BEYOND CLINICAL COMPLIANCE

RISK, QUALITY, AND INNOVATION IN THE R3 ERA

Hybrid Event | Sept 9-10 in Philadelphia and Virtually

Clinical research is evolving—and so are the expectations for compliance. *Beyond Clinical Compliance* is a working conference for quality, operations, and compliance professionals who are **ready to think differently about risk, oversight, and inspection readiness in the era of ICH E6(R3)**.

This event goes beyond frameworks and checklists. It **creates space for real conversations and shared problem-solving across roles and organizations**. Whether you're managing trials, overseeing vendors, optimizing systems, or building inspection readiness strategies, you'll leave with actionable insights and renewed focus. Click here to register.

Cut through the noise.	*Get clarity on E6(R3), AI, and smarter oversight.*
Find your people.	*Real talk, shared challenges, honest solutions.*
Leave recharged.	*With strategies you'll actually use.*
Do better—together.	*For patients. For teams. For the future.*
Trust the source.	*Backed by 20 years of industry intelligence.*

CHOOSE YOUR EXPERIENCE

Attend in person to experience the full event—every session, every connection, and every opportunity to engage. Gain fresh perspective, practical tools, and the inspiration to lead with clarity in the R3 era.

Can't attend in person? You can still be part of the event. Join virtually to live-stream select sessions and engage with the full community through the event app.

Lead Sponsor Just in Time® GCP

Agenda

Tuesday, September 9 – Main Conference Day One

8:00 AM ET	**Registration and Networking Breakfast**
9:00 AM ET LIVE STREAM	**Conference Welcome and Chairperson's Opening Remarks** *Sharon Reinhard, Clinical Quality and Compliance Thought Leader; Acting Head of Quality for Late Stage Biotechs* *Kristen Hunter, Principal, KH CONFERENCES*
9:30 AM ET LIVE STREAM	**KEYNOTE PRESENTATION** **When Quality Fails Quietly: A Cautionary Tale from Inside Theranos** *Tyler Shultz, Scientist, Entrepreneur & Whistleblower* What happens when scientific rigor is replaced by secrecy, quality oversight is sidelined, and pressure to deliver overtakes the responsibility to get it right? In this keynote, Tyler Shultz takes attendees behind the scenes of Theranos—not just to recount what went wrong, but to expose the systemic cultural and operational breakdowns that enabled the deception. **It's a real-world case study in everything a quality-driven organization should avoid**: from falsified data and inadequate documentation to intimidation of staff and the silencing of dissent. This session isn't about scandal. It's about **lessons**. And it's a powerful reminder of why clinical quality professionals matter more than ever. **Key Takeaways** • How the absence of quality systems and controls contributed to regulatory risk and scientific harm • What early warning signs were missed—and how to recognize them in your own organization • Why psychological safety is foundational to any functioning quality culture • How internal reporting structures failed—and what robust escalation pathways should look like

	• The human cost of ignoring compliance: to patients, to professionals, and to progress
10:15 AM ET 	**Keynote Q&A with In-Person and Virtual Audiences**
10:30 AM ET	**Networking and Refreshment Break**
11:00 AM ET 	**CHAMPIONS OF QUALITY** **Learn How Senior Leaders Are Defining the Future of Clinical Quality—from the Inside Out** **Moderator** *Sharon Reinhard, Clinical Quality and Compliance Thought Leader; Acting Head of Quality for Late Stage Biotechs* **Panelists** *Teresa DeVincentis, Head of Quality, SOLID BIOSCIENCES* *Jim Sheets, Vice President, Global Quality Assurance, GOSSAMER BIO* • Understand what it really takes to lead quality in today's complex, evolving trial environment • Hear how they're navigating competing priorities, resource limitations, and organizational change • Explore the skills and qualities today's leaders are cultivating—and what they look for in the next generation • Gain practical insight into shaping quality strategy that supports innovation without sacrificing compliance • Walk away with new ways to influence, inspire, and lead—regardless of your title or function
11:45 AM ET 	**Panel Q&A with In-Person and Virtual Audiences**
12:00 PM ET 	**ALIGNING PROCESSES FOR R3** **How to Prioritize Updates So Your Clinical Team Doesn't Waste Time or Miss Critical Risks** *Donna Dorozinsky, Founder & CEO, JUST IN TIME GCP* • Find out which R3-driven process changes are non-negotiable for inspection readiness—and which ones you can safely delay

