QACV CONSULTING

NEWSLETTER

OCTOBER 2025 | ISSUE 6

Key takeaways for QA Professionals

UNDERSTANDING GLOBAL REGULATORY NUANCES

A comparative look at PMDA vs. MHRA, highlighting some of the nuanced differences that can impact clinical operations, submissions, and quality oversight.

Understanding Global Regulatory Nuances

Comparative look at **PMDA vs. MHRA**, highlighting some of the nuanced differences that can impact clinical operations, submissions, and quality oversight.

As clinical research continues to expand across borders, quality professionals are increasingly challenged by the variability of national regulations. While many organizations are well-versed in FDA requirements, understanding how other global agencies—like **Japan's PMDA (Pharmaceuticals and Medical Devices Agency) and the UK's MHRA (Medicines and Healthcare products Regulatory Agency)**—approach GxP compliance is critical for effective global trial management and regulatory alignment.

PMDA (Japan)	MHRA (UK)
Regulatory Philosophy and oversight models	
1 • Operates under a centralized review model tightly aligned with MHLW (Ministry of Health, Labour and Welfare). It focuses heavily on safety and risk minimization, and sponsors often engage with PMDA early through formal pre-submission consultations. • → Emphasis: Safety-first, culturally rooted in risk aversion, detailed documentation, and local language translation requirements.	• Post-BrExit, MHRA functions independently of the EMA and has taken steps to streamline its processes to maintain the UK's attractiveness for research and innovation. Sponsors benefit from adaptive licensing pathways and expedited reviews for high-priority therapies. • → Emphasis: Agile regulation, post-BrExit reform, digital-friendly infrastructure.
Inspection and GCP Focus	
2 • Inspections are generally announced and conducted with a strong focus on process documentation, informed consent procedures, and data traceability. They are extremely detail-oriented and expect precise adherence to SOPs and timelines.	• MHRA inspections can be announced or unannounced, with an increasing focus on risk-based approaches, data integrity, and IT system validation. MHRA actively reviews sponsor oversight and CRO relationships.
Document Requirements & Language	
3 • Requires most documentation, including clinical trial protocols and patient materials, to be in Japanese. Translation accuracy is critical, and even minor inconsistencies can cause delays.	• Accepts documentation in English, with more flexibility on formatting. However, documentation must clearly demonstrate compliance with UK-specific GCP guidance, especially in post-approval safety reporting.
Regulatory Harmonization	
4 • Participates in ICH but often maintains localized standards for data formats and submission structure. Integration with global submissions (e.g., FDA or EMA) requires careful bridging.	• While diverging from EMA post-BrExit, MHRA has worked toward regulatory alignment through international initiatives like ACCESS Consortium and Project Orbis, offering opportunities for simultaneous submissions with other countries (e.g., Australia, Canada, Singapore, and Switzerland).

Key takeaways for QA professionals

- Don't assume that one-size-fits-all. Understanding the regulatory culture and expectations of each agency is critical.
- Build a country-specific regulatory strategy, especially when planning site inspections or data submissions.
- PMDA may require longer timelines due to translation and pre-submission consultations, while MHRA may offer flexibility for rapid review but expects strong oversight and innovation readiness.

FDA October 2024 Guidance

OCTOBER GUIDANCE 2024

Electronic Systems, Records & Signatures in Clinical Trials

In October 2024, the U.S. Food and Drug Administration issued a pivotal update titled "Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers." This guidance builds on the longstanding Part 11 framework, reflecting advancements in digital technology and clinical trial operations. Here's what QA teams need to know:

The October 2024 Q&A guidance offers a comprehensive blueprint for integrating electronic systems into clinical investigations—without compromising quality or compliance.

Now is the time to review your validation, data management, and IT contracts to align with FDA expectations.

Why this guidance matters

Technology in clinical trials is evolving—from cloud computing to DHTs and EDC. The FDA's updated guidance provides clarity on how to maintain data integrity, reliability, and regulatory compliance in this digital era. Sponsors, CROs, and investigators should:

- Reassess system validation strategies through a risk-based lens.
- Ensure certified copies and data redundancy safeguards.
- Strengthening oversight of IT service providers.
- Prepare DHT data structures and audit trails.
- Implement compliant electronic signature systems, including non-repudiation letters.

1. Applicability to Electronic Records:

- Applies to all electronic records and signatures used in FDA-regulated clinical investigations—drugs, biologics, devices, food trials.
- Clarifies that real-world data sources (e.g., EHRs) are not subject to Part 11 compliance until data enters a sponsor's EDC system.

2. Certified Copies & Data Integrity:

- Emphasizes use of certified copies that faithfully replicate originals—including metadata—before original disposal.
- Encourages secure retention methods, including cloud storage, with integrity and confidentiality safeguards throughout the data lifecycle.

