The Quality Manager's Guide to Using AI in GMP Audit Readiness

*By **Batch Buddy** Team*

*How **Batch Buddy's AI Copilot** works, where it applies regulatory frameworks, and exactly where a human must verify every output before it counts.*

Defensible AI: Learn how to leverage Batch Buddy's AI Copilot to maintain full regulatory compliance, ensuring your quality processes remain robust and audit-ready at every step.

Most quality professionals encounter AI tools the same way: a vendor demo shows the AI doing something impressive, the QA team asks how it works, and the answer is some version of "it's trained on your data."

That answer is not good enough for a regulated facility.

If you are responsible for an FDA inspection, a SQF audit, a BRC certification, or a customer quality review, you cannot defend a batch record by saying an AI generated it and you trusted the output.

You need to know what the AI evaluated, what framework it applied, and where your signature confirmed the result.

This guide explains exactly that for the Batch Buddy AI Copilot — how it makes recommendations, how it maps to the regulatory frameworks your facility operates under, and how to use it in a way that is defensible in front of an auditor.

Section 1: How the Copilot Makes Recommendations (Not a Black Box)

The Batch Buddy Copilot is not a general-purpose chatbot. It operates within a defined scope: your formulations, your production records, your lot numbers, and your ingredient inventory.

When you ask it a question, it is querying your actual account data rather than a generic training database.

Operational Workflow

The Copilot follows a structured process when you ask a compliance question to ensure transparency and accuracy.

01

Identify Framework

It identifies which regulatory framework applies based on your facility type and the question context (supplement = 21 CFR Part 111, food = 21 CFR Part 117 / FSMA 204, cosmetics = ISO 22716).

02

Retrieve Records

It retrieves the relevant records from your Batch Buddy account — batch records, lot numbers, production steps, signatures, and ingredient COAs.

03

Compare Against Requirements

It compares what exists in your records against the documentation requirements for that framework.

04

Report Findings

It tells you what it found, what is missing, and what it recommends — with explicit statements about confidence level.

05

Log to Audit Trail

It logs every interaction to your FDA 21 CFR Part 11 audit trail, including the question, the context it retrieved, and the recommendation it made.

What it does NOT do

- It does not modify your data without your explicit confirmation.
- It does not access records from other Batch Buddy accounts.
- It does not make regulatory determinations that require human professional judgment.
- It does not guess. If it cannot find a record or does not have enough context, it says so.

The Confidence System

Every Copilot response carries an internal confidence score.

For routine queries, such as looking up a lot number or summarizing a formula, confidence thresholds are lower.

For high-stakes actions — starting a production run, logging a deviation, or releasing a quarantined lot — the system requires a higher confidence threshold *and* password re-authentication before executing.

This is not a UX choice; it is a design requirement for FDA 21 CFR Part 11 e-signature compliance.

Key Takeaway: The Batch Buddy Copilot is designed as a transparent tool that maps directly to your regulatory frameworks, ensuring that every AI-assisted action is documented, verified, and defensible in an audit trail.

Section 2: ALCOA+ and How Batch Buddy Satisfies Each Principle

ALCOA+ is the FDA's core data integrity framework. Any electronic batch record system evaluated by an FDA inspector will be measured against these principles.

Batch Buddy is built from the ground up to ensure your data stays compliant. Below is a mapping of how Batch Buddy satisfies each ALCOA+ principle, and how our Copilot interacts with these requirements in real-time.

Data Integrity Mapping

The following table outlines how Batch Buddy manages core compliance principles while leveraging AI-assisted oversight.

ALCOA+ Principle	What It Requires	How Batch Buddy Satisfies It	Copilot Relevance
Attributable	Every entry must be traceable to the person who made it	User authentication on every write action; Copilot-executed actions are attributed to the logged-in user with e-signature binding	Copilot cannot act without a logged-in session; all actions show the user's name in the audit trail
Legible	Records must be readable and permanent	Digital records stored in structured PostgreSQL database; human-readable exports as PDF/EBR	Copilot outputs are plain-language summaries, not encoded outputs
Contemporaneous	Records must be created at the time of the activity	Timestamps generated server-side at time of event, not editable by the user	Copilot logs the timestamp of every recommendation and every confirmation
Original	The first-captured record is the authoritative version	Soft-deletion pattern — no record is permanently deleted; the original is always preserved	Copilot can retrieve original records; it cannot overwrite them
Accurate	Records must truthfully reflect what occurred	Input validation, numeric precision (no floating-point rounding), pre-production inventory checks	Copilot flags discrepancies between planned and actual quantities
Complete	No required fields may be missing	Required field enforcement at form level; Copilot gap assessments check for missing signatures, COAs, and production steps	Gap assessment prompts identify incomplete records before an auditor does
Consistent	Records across a batch must not contradict each other	Lot traceability links ingredient receipts → formulas → production runs → shipments in a single chain	Copilot can verify the chain is unbroken for any lot number
Enduring	Records must be retained for the required period	Soft deletion with retention; records cannot be permanently removed by end users	Copilot reads from the full retained record set, including soft-deleted items
Available	Records must be retrievable on request	Full export capability; search by lot number, date range, product, customer	Copilot can pull and summarize any record on demand — useful during a live inspection