	• Hear how regulators are likely to interpret R3 and why "good enough" processes won't be enough anymore • Learn where sponsors are already stumbling in implementation—and how to avoid the same mistakes • Walk away with a clear order of operations so you can move forward with confidence instead of confusion
12:30 PM ET 	**Speaker Q&A with In-Person and Virtual Audience**
12:45 PM ET	**Conclusion of Virtual Experience**
12:45 PM ET	**Lunch for In-Person Audience**
1:45 PM ET	**MAKING THE CASE FOR QUALITY** **Learn How to Document Risk, Quantify Impact, and Justify Investment Needed to Protect Your Trial** • Use ICH E6(R3) language and regulatory expectations to strengthen your internal argument • Translate quality risks into business risks leadership understands • Document the cost of inaction—from inspection findings to operational delays • Build a case for resources, remediation, or tech upgrades that leadership can't ignore, your work is too important
2:30 PM ET	**INTERACTIVE CROWD-SOURCE: FIT-FOR-PURPOSE** **How Do YOU Define Fit-For-Purpose Data Governance?** **Facilitator** *MyLe Hoang, Head of North America and EU Clinical Quality Assurance, EISAI* ICH E6(R3) raises the stakes on data governance—but leaves "fit for purpose" wide open to interpretation. In this interactive session, we turn to the experienced experts in the room to define what good looks like. • How are you managing oversight across vendors, systems, and decentralized models? • What documentation is enough—and what's just noise? • How are you balancing audit readiness with operational sanity? No slides. No theory. Just real strategies and shared experience from clinical pros doing the work.
3:00 PM ET	**Networking and Refreshment Break for In-Person Audience**

3:30 PM ET	**PRACTICAL QUALITY MANAGEMENT** **Build a Quality Management System (QMS) that Remain Effective in Supporting Compliance as Regulations and Trials Evolve** *Dawn Lundin, Global Quality Executive Leader* • Understand the principles and behavior that drive a quality mind-set and culture from a historical perspective • Examine the core elements and how they relate to current regulatory expectations (i.e. SOP training, vendor oversight) • Evaluate a practical framework to visually see how principles, behaviors, and elements drive the quality system of today • Walk away with actionable strategies and maturity markers to evaluate your own organization's QMS and know the next steps in its evolution
4:00 PM ET	**PANEL: INNOVATION VS. COMPLIANCE** **How Leading Companies Are Reengineering Clinical Compliance with Next-Gen Tech** **Moderator** *Tim Stoddard, Quality and Regulatory Advisor: Life Sciences, Health Tech, Real World Data/Evidence* **Panelists** *Niloy Shah, Executive Director, Research & Development Quality, REPLIMUNE* *Aaron Grant, Head of Innovation, JUST IN TIME GCP* • See how leading teams are using AI and automation to rethink clinical compliance • Learn how roles, risks, and responsibilities are shifting in a tech-enabled environment • Explore how innovation aligns—or conflicts—with ICH E6(R3) expectations • Hear what early adopters have learned, and what they'd do differently next time
4:45 PM ET	**ROUNDTABLE DISCUSSIONS: CHOOSE YOUR TOPIC** **Informal Discussion with Like-Minded Quality-Driven Clinical Professionals on the Topic of Your Choice** *Engage in an intimate and informal discussion on your choice of topic below. You'll be contacted about a week or two before the conference requesting your topic preference.* 1. **Innovation vs. Outsourced Incentives** *Discuss the Hidden Conflict of Interest as Technology-Driven Efficiencies in Clinical Research Reduce the Need for Outsourced Work*

