Compliance

Events

SUMMITS, WEBINARS, WORKSHOPS & CONFERENCES

2025 | QACV GLOBAL PRESENCE & LOCAL IMPACT

Proud to share our continued Global Presence and Thought Leadership across major industry events in 2025!

As we move into the second half of 2025, we're proud to share the incredible momentum and success **QACV Consulting** has experienced across key global industry events this year.

SQA 41ST ANNUAL CONFERENCE

April 6–11 | Orlando, FL

QACV Consulting was honored to serve as a Gold Sponsor at the SQA 41st Annual Conference, held on April 6–11, 2025, in Orlando, Florida.

As both an exhibitor and featured presenter, **QACV Consulting** brought forward key discussions on global GxP auditing, regulatory harmonization, sustainability in clinical trials, and inspection readiness strategies.

Our sessions were met with strong engagement and meaningful conversations with colleagues across the industry.

It was a true pleasure to connect with so many SQA members, peers, and clients in person—strengthening partnerships and sharing our passion for quality, compliance, and continuous improvement.

We thank the SQA community for the opportunity to contribute, sponsor, and support this vital annual event.

The energy, insights, and collaboration from this conference continue to inspire our global initiatives.

Thank you to everyone who visited our Booth #2015 and joined our discussions on quality, compliance, and sustainability in global clinical trials.

STRENGTHENING GLOBAL IMPACT

THROUGH COLLABORATION AND INNOVATION

QACV CONSULTING
24 YEARS ANNIVERSARY

ISPE EUROPE ANNUAL CONFERENCE
May 12 - 14 | London, UK

QACV Consulting made its official international debut at the ISPE Europe Annual Conference, showcasing our expertise in global regulatory standards and multilingual auditing capabilities.

Our very first participation in the ISPE Europe Annual Conference was a major milestone for **QACV Consulting**. This event marked our official international debut, where we proudly highlighted our global reach, multilingual expertise, and deep regulatory knowledge. It was an honor to connect with industry peers across Europe and demonstrate QACV's growing presence on the world stage. This first international appearance marked a new chapter in our expansion—and we are just getting started.

JOIN US !

DIA 2025 GLOBAL ANNUAL MEETING
June 15 - 19 | Washington, DC

We are thrilled to announce that DIA 2025 in Washington will be a major success! Our collaboration with **Ascendia Clinical** will showcase the power of partnership—bringing together our expertise in GxP compliance and clinical operations to deliver integrated solutions for the life sciences industry.

Join us at our **Booth #1715**. We look forward to sharing this exciting week with you in DC!

WHERE TO FIND US NEXT !

DIA JAPAN 2025
October 19–21 | Tokyo

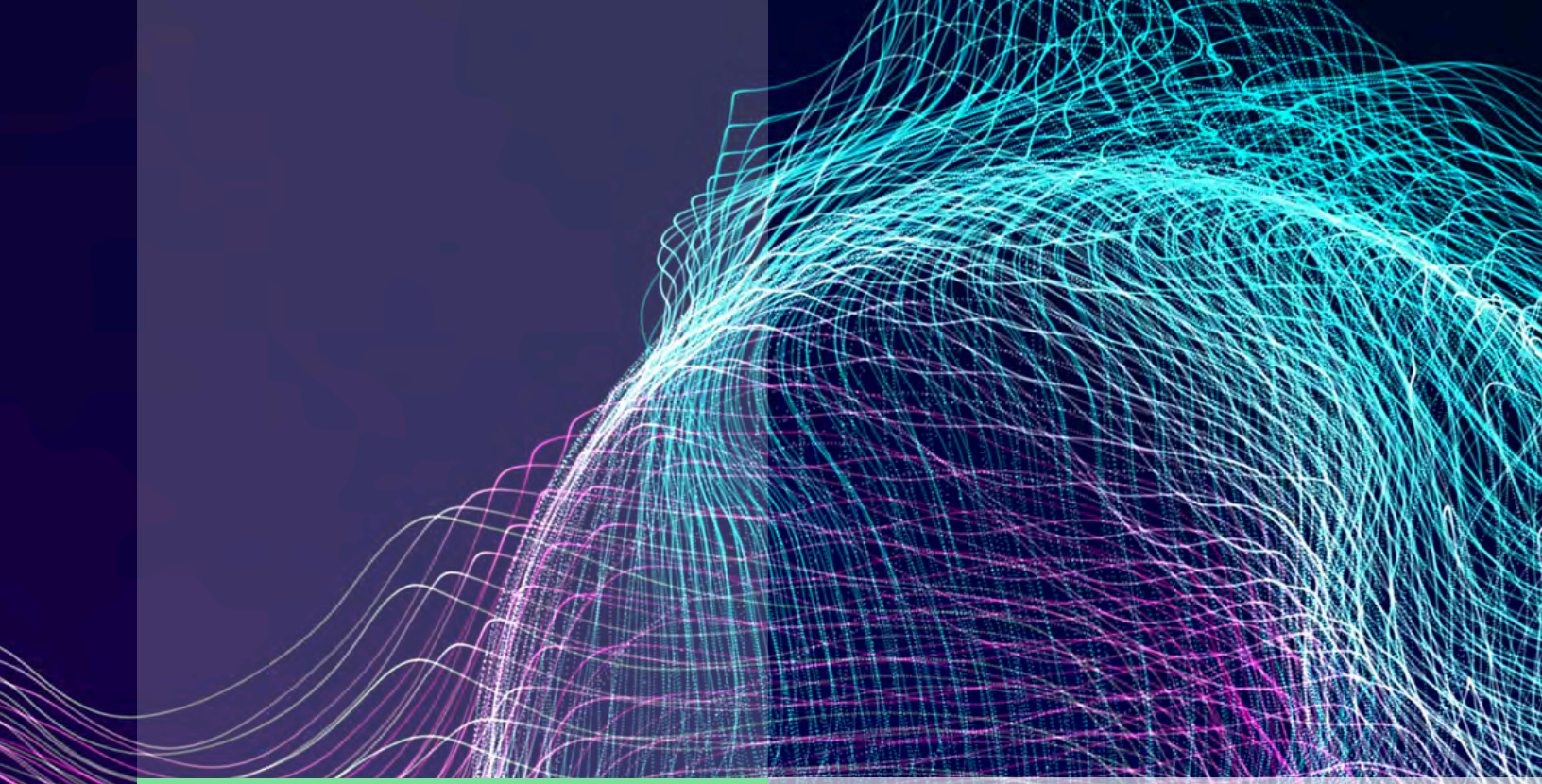
We're headed to **Tokyo!**
Join us in Asia, as we continue the conversation on cross-border compliance, strategies, digital health innovation, and patient safety in **Asia-Pacific.**

RQA INTERNATIONAL QA CONFERENCE
November 5–7, 2025 | ICC Belfast

We are thrilled to announce that **QACV Consulting** is an official Sponsor of the RQA 2025 International Conference!

Join us in Belfast as we engage with global leaders on sustainability, global quality oversight, and the evolving future of quality assurance.

"Our international engagements reflect our mission: To drive global compliance through partnership, innovation, and a commitment to quality."
– The QACV Team



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