Key Takeaway for Audits: The Copilot prompt "Check my ALCOA+ compliance for [product name] lot [lot number]" will retrieve the relevant records and flag any principle where documentation appears incomplete. This does not replace a formal validation study but it is a useful pre-audit sweep.

Section 3: Regulatory Frameworks the Copilot Applies

Our Copilot is built with deep-context awareness for global regulatory standards. It can reference these specific frameworks when evaluating your batch records, helping you maintain compliance across different product categories.

The following table outlines the key standards supported by the system:

FDA 21 CFR Part 111

Dietary Supplements

This is the primary GMP standard for supplement manufacturers. The Copilot checks batch record completeness against:

- Subpart J (batch production records)
- Subpart L (laboratory operations)

It proactively flags missing lot numbers, unsigned production steps, and absent COAs.

FDA 21 CFR Part 117

Food / CGMP

For food manufacturers, the Copilot monitors compliance with Part 117 requirements, specifically focusing on:

- Allergen controls
- Sanitation monitoring records
- Supplier verification documentation

FSMA 204

Food Traceability

For facilities covered by the FDA's Food Safety Modernization Act Section 204, the Copilot retrieves Key Data Elements (KDEs) for Critical Tracking Events (CTEs), including receiving, transformation, and shipping. It can generate comprehensive traceability reports for any ingredient lot back to the supplier.

ISO 22716

Cosmetics GMP

The Copilot applies specific ISO 22716 criteria tailored for cosmetics manufacturers, focusing on batch documentation, raw material specification compliance, and essential quality control records.

21 CFR Part 11

Electronic Records and Signatures

The Copilot platform is architected for Part 11 compliance. Every action requires explicit user confirmation and is logged with a permanent timestamp and user identity. The audit trail remains read-only to ensure non-repudiation.

SQF and BRC

Third-Party Certification

For facilities pursuing SQF or BRC certification, the Copilot provides specialized gap assessment capabilities, allowing you to audit your batch documentation against these specific code requirements.

Note on Scope: While the Copilot is highly effective at identifying gaps and verifying requirements, its assessments are intended as a pre-audit tool and do not replace the necessity of a formal, documented validation study.

Section 4: AI-Assisted Audit Readiness — A Step-by-Step Workflow

This workflow is designed to be used as a Standard Operating Procedure (SOP) for pre-audit preparation. If an auditor asks how you used AI in your quality system, this document and this workflow are your answer.

Follow these steps to systematically prepare your records for inspection. By leveraging the Copilot for pre-audit assessments, you ensure that potential gaps are identified and addressed well before an inspector arrives on-site.

> **SOP Tip:** Always maintain a record of your Copilot interaction logs. Showing an auditor that you proactively used these tools to maintain compliance demonstrates strong quality oversight.

1

Step 1: Run a Full Gap Assessment (2–4 weeks before audit)

Use the Copilot to identify missing or incomplete records before the auditor arrives.

Prompt: Run a gap assessment on my batch records from the last 90 days. Flag any production runs with missing signatures, unsigned deviations, or COAs that have not been uploaded.

Review the output carefully. For each flagged item, open the record directly in Batch Buddy and correct it through the normal workflow.

Important: Do not ask the Copilot to correct it automatically. The correction needs a human decision and a dated signature.

2

Step 2: Verify Your Lot Traceability Chain

An FDA inspector or SQF auditor will almost certainly ask you to trace a specific lot from raw material to finished product (or from finished product back to raw material). Practice this before they arrive.

Prompt: Trace lot number [LOT-XXXX] from receipt to shipment. Show me every production run it was used in and every customer order it was shipped to.