3. Risk-Based Systems Validation:

- Promotes a risk-based approach to system validation, evaluating intended use, data criticality, and potential effects on subject safety and data reliability.
- Requires validation of all system functions, configurations, customizations, interfaces, and subsequent changes.

4. Managing IT Service Providers:

- Outlines expectations for sponsors contracting IT services (e.g., EDC, randomization): thorough validation, documentation, secure access, change control, and clear contractual roles.
- FDA inspections will focus on data handling, system lifecycle, access controls, change management, audit trails, and service provider oversight.

5. Digital Health Technologies (DHT):

- Clarifies Part 11 expectations for wearables, sensors, and DHTs, ensuring data origin attribution, secure access, and prevention of unauthorized data modifications.

6. Electronic Signatures:

- Confirms multiple methods (e.g., biometrics, digital PKI-based, or user ID/password) are acceptable under Part 11.
- Requires linkage between signature and records, audit trails for changes, and submission of "letters of non-repudiation" certifying legal equivalence to handwritten signatures.
- Notes that signatures drawn with a stylus or finger are still considered handwritten, not electronic, and must be linked accordingly.

QACV Services Spotlight

PV AUDIT SERVICES

We conduct audits of pharmacovigilance (PV) systems to ensure compliance with regulatory.

- GCP Audits, including Central Laboratories, Bioanalytical Laboratories, IRBs, CROs, Trial Master Files, Investigator Sites, Sponsors
- GVP Audits
- GMP Audits
- GLP Audits
- QA Support
- Contract Manufacturers, Laboratories, and Packages
- Excipient Supplier Audits
- Computer Validation Audits

To learn more about our services, visit www.QACVconsulting.com

Meet our QACV Global Team

STRONG AUDIT PERFORMANCE DRIVES FOLLOW-UP PHASE

Melanie Willis
Sr. Compliance Consultant (GCLP, GLP Adviser)

We're pleased to share positive recognition for an exceptional audit performance from a recent project conducted by QACV Consulting GCLP/GLP Sr. Compliance consultant Melanie Willis.

Following her excellent audit work with our GLP client, they have expressed satisfaction with her professionalism and expertise. As a result of her thorough evaluation, additional on-site follow-up is being scheduled to further assess the scope of the findings.

Our GLP client has requested Melanie's continued support during the next phase of the project, a clear reflection of the trust and value she brings to our compliance services.

At QACV Consulting, we take pride in delivering meaningful, actionable insights—and we're proud to see our consultants making a lasting impact.

30 YEARS DRIVING INNOVATION IN COMPLIANCE PHARMACOVIGILANCE

Penny Jegede
Sr. Compliance Consultant (GVP, eSystems)

With over 30 years of experience in clinical research, pharmacovigilance, IT compliance, and quality assurance, Penny brings unmatched regulatory expertise and leadership to our team.

Her distinguished career includes roles at Johnson & Johnson, Merck, and Pfizer, with a strong focus on GCP and PV audits, Computer System Validation (CSV), and global Quality System assessments. At QACV Consulting, Penny leads End-to-End (E2E) PV audits, serves as an IT/CSV Subject Matter Expert, and provides advanced regulatory training on topics like AI/ML in GxP systems and CSA principles.

She is widely recognized for her innovative work in risk-based auditing, particularly in pharmacovigilance IT systems. Her expert presentations—such as "Auditing a GxP System with an AI/ML Component" and "E2E Audit Management for IT Suppliers"—reflect her deep understanding of evolving regulatory landscapes.

Penny's ability to combine strategic oversight with technical detail makes her a trusted advisor to clients and colleagues alike. Her commitment to excellence continues to ensure QACV Consulting delivers high-impact, inspection-ready compliance solutions worldwide.

ASK THE EXPERT

Is Improper Storage of Clinical Tubes a Major Finding?

We turned to **QACV's CEO and Principal Consultant, Chris Wubbolt**, for his expert perspective.

During a recent audit, a thoughtful question was raised by one of our consultants regarding the classification of an observation:

Observation: Tubes for clinical pathology (Hematology, Coagulation, and Chemistry) were stored in an office rather than in a temperature-controlled environment.

Question: Does this constitute a Major finding that could affect test reliability—or can it be considered Minor if informal controls (e.g., temperature monitoring) are in place?

Key Takeaway:

"It's not always black and white"

As Chris emphasized, "Findings like this often require **supporting information and judgment**.

It's not just about where the tubes were stored—it's about whether the storage conditions met validated specifications."

He also shared a broader reflection from a past debrief:

"I once classified a finding related to a non-critical system that hadn't been validated as **Major**. A client QA rep argued that any system not validated should be a **Critical** finding.

I explained that if the system is non-critical, it can't reasonably rise to that level. Everyone agreed—context and classification **nuance** are essential."