	2. **Sponsor Oversight vs. Vendor Execution** *Explore the Blurred Boundaries of Responsibility in Decentralized and Outsourced Trial Models* 3. **Risk-Based Monitoring: Are We There Yet?** *Share What's Actually Working in the Shift from Comprehensive Monitoring to Proportionate Oversight* 4. **Clinical Data By Design** *Translate R3 into Risk-Based Workflows that Improve Oversight and Inspection Readiness* 5. **Risk-Based Quality for Lean Teams** *Trade Tips on Implementing R3's Proactive Quality Mandates Without a Dedicated Function or Big Budget* 6. **TMF Reality Check** *Compare Best Practices for Balancing Completeness, Timeliness, and Quality in a Risk-Based Documentation Landscape* 7. **Technology vs. Time** *Debate Whether Automation and AI Are Saving Time—or Just Creating New Operational Tradeoffs* 8. **Leading Change Without Losing Your Mind** *Discuss How Clinical Teams are Driving Real Adoption of R3—Not Just Updating SOPs*
5:30 PM ET	**Booze and Schmooze / Mock and Talk Reception** *Have a drink and enjoy some refreshments as we casually discuss today's learnings and catch up with old friends.*
6:30 PM	Day Concludes

Wednesday, September 10 – Main Conference Day Two

8:30 AM ET	**Registration and Networking Breakfast**
9:00 AM ET	**Welcome to Day Two** *Sharon Reinhard, Clinical Quality and Compliance Thought Leader; Acting Head of Quality for Late Stage Biotechs*
9:15 AM ET	**PANEL: PARTNERSHIP BY DESIGN** **Managing Vendor Partnerships that Protect Your Trial and Support Clinical Quality—Not Compromise It**

	Panelists *Reetu Dandora, Senior i, Quality & Regulatory Compliance, AVEO ONCOLOGY* *Dennis Salotti, Executive Director & Head, Clinical Outsourcing & Innovation, JAZZ PHARMACEUTICALS* • Spot the signals your partnership may be putting your trial at risk • Ask the questions that drive alignment, accountability, and trust • Build oversight that supports compliance—without adding burden • Hear what sponsors wish they'd done differently from the start
10:00 AM ET	**FDA IN TRANSITION** **Understand the Recent Changes in the FDA and Impacts to Oversight and GCP Inspection Readiness** *Niloy Shah, Executive Director, Research & Development Quality, REPLIMUNE* • Understand how shifting FDA leadership and priorities are rewriting the playbook for inspections and accelerated approvals • Learn what sponsors must do to stay inspection-ready and avoid late-stage regulatory surprises • Gain insider perspective on proactive engagement with FDA during a period of heightened scrutiny • Walk away with actionable strategies to protect your programs in the era of public CRLs and tougher approvals
10:30 AM ET	**CASE STUDY: REMOTE REGULATORY ASSESSMENT** **From Inherited Trial to Inspection Success—Lessons from One of the First Sponsor RRAs Under the New FDA Guidance** *Michele Weitz, Principal, GCP VISION CONSULTING* • Learn how a small team with no CQA presence prepared for inspection of the company's first clinical trial, already in progress at the time of acquisition • Discuss challenges that were overcome to demonstrate compliance, with limited access to key legacy systems, documentation, and study team • Gain a clear understanding of how to navigate new Remote Regulatory Assessment (RRA) expectations and apply strategies with confidence
11:00 AM ET	**Networking and Refreshment Break**
11:30 AM ET	**GCP INSPECTION GOSSIP** **What Teams Have Experienced During Recent Inspections—and How They Are Adapting in a Time of Change** **Moderator** *Dawn Lundin, Global Quality Executive Leader*

	Panelists *Samelyse Lees, Senior Quality Advisor, GSK* *Loreena Sadowski, Senior Director, Global Quality Inspection Management, BRISTOL MYERS SQUIBB* *MyLe Hoang, Head of North America and EU Clinical Quality Assurance, EISAI* • Hear firsthand accounts from recent inspections across FDA, MHRA, EMA, and more • Learn how inspection styles are shifting in response to regulatory change and global uncertainty • Explore how ICH E6(R3) is shaping inspection focus, questions, and expectations • Bring your stories and questions—this interactive session is powered by shared experience and peer insight
12:30 PM ET	**Close of Main Conference / Lunch for In-Person Attendees**
	HANDS-ON INTERACTIVE WORKSHOPS
1:30 PM ET	**R3 GAP ASSESSMENT** **Evaluate Clinical Compliance Readiness and Build a Practical Plan for R3 Alignment** *Leslie Sam, President, LESLIE SAM ASSOCIATES, LLC* Asses your organization's current alignment with ICH E6(R3) and identify the most relevant compliance gaps. Using a structured framework, attendees will evaluate risk management practices, oversight models, and documentation strategies to develop a prioritized action plan tailored to their organization's needs. **In this workshop, you will:** • Evaluate clinical operations and oversight processes against ICH E6(R3) expectations • Identify gaps in risk management, documentation, and fit-for-purpose data strategies • Work through scenarios based on challenges surfaced during the conference • Prioritize next steps based on feasibility, business impact, and regulatory expectations • Leave with a structured, actionable plan to guide internal alignment and process updates
5:00 PM ET	**Workshop and Conference Concludes**