The Copilot will pull the full traceability chain. Verify that the chain is complete with no gaps between receipt, production, and shipment. If there are gaps, investigate and document the explanation before the audit.

3

Step 3: Confirm Electronic Signature Coverage

Part 11 requires that every required record entry is signed by the person responsible.

Prompt: List all production runs completed in [date range] that have unsigned steps or missing operator signatures.

Any unsigned steps identified here represent a genuine audit finding. Correct them before the audit date, ensuring you document why they were unsigned and when they were resolved.

4

Step 4: Prepare Your ALCOA+ Summary

Prompt: Summarize the ALCOA+ compliance status of my batch records for the last quarter. Flag any principle where I have incomplete coverage.

Use this output as the basis for an internal pre-audit ALCOA+ review meeting.

Print or export the Copilot's response. It is logged to your audit trail automatically, which serves as objective evidence for the auditor that you conducted this check.

5

Step 5: Brief Your Team on Human-in-the-Loop Requirements

Before any audit, remind every team member of the rule in Section 5 of this guide: the Copilot's output is a recommendation, not a signed record.

Every Copilot recommendation that affects a batch record, a lot status, or a deviation log requires a human to review, confirm, and take responsibility for the action.

Section 5: Where a Human Must Always Verify

This section is the most important in the guide. Please review it carefully.

> **CRITICAL REMINDER:** The Copilot is an assistive tool designed to increase efficiency and support oversight. However, it does not replace professional human judgment. For any decision affecting product safety, compliance, or quality disposition, final authority and responsibility must rest with a qualified individual.

The Copilot is a tool that improves speed and catches things humans might miss; however, it does not replace human judgment for the following critical decisions. Below are the key areas where human verification is mandatory:

Lot Release Decisions

Scope: Determining if a lot is safe for release.

The Copilot can check whether all required QC records are present and whether any open deviations exist for a lot. It cannot decide that a lot is safe to release. That decision belongs to a qualified person — QA manager, quality director, or designated release authority.

Deviation Classification

Scope: Assessing discrepancies and determining reportability.

When the Copilot identifies a discrepancy (e.g., actual batch weight differs from target by more than tolerance), it will flag it as a potential deviation. A human must determine whether it is a reportable deviation, a documentation error, or within acceptable limits — and must document that determination with a signature and date.

Out-of-Specification (OOS) Results

Scope: Conducting investigations and impact assessments.

If a COA or in-process test result is OOS, the Copilot can retrieve the relevant records and prompt you through the required steps. The investigation itself — root cause analysis, impact assessment, disposition decision — requires human expertise and a signed record.

Supplier Qualification Decisions

Scope: Approving suppliers and accepting COA deviations.

The Copilot can pull supplier COAs and check them against your ingredient specifications. Whether a new supplier is approved, or a deviation in a supplier's COA is acceptable, is a qualified person's decision.

Customer Complaint Dispositions

Scope: Determining corrective actions and market actions.

The Copilot can retrieve all lot and production data related to a complaint. The determination of whether to issue a voluntary recall, a market withdrawal, or a corrective action is a human decision with legal and regulatory consequences.

> **Rule of thumb:** The Copilot helps you find the record and understand what it says. You decide what to do about it, and you sign your decision. That is human-in-the-loop manufacturing.

Section 6: Prompt Library — Batch Records & Lot Traceability

Copy and paste these prompts directly into the Batch Buddy Copilot to quickly retrieve production insights. Use the examples below as templates for your inquiries.

Tip: Make sure to replace all bracketed text (e.g., [RUN-XXXX]) with your specific data or values before sending the prompt.

Batch Record Review

- Show me the complete batch record for production run [RUN-XXXX] including all signed steps, ingredient lots used, and deviations logged.
- Which production runs completed this month are missing a final release signature?
- Compare the theoretical yield vs. actual yield for all production runs in [product name] over the last 6 months.

Lot Traceability

- Trace ingredient lot [LOT-XXXX] from receipt through every production run it was used in.
- Which finished goods lots contain ingredient [ingredient name] from supplier [supplier name]?
- Show me all customer orders that shipped finished goods from lot [LOT-XXXX].
- Which ingredient lots are expiring in the next 30 days and have not been used in production?

Section 6 (Continued): Prompt Library — Compliance, FSMA, SQF/BRC & Operations

This continuation of our prompt library focuses on regulatory compliance, traceability, and operational insights to streamline your daily workflows.

