

ASQ Audit Division

March Webinar

Title:

Using AI for Critical Audit Workflows



Friday

March 13, 2026



Time

11:00AM - 12:00PM (CST)

Speaker:

George Kwiecinski



Special Guest: Daniel Barreto

Using AI for Critical Audit Workflows ASQ Audit Division Webinar

March 13, 2026 | 12:00 PM EST

What we'll cover today.

A practical session for quality, compliance, and audit professionals on applying AI to the audit lifecycle — from preparation through reporting.

How AI works in a GMP environment.

What to look for in the technology.

A deep dive into AI's capabilities across the audit workflow.



March 13, 2026 at 12pm EST / 11am CST

Register Here: <https://lnkd.in/gJVDU7U7>

Speaker Intros



KeyPedia™ Intro



KEYPEDIA™

KeyPedia™ Intro



G Please Introduce Yourself.

Hello! I'm your FDA regulatory assistant. I can help you find information from FDA databases, including 483s, Warning Letters, inspections, and enforcement actions. I can also access international regulatory data, company profiles, and the FDA Orange Book. If you have any questions about these resources, feel free to ask!

● Thought process

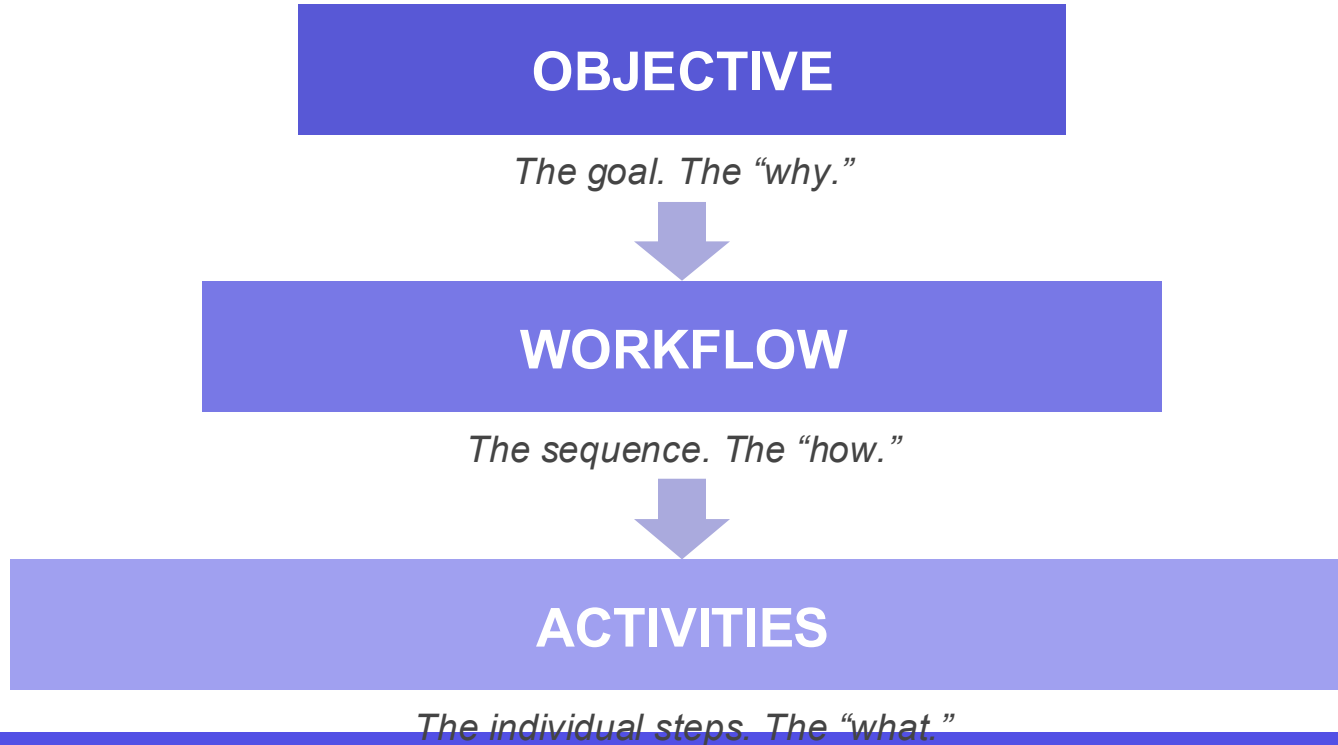
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Agenda

- **Speaker Introductions & KeyPedia Overview**
- **The Audit Lifecycle: Principles, Process & What Makes Each Phase Critical**
- **AI for Audit Workflows: Preparation, Investigation, Frontroom/Backroom, Reporting**
- **Live Demo: KeyPedia in Action**
- **Q&A**

