



GCP REWIRED WITH KEVIN RICHARDS

Real conversations about digital transformation in clinical research.

Real AI Use Cases for GCP Inspection Readiness, Scaled for Any Organization

Kevin Richards | Head of Clinical Quality | AstraZeneca
In conversation with Kristen Hunter, KH Conferences

Virtual | 90 Minutes | November 10

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AGENDA

11:00 AM ET | WHERE THE INDUSTRY ACTUALLY IS

Opening Conversation | Kevin Richards with Kristen Hunter

- See where your organizations stand on **AI and inspection readiness** compared to peers across the industry.
- Hear Kevin's perspective on **where the industry stands** in translating digital quality investments into meaningful operational improvements.
- Discover what inspection readiness looks like at **an organization that isn't scrambling** before every audit, and how that changes where time and resources belong.

11:10 AM ET | THE FRAMEWORK THAT MAKES AI WORK IN A GxP ENVIRONMENT

Why AI in Quality Stalls, and What Helps Move It into Practice

Before the use cases: the model behind all of them, and why organizations can end up building the wrong thing first.

- Examine the design decisions that can determine whether a quality AI tool **changes how work gets done** or simply generates more information.
- Explore the approach AstraZeneca uses to evaluate potential use cases before building, and why **skipping this step is where most failed implementations begin**.
- Recognize why treating **structured and unstructured quality data** the same can cause inspection readiness initiatives to stall before producing results.
- **Explore how technology enablement is changing risk-based quality approaches**, creating opportunities to identify emerging risks earlier and move toward proactive quality oversight.

11:30 AM ET | INSIDE THE USE CASES: WHAT AZ ACTUALLY BUILT

Real Examples. Real Results. Running Today.

USE CASE 1 | Stop Searching. Start Acting.

Automated Signal Detection from Structured Data

- Examine how AstraZeneca **eliminated thousands of hours of manual data review** across their study portfolio and what made it work in a GxP environment.

- Identify the difference between a quality signal **appearing on a screen versus entering a controlled workflow**, and why it determines whether an AI investment produces results or just reports.
- Hear what didn't work as expected after implementation, what the team had to adjust, and what they would design differently today.
- Explore what your study teams would be able to stop doing if this capability existed at your organization.

USE CASE 2 | Make Inspection Readiness Continuous, Not a Scramble

Proactive Inspection Readiness at Scale

- See what it means to **measure inspection readiness** instead of estimate it, and how teams respond after making the shift.
- Learn how connecting data across systems gave global study managers **a view of their readiness posture** that was not previously possible, and what changed as a result.
- Hear Kevin's argument that **proactive quality at scale is not achievable without technology**, and assess it against your own organization's experience.
- Explore what was harder than expected in moving from periodic readiness activities to a more continuous model, including where technology alone wasn't enough.

USE CASE 3 | See Quality Issues as a System, Not a Stack of Tickets

Systematic Risk Identification Using NLP

- Examine what AstraZeneca found when they stopped reviewing quality issues one at a time, and why **recurring patterns had been invisible in their QMS for years**.
- **Explore how NLP makes it possible to analyze unstructured quality information at scale**, revealing relationships and trends that traditional review processes may overlook.
- Assess how **systematic pattern detection redirects quality team focus** — from resolving individual tickets to addressing root causes — and what that means for your inspection posture.
- See what the team learned about the quality and usability of its existing data, what had to change, and what that means for organizations considering a similar approach.

12:00 PM ET | HOW TO APPLY THIS AT YOUR ORGANIZATION

From AstraZeneca's Scale to Yours | A Conversation with Kevin Richards and Kristen Hunter

Kristen puts Kevin in the hot seat to explore what it actually takes to move from inspiration to implementation.

- **If you were starting at a 200-person biotech tomorrow, where would you begin?** Which capabilities would you prioritize, which would you defer, and what wouldn't you invest in yet?
- **What's the biggest mistake organizations make when getting started?** What seems like a logical first step but can actually create problems down the road?
- **How do you align your technology roadmap with your quality strategy?** How can organizations avoid investing in technology simply because it's available and instead use it to advance risk-based quality and proactive oversight?
- **What indicators demonstrate that your organization is truly ready?** What needs to be in place from a data, technology, governance, and operational perspective before pursuing these types of use cases?
- **What can smaller organizations realistically accomplish without significant technology investments?** Where can existing systems, processes, or data be leveraged to make meaningful improvements in quality oversight?

12:15 PM ET | OPEN Q&A

Your Questions for Kevin | Facilitated by Kristen Hunter

Off the record. Unscripted. Unfiltered. This portion of the program will not be recorded, creating space for a candid conversation where you can ask Kevin the questions that matter most to your organization.

WHAT ATTENDEES WILL WALK AWAY WITH

- **A firsthand look at how AstraZeneca is operationalizing AI** to strengthen GCP quality oversight and continuous inspection readiness.
- **Three real-world AI use cases**, including how they were developed, what worked, what didn't, and lessons learned.
- **An understanding of where AI can deliver the greatest impact across GCP quality**, from identifying emerging risks to enabling proactive oversight and strengthening inspection readiness.
- **A practical approach to evaluating AI opportunities**, including how to assess organizational readiness and align technology investments with quality priorities.
- **Realistic next steps for your organization**, including what to prioritize, what to defer, and how to make progress with the resources you have.

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