Compliance Gap Assessment

- Check my batch records from the last 90 days for missing signatures against 21 CFR Part 111 requirements.
- List all production deviations logged in the last 6 months that have not been closed with a corrective action.
- Which of my active formulas are missing a complete ingredient COA on file?
- Run an ALCOA+ check on batch record [RUN-XXXX] and flag any gaps.

FSMA 204 Traceability

- Generate a Key Data Element report for ingredient [ingredient name] lot [LOT-XXXX] including Critical Tracking Events from receipt to transformation.
- Which of my finished goods in the last quarter can be traced back to a single ingredient lot in under 2 hours?

SQF / BRC Preparation

- Summarize all open CAPA (corrective and preventive actions) from the last 12 months with their current status.
- List all supplier COAs received in the last 90 days and flag any where the certificate of analysis is expired.

Inventory and Cost

- What is the current on-hand quantity of [ingredient name] and which lots are available?
- Which ingredients are below their reorder point right now?
- Show me the cost per batch for [product name] using current ingredient costs.

Production Planning

- Do I have enough inventory to run [quantity] batches of [product name] next week?
- Show me all planned production runs for the next 14 days and flag any where ingredient availability is at risk.

Tip: Remember to adapt these prompts to the specific context of your facility, including your unique product names, naming conventions, and local regulatory requirements.

Section 7: Creating Your Company SOP for AI Copilot Use

Establishing formal procedures is essential for maintaining compliance. By integrating your AI tool into a written Standard Operating Procedure (SOP), you demonstrate control and transparency to auditors.

Auditor Readiness Tip: When an auditor asks, "Do you have a written procedure for how you use this AI tool?" you should be able to provide one immediately. Use the template below to formalize your facility's requirements.

This template structure is designed to be adapted for your specific operational needs and regulatory environment.

SOP Title & Purpose

Title: Use of AI-Assisted Audit Readiness Tools in the Quality Management System

Purpose

To define the approved uses of the Batch Buddy AI Copilot in the quality management system, establish human review requirements for all AI outputs, and ensure all Copilot interactions are logged to the FDA 21 CFR Part 11 audit trail.

Scope

All quality, production, and regulatory personnel with access to the Batch Buddy platform.

Approved Uses

- Pre-audit gap assessment (see Section 4, Steps 1–4 of the Quality Manager's Guide to AI Audit Readiness)
- Lot traceability queries during inspections
- Batch record completeness checks
- ALCOA+ compliance sweeps
- Routine record retrieval during production

Prohibited Uses

- Using AI output as the final record without human review and signature
- Using Copilot recommendations to justify a lot release, deviation closure, or OOS disposition without a qualified person's independent review
- Using Copilot for regulatory submissions or responses to regulatory agencies

Review, Approval & Training

Review and approval

All Copilot outputs used in quality decisions must be reviewed by a qualified person and documented in the relevant record (deviation log, batch record, CAPA). The Copilot interaction is automatically logged to the Batch Buddy audit trail.

Training requirement

All users of the AI Copilot must read Batch Buddy's Quality Manager's Guide to AI Audit Readiness and sign a training record confirming completion.

Conclusion

The goal of this guide is not to convince you that AI is always right.

It is to give you enough transparency about how the Copilot works—what frameworks it applies, what data it retrieves, where it logs its actions, and where it explicitly defers to human judgment—so that you can use it confidently and defend its use in front of an auditor.

What the Copilot Does Best

Finding What You Missed

Finding things you would have missed (unsigned steps, expiring lots, incomplete COAs) before the auditor finds them.

Retrieving Information Fast

Retrieving information quickly during a live inspection when an investigator asks to see the traceability chain for a specific lot.

Neither of those uses replaces the qualified person. They make the qualified person faster, better-prepared, and less likely to face a 483 observation for a documentation gap that could have been caught in advance.

Next Steps

If you have questions about any of the capabilities described in this guide or want help building out the SOP for your facility, the Copilot is a good starting point—and your Batch Buddy account team is available for questions that go beyond what an AI should answer.

This guide reflects the Batch Buddy platform as of Q1 2026. Regulatory frameworks cited (21 CFR Part 11, 21 CFR Part 111, 21 CFR Part 117, FSMA 204, ISO 22716) are summarized for operational context—consult a qualified regulatory specialist for determinations that affect your facility's compliance status.