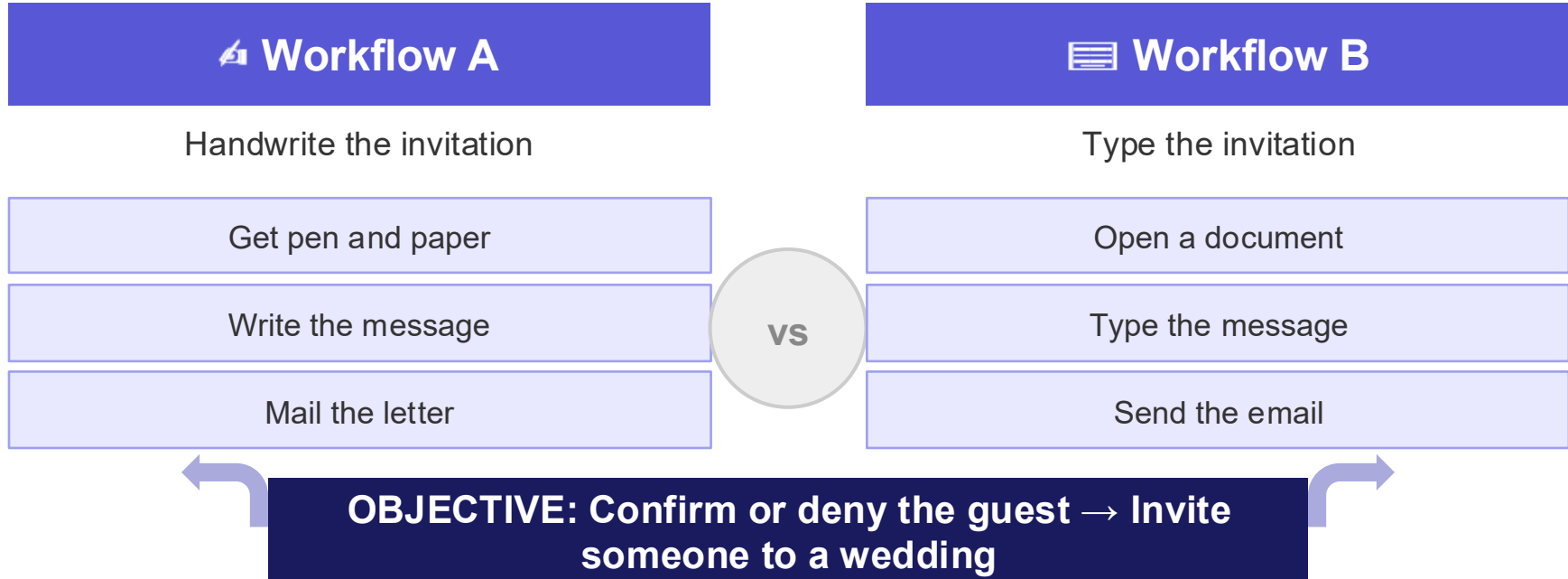
Activities. Workflows. Objectives.

- These three things are different. Understanding the difference changes how you audit.



One Objective. Many Workflows.

The workflow is not the objective. It just serves it.



So What Is an Audit?

In Principle

A verification activity.

Confirming organizations do what they're supposed to do.

In Practice

A form of scrutiny.

Finding what people are doing wrong — often after internal audits already missed it.

The Goal: Self-Regulation — A good audit program should make external enforcement redundant.

Applied through the DOM framework: **Design** (intent) → **Operating** (execution) → **Monitoring** (verification). Each audit phase maps to all three.

The Audit Lifecycle

What Is an Audit Workflow?

- **An audit workflow is a structured sequence of activities with a defined objective.**
- **In principle, audits are a verification activity, confirming an organization is doing what it's supposed to do.**
- **In practice, when audits fail to catch real problems, they give false confidence, and that's when the FDA finds what the internal audit missed.**
- **A robust audit program should drive self-regulation; the goal is to make external enforcement redundant.**
- **Each workflow step must serve a clear objective, not just be completed.**
-

The Audit Process Flow

Five stages. Each with a distinct objective. All interdependent.

- 1. PREPARATION → Goals & objectives. Why are we doing this audit? What are we looking for?
- 2. AUDITOR SELECTION → Match the auditor to the audit. Right skills, right scope.
- 3. ACTIVE AUDIT → Execution of the audit plan. Prioritization and questioning.
- 4. REPORTING → Clarity, precision, systemic findings. Expectations for correction.
- 5. POST-AUDIT → Corrective action plan feedback. Did the audit strengthen the auditee?