Chris Wubbolt Response: "It Depends—Follow the Manufacturer's Requirements".
Chris began by pointing out that the critical factor is **manufacturer storage specifications**:
"Some hospitals or clinics do store tubes outside of controlled areas, but it comes down to what the **manufacturer states** as acceptable storage conditions. For example, certain hematology tubes might even require refrigeration."

He referenced two key regulations:

- **CLIA (42 CFR §493.125)**: Requires that clinical labs follow the manufacturer's instructions for reagent and specimen storage.
- **GLP (21 CFR §58.43)**: Mandates that environmental controls must be adequate to "minimize contamination or deterioration… and ensure the integrity of study data."

If the tubes were **not stored according to manufacturer requirements**, this could **justify a Major finding**. However, **context matters**.
"If temperature logs show that conditions have stayed within acceptable ranges—even in a non-controlled room—then the observation might be considered **Minor**," Chris advised.

Final Thoughts
Before classifying a finding as Major, ensure the following:

- Check manufacturer specifications for storage conditions
- Review temperature logs for compliance
- Assess whether the storage deviation impacts data integrity
- Document supporting evidence clearly in the audit report

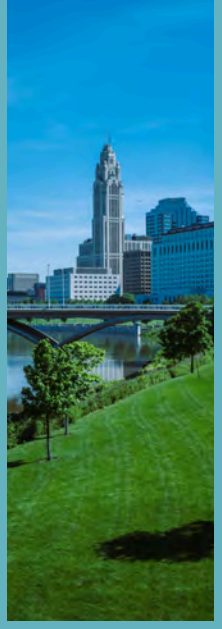
Audit insight of the month: Classification requires more than definitions—it requires judgment, evidence, and regulatory understanding.

Latest News & Events

SUMMITS, WEBINARS, WORKSHOPS & CONFERENCES

QACV 2025 GLOBAL PRESENCE & LOCAL IMPACT

Proud to share our continued global presence and thought leadership across major industry events.

August 01 | Houston, TX

QACV CONSULTING OPENS NEW OFFICE IN HOUSTON'S TEXAS MEDICAL CENTER

We are thrilled to join a thriving and rapidly growing life sciences community in the Houston area. We are excited to announce the August 1st opening of our new office location in the Texas Medical Center Innovation Building.

We will host events and complimentary GxP training sessions at this new office location. We will also participate in the Texas Life Science Forum held at the Rice University campus on November 11th, 2025.
This move marks a strategic step toward building meaningful local partnerships and future business opportunities, allowing us to engage directly with Houston-based researchers, startups, and thought leaders developing the next generation of therapeutics.

QACV Consulting welcomes our established and prospective clients to come visit us at our new location at **2450 Holcombe Blvd., Suite X, Houston, TX 77021.**

July 21-24 | Columbus, OH

MWSQA-SRCSQA-NCARSQA ANNUAL MEETING

Chris Wubbolt, CEO of QACV Consulting, delivered a well-received presentation on Computer Systems Validation (CSV) titled:

"GxPs – Differences and Similarities between GLP, GCP, and GMPs"at the joint MWSQA-SRCSQA-NCARSQA Annual Meeting and Quality College, held at The Estate at New Albany near Columbus, Ohio.

In this engaging 60-minute session, Chris offered a comparative overview of the Good Laboratory Practices (GLP), Good Clinical Practices (GCP), and Good Manufacturing Practices (GMP), addressing their regulatory frameworks, scopes, and operational impact.
The presentation served as both a foundational training and a strategic discussion, with a focus on the critical role of Quality Assurance within each GxP.

Key takeaways included:
Understanding the distinct goals of each GxP: safety and integrity of data (GLP), protection of human subjects (GCP), and product quality and consistency (GMP).

- Exploring the similarities across the regulations, such as documentation, change control, and data integrity.
- Discussing overlapping responsibilities and organizational structures within quality systems.
- Emphasizing the importance of tailoring QA oversight to the unique demands of each regulated area.

We are grateful for the opportunity to contribute to the broader QA community and look forward to continued collaboration with SQA regional chapters and quality professionals nationwide.

Looking ahead, QACV Consulting, will continue building on this momentum, delivering workshops and strategic advisory services focused on computerized systems validation and GxP compliance.

東京で一緒に参加しましょう

October 19-21 | Tokyo

HEADING TO TOKYO ! 22ND DIA JAPAN 2025

We're thrilled to attend the 22nd DIA Japan (Booth 24) at the amazing Tokyo Big Sight in Ariake, Koto-ku.

