DIGITAL QUALITY ASSOCIATES
WHERE EXPERIENCE COUNTS

The New Imperative: IT Supplier Quality Assurance Under ICH E6(R3)

As the July 2025 implementation date for ICH E6(R3) approaches, a significant evolution in regulatory expectations is becoming clear. Discussions at the recent ACT Workshop confirmed what many quality professionals have anticipated: regulatory authorities are intensifying their focus on IT service provider oversight, and eliminating the current gap of not conducting direct routine inspections of IT vendors supporting clinical trials.

A Paradigm Shift in Regulatory Scrutiny

This represents a paradigm shift in how regulators approach clinical trial oversight. Historically, inspections primarily targeted sponsors and investigator sites, with vendor compliance viewed through the lens of sponsor oversight. Now, IT service providers themselves will face regulatory examination. We have seen this before, and it seems that the cycle is starting again, where Sponsor's accountability for cloud service providers will be brought into context, and that those providers will have a direct level of inspection scrutiny.

ICH E6(R3) provides a clear framework for this enhanced scrutiny. Section 3.6.9 of the guideline explicitly requires sponsors to "ensure appropriate oversight of important trial-related activities that are transferred to service providers, including activities further subcontracted." Meanwhile, section 3.6.8 mandates that "the sponsor should have access to relevant information (e.g., SOPs and performance metrics) for selection and oversight of service providers."

The Quality Assurance Challenge and the Value of Senior Leadership

These requirements create significant challenges for many organizations, as effective IT supplier oversight demands specialized expertise in both GCP and IT technical skills, including computer system validation. Most sponsors lack sufficient internal resources with this dual competency. Even sophisticated life sciences companies with robust quality teams often need supplementary expertise for thorough IT vendor assessments.

The critical difference-maker in this environment is senior leadership expertise. While many consultancies offer CSV professionals, there's a stark difference between less experienced staff following audit checklists and seasoned leaders who can view challenges holistically. Time-served senior leaders bring context, nuance, and real-world experience that allows them to provide strategic solutions rather than merely documenting minor observations.

Generic, one-size-fits-all approaches implemented by less experienced consultants may appear cost-effective initially but often result in:

1. Surface-level findings that miss systemic risks
2. Cookie-cutter recommendations that don't fit organizational needs
3. Excessive documentation without practical value
4. Implementation challenges due to lack of organizational understanding
5. Higher total costs as initial work requires remediation or expansion

In contrast, senior leaders with decades of experience can rapidly identify root issues, develop tailored strategies, and implement sustainable solutions that address both immediate compliance needs and long-term operational excellence.

Strategic Quality Assurance Frameworks

Strategic Quality assurance leaders must now develop frameworks that address several critical areas:

1. Qualification Audits

Independent qualification audits must thoroughly evaluate not just quality systems but technical competencies and data integrity, including:

- Validation practices and documentation
- Software development life cycle processes
- Data integrity controls
- Security measures and data privacy safeguards
- Disaster recovery capabilities

These audits need to be conducted by professionals who understand both clinical trial requirements and IT system validation - a relatively rare combination of expertise found primarily among senior leaders who have navigated both disciplines throughout their careers.

2. Risk-Based Oversight

Rather than treating vendor qualification as a point-in-time assessment, quality teams must implement continuous oversight mechanisms proportionate to risk. This includes:

- Periodic technical re-assessments
- Review of quality metrics and KPIs
- Change management evaluation
- Incident response monitoring

The level of oversight should reflect both the criticality of the systems to patient safety and the reliability of trial results. Experienced senior consultants can help organizations implement these mechanisms efficiently, avoiding

both oversight gaps and resource-draining over-monitoring.

3. Subcontractor Management

The guideline's explicit mention of subcontractor oversight creates additional complexity. Many IT vendors rely on cloud infrastructure providers, offshore development teams, or specialized service components. Quality assurance approaches must now include protocols for evaluating how primary vendors manage these nested relationships.

The False Economy of Less Experienced Consultants

Organizations often make the mistake of engaging consultancies that deploy less experienced staff to execute against standardized templates. This approach creates a false economy where the apparent cost savings are quickly eroded by:

1. **Extended project timelines** as less experienced staff navigate unfamiliar territory
2. **Multiple iterations** of deliverables requiring extensive revisions
3. **Gaps in coverage** that become apparent during regulatory inspections
4. **Implementation challenges** due to impractical recommendations
5. **Knowledge transfer failures** when consultants depart

The total cost of ownership for generic solutions implemented by less experienced consultants typically exceeds the investment in senior expertise that delivers right-sized, practical solutions the first time.

The Senior Leadership Advantage

Time-served senior leaders bring several distinct advantages to IT vendor oversight:

1. **Regulatory perspective** - Understanding what truly matters to inspectors versus bureaucratic paperwork
2. **Cross-industry experience** - Applying best practices from multiple life sciences contexts
3. **Strategic vision** - Seeing beyond tactical compliance to long-term operational excellence
4. **Efficient execution** - Rapidly identifying critical issues without unnecessary investigation
5. **Organizational savvy** - Navigating complex stakeholder landscapes to build consensus
6. **Change leadership** - Driving sustainable implementation rather than merely recommending changes

This depth of experience allows senior consultants to provide value from day one, often reducing total project timelines and costs while delivering superior outcomes.

How Quality Teams Can Prepare

Quality assurance professionals should take several steps to prepare for the new regulatory landscape:

1. **Inventory IT Service Providers**: Create a comprehensive inventory of all IT vendors supporting clinical trials
2. **Risk Assessment**: Categorize vendors based on GCP impact and data criticality
3. **Identify Expertise Gaps**: Honestly assess internal capabilities for technical vendor oversight
4. **Develop Audit Plans**: Create risk-based audit schedules for both initial qualification and ongoing oversight
5. **Engage Senior Expertise**: Partner with time-served senior leaders rather than less experienced staff-heavy consultancies

Looking Ahead

As one inspector emphasized at the ACT Workshop: "We'll be looking beyond documentation to evidence of actual quality oversight activities. Sponsors need to show how they're actively ensuring their IT service providers are maintaining compliance."

Organizations that proactively implement robust IT supplier quality assurance programs led by experienced senior consultants will not only reduce regulatory risk but will realize significant operational benefits. The initial investment in senior expertise typically delivers substantial returns through more effective vendor management, reduced remediation costs, and streamlined regulatory interactions.

With proper preparation guided by seasoned leaders, the enhanced expectations of ICH E6(R3) can serve as a catalyst for overall quality improvement rather than simply a compliance burden.

The DQA Difference

Our team brings together clinical research quality specialists and IT validation experts with decades of senior leadership experience to deliver comprehensive, strategic solutions that address both GCP and technical compliance requirements. We provide the independent scrutiny, pragmatic recommendations, and effective implementation support that demonstrates your commitment to quality oversight and regulatory compliance.

Contact us to discuss how our specialized senior-led services can strengthen your compliance position and protect trial integrity while delivering long-term operational value.

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