No virtual presentations. All speakers are in-person and most stay for the duration of the event.

Speakers receive complimentary registration to the full two-day event, including a post-conference workshop. For more details on speaking reach out Kristen Hunter at kristen@khconferences.com.

THE IN-PERSON EXPERIENCE

KH Conferences

Join us in Philadelphia for the full experience—every session, every connection, every opportunity to shape what's next.

- **Dates and Timing**
  - Tuesday, September 9th, 8:00 AM ET – 6:30 PM ET
  - Wednesday, September 10th, 8:30 AM ET – 1:30 PM ET
    - Optional Post-Conference Workshop on R3 Gap Assessment 1:30 PM ET – 5:00 PM

- **Location**
  - CYTO|PHYL @ Cira Centre, 2929 Arch Ste 250, Philadelphia, PA 19104

- **Accommodations**
  - The event space is not part of a hotel, so please secure your own accommodations if needed.
    - The following locations are all within walking distance to the event venue
      - The Study at University City – 0.6 mile
      - AKA University City – 0.4 mile
    - These hotels are just a short drive away
      - Sonesta Philadelphia Rittenhouse Square – 0.9 mile
      - The Inn at Penn, a Hilton Hotel – 1 mile

- **In-Person Pricing**
  - Pharma/Biotech/Device Company Registration
    - Main Conference - $1,499
    - Post-Conference Workshop + $350
  - General Registration
    - Main Conference - $1,999
    - Post-Conference Workshop + $350

- **What does that Include?**
  - Two days out of the office to be face to face with like-minded peers and walk through common challenges and leave inspired and motivated to take action and make change.
  - In-Person access to all sessions and presentations listed in agenda
    - PDF versions of all slides presented, pending speaker approval
    - Your choice of roundtable discussion
    - Optional post-conference workshop add-on
  - All networking breaks and Booze and Schmooze/Mock and Talk Reception
  - Breakfast, lunch and ample snacks and beverages for the duration of the conference
  - Access to the conference app for pre, during, and post event engagement with entire audience (both in-person and virtual)
  - On-demand access to the live-streamed sessions via the conference app

THE VIRTUAL EXPERIENCE

Can't attend in person? Stream selected sessions live and engage with the full community—on your schedule, from anywhere.

- **Dates and Timing**

- Live Stream Access – Real-Time Engagement with Speakers and In-Person Audience
  - Tuesday, September 9th, 9:00 AM ET – 12:30 PM ET
- On-Demand Access to Streamed Sessions – Available shortly following session conclusion through conference app

- **Virtual Pricing**
  - Pharma/Biotech/Device Company Registration - $599
  - General Registration - $799

- **What does that Include?**
  - Live-stream access to select main stage sessions on September 9
  - Real-time participation in Q&A and chat during live-streamed sessions
  - On-demand access to all streamed sessions via the conference app after the event
  - Access to the conference app for pre-, during-, and post-event engagement with the full audience (in-person and virtual)
  - Downloadable session slides (PDFs) from streamed presentations, pending speaker approval

SPONSORSHIP OPPORTUNITIES

There are a limited amount of available speaking and exhibition opportunities at this conference for service and technology providers. This ensures maximum exposure and a balanced audience. For more information on the available opportunities, please click here.

AUDIENCE SNAPSHOT

- 50-65 in-Person Participants
- 50-75 Virtual Participants
- Mostly Trial Sponsors with 20+ years of industry experience
- Key functions/departments
  - Clinical Compliance
  - Clinical Quality
  - Clinical Operations