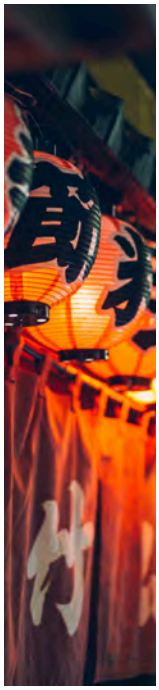
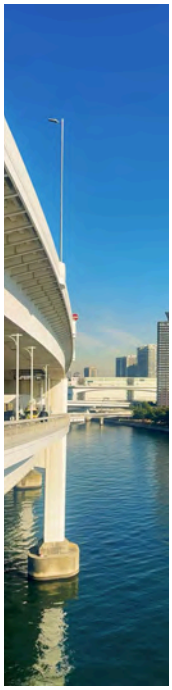
Join QACV Consulting in Asia as we continue the conversation on cross-border compliance, regulatory strategies, digital health innovation, and patient safety across the Asia-Pacific region.

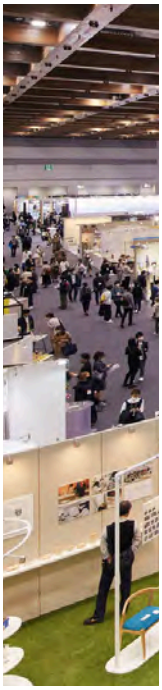
As proud participants in the 22nd DIA Japan Annual Meeting, we're excited to engage with global and regional stakeholders in discussing how to deliver "Tomorrow's Normal"—a future of healthcare that is safer, more efficient, and deeply connected through innovation and collaboration.

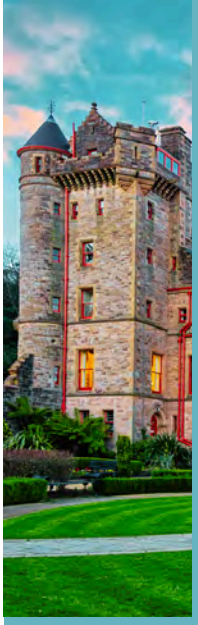
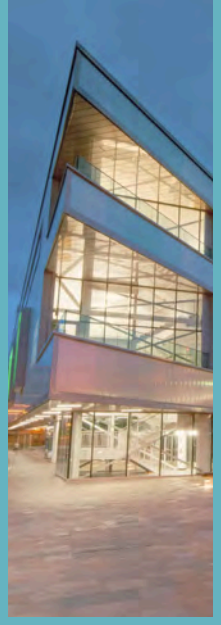
This year's meeting highlights the importance of strong international ties, especially between Japan, Asia, and the global community, in shaping the future of medical product development and post-marketing surveillance. The addition of an English-language track will further enhance global dialogue and learning.

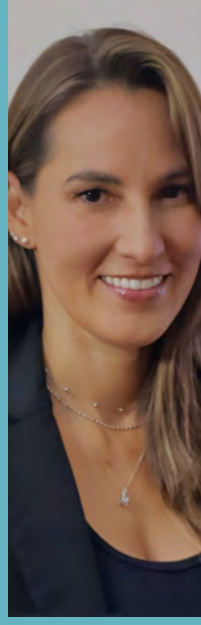
We look forward to sharing insights, learning from peers, and exploring ways to collectively build healthcare systems that support vibrant and healthy lives for all.

Let's connect in Tokyo! Reach out at **contact@qacvconsulting.com** to schedule a meeting with our QACV Consulting team during the event.





November 5-7 | ICC, Belfast

RQA INTERNATIONAL QA CONFERENCE

We are proud to announce that Erika Reategui, VP of Operations and Compliance at QACV Consulting, will be presenting at the upcoming RQA 2025 International QA Conference in Belfast, Northern Ireland. The event will gather global quality professionals to address the most pressing challenges in regulatory science and quality assurance.

Presentation Title: "One World, One Quality: Streamlining Sustainable QA Across Borders"

Erika's session will explore the evolving role of Quality Assurance in the face of Environmental, Social, and Governance (ESG) pressures, and the rapid globalization of clinical trials. As trial sponsors and regulators increasingly emphasize sustainability and harmonization, her talk will provide practical insights on:

- Minimizing travel-related emissions through hybrid and remote QA models
- Adapting quality oversight frameworks to support ESG goals
- Addressing regulatory fragmentation that slows approvals—such as varying submission formats required by the FDA (US), EMA (EU), and PMDA (Japan)
- Embedding sustainability into trial design, vendor oversight, and QA governance

Drawing from QACV Consulting's cross-border audit expertise, Erika will share tools and strategies for harmonizing global QA processes while maintaining data integrity and compliance. Attendees will leave with actionable ideas to reduce redundancy, increase operational efficiency, and align quality practices with global ESG expectations.

We invite all participants to join Erika's presentation and be part of the conversation on building a unified, future-ready QA ecosystem.

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Empowering Excellence in
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