Critical Factor at Each Stage

Each step has a most important activity. Get that wrong and the whole step fails.

- Preparation: Goals & objectives — know exactly what you need to verify before you walk in. Auditor Selection: Match auditor expertise to the audit scope. The wrong auditor misses the right findings.
- Active Audit: Audit plan execution — the right questions, in the right order, with limited time. Reporting: Clarity and precision. Systemic issues must be named, not buried. Post-Audit: The corrective action feedback loop. An audit that doesn't improve the auditee wasn't worth the cost.

Audits Are Expensive. And most organizations aren't getting the return they should.

- The cost is direct: auditor fees, travel, preparation time, backroom staffing, document retrieval. For regulated industries, this can run \$50K–\$200K+ per audit cycle.
- The cost is also indirect: if a company received a warning letter in 2026, their internal audit program ran in 2021, 2022, 2023, 2024, and 2025 — and missed it every time. Those audits did not pay for themselves. Remediation after a warning letter dwarfs the cost of better audits earlier.

AI for Audit Workflows

KeyPediaAI for Preparation: Smarter Audit Readiness

KeyPediaAI for Investigation: Who, What, When, Why

AI in the Audit Room: Frontroom & Backroom

- **Frontroom:** The auditor faces the auditee. Every question must count. AI helps you ask the right ones.
- **Backroom:** The support team is under pressure. Finding the right documents, the right SME, the right language — fast.
- **The challenge:** communicating across functions. AI can help translate technical language so the right answer reaches the right person in time.
- **KeyPedia** helps you locate the right regulatory data and context in real time — so your SME speaks with confidence, not guesswork.

AI for Reporting: Quality Matters

Writing observations is the easy part. Writing good ones is the hard part.

- General-purpose AI (ChatGPT, etc.) can help draft observations — but data quality and regulatory accuracy are still a concern. An observation is only as good as the evidence and context behind it.
- The best audit reports use agency-level language — precise, systemic, and defensible. KeyPedia’s regulatory dataset gives you the right framing: how FDA actually writes observations, what language triggers escalation, and what an effective corrective action response looks like. Reporting will only get simpler — quality is what separates good from great.

Where to find more answers?



GKS Researchers Publish Study on FDA's Foreign Drug Inspection Gap

Mar 9, 2026 · George Kwiecinski & Kevin Y...

GKS publishes peer-reviewed research on FDA's foreign GMP inspection gap. A decade of import growth vs. declining inspections. Read the open...

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50th International GMP Conference Days 2 and 3 Recap | GKS

Mar 6, 2026 · George Kwiecinski

GKS recap of Days 2 and 3 at the 50th GMP Conference: GMP case studies, OPQ update, and fireside chat with former FDA Commissioner Califf.

Read more →



50th International GMP Conference Day 1 Recap: AI, Inspections, and the Future of...

Mar 3, 2026 · George Kwiecinski

GKS recap of Day 1 at the 50th International GMP Conference. Firsthand notes on AI in FDA compliance, 483 guidance, and sterile manufacturing.

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KEYPEDIA™

KeyPedia™ Lite

Your free gateway to global regulatory intelligence. Explore and evaluate our comprehensive databases. Browse regulatory records, registered companies, agency offices, and key personnel across FDA, EMA, and other international bodies at no cost.

Q Search KeyPedia for FDA regulations, compliance data, and more...

Try asking:

What are the latest FDA warning let...

Show me violation patterns for me...

How can I prepare for an FDA inspe...

What are the common compliance...

Browse the Data LITE

KeyPedia™ Lite gives you free, direct access to four core regulatory datasets. Click any section below to search, filter, and explore the data.



Records

Regulatory records, compliance documents, and enforcement actions from global agencies.

Warning Letters FDA Form 483s Recalls EMA Decisions
Brazil GMP Certificates



Companies

Companies registered with global regulatory agencies, searchable by name, location, and facility type.

Pharmaceutical Medical Devices Food Facilities FEI Numbers
Global Coverage



Offices

Regulatory offices and affairs centers worldwide including FDA, EMA, and other international agencies.

FDA Districts EMA Offices International Agencies Inspection Centers



People

Regulatory personnel including investigators, compliance officers, and regulatory affairs specialists.

Investigators Compliance Officers Inspectors Regulatory Officials

<https://www.globalkeysolutions.net/browse>

Q & A

Thank you! **Let's Connect.**



Free Webinar

Warning Letter Wednesday

 March 11, 2025

 Zoom

 12PM EST

Featured Speaker: TBD



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