InstantGMP™ Expands AI to Quality Control Testing and 21 CFR Part 11 Audit Trail Data for Faster Inspection Readiness

CARY, NC, UNITED STATES, October 28, 2026 /EINPresswire.com/ -- InstantGMP™ Expands AI to Quality Control Testing and 21 CFR Part 11 Audit Trail Data for Faster Inspection Readiness Across All Manufacturers

> “What we have built is not a chatbot bolted onto a manufacturing system — it is an intelligence layer that works across every part of the platform at once.”
>
> *Dr. Richard Soltero*

InstantGMP™, an ISO 9001 certified Global Manufacturing Platform (GMP) for regulated and non-regulated producers alike, today announced the expansion of its AI capabilities to the InstantGMP™ LIMS Quality Control (QC) module and the platform’s full 21 CFR Part 11 audit trail. For the first time, users can query sample status, test protocol results, and system-wide data change history in plain language. Building on the agentic AI capabilities InstantGMP introduced in July, the expansion extends AI-powered intelligence across production, quality, and laboratory workflows — from incoming materials through QC testing to audit readiness — for pharmaceutical, food and beverage, dietary supplement, cosmetics, medical device, and industrial manufacturers.

Critical Data Now Instantly Accessible — Without Manual Reporting

Ahead of any regulatory inspection or customer audit, two of the most important questions a quality team must answer are also among the hardest to answer quickly: What is the current status of every open QC test? and Who changed what in our system, and when? Answering them has traditionally meant navigating multiple screens, exporting data to spreadsheets, and manually cross-referencing test protocol records against sample registers and audit logs — a process that can consume hours of quality team time each week. InstantGMP’s AI expansion replaces that work with instant, plain-language queries connected to live system data.

AI Now Covers the Full QC Testing Pipeline

The expanded AI connection to InstantGMP™ LIMS gives users direct, conversational access to the complete QC sample and testing workflow. Every sample — whether drawn from an incoming inventory receipt or pulled from a production batch — can be queried by status, material, test type, method, and batch number. Active Test Protocols (ATPs), the individual

executions of a validated Master Test Protocol (MTP) against a specific sample, are fully accessible, including submission, testing, and review dates and current status.

AI-powered QC queries now available include:
• Sample pipeline status: “Which samples are currently checked in but not yet in testing?” or “Show all samples in review for a specific material this quarter.”
• Test protocol backlog: “How many ATPs are currently In-Process across all materials?” or “Which sterility tests have been issued but not yet started?”
• Batch-level testing status: Link QC test results directly to production batch records in InstantGMP™ EBR.
• Method and protocol tracking: Query by United States Pharmacopeia (USP) method, including Sterility (USP <71>), Bacterial Endotoxins (USP <85>), pH (USP <791>), Osmolality (USP <785>), Conductivity (USP <645>), Total Organic Carbon (USP <643>), high-performance liquid chromatography (HPLC) identification, and visual appearance methods.
• Overdue and at-risk tests: Surface ATPs issued or in-process beyond expected timelines before they become inspection findings.

End-to-End Traceability: From Incoming Material to QC Release
Because InstantGMP’s QC module links samples to both inventory receipts and production batch numbers, the AI can complete a traceability chain that previously required navigating four separate screens and manually joining records. A single query can trace an incoming raw material lot through its QC sample, the test protocol executed, the result and reviewer, and into the production batch it was released into. Connecting Inventory Management, LIMS, and Electronic Batch Records in one AI-generated view delivers the traceability inspectors expect under FDA Current Good Manufacturing Practice (CGMP) regulations and 21 CFR Part 111 for dietary supplements — in seconds rather than hours.

21 CFR Part 11 Audit Trail Now Queryable Through AI
The second major expansion connects InstantGMP’s complete data audit trail — covering every insert, update, and deletion across more than 200 audited entity types, with history dating back to 2018 — to natural language AI queries. The access log layer adds a second dimension: not just what changed, but who viewed each record and when. Users can now ask:
• Data change history: “Who modified the deviation log for a specific lot and when?” or “Show all changes made to corrective and preventive action (CAPA) records this month.”
• User access patterns: “Which users accessed the batch production records screen last week?”
• System integrity checks: “Were any batch records modified after final approval?” or “Show all deletions made to inventory records in the past 30 days.”
• Inspection preparation: Generate a complete audit trail summary for a specific record, batch, or time period in seconds rather than through manual report generation.

The audit trail spans the full InstantGMP™ platform, including batch production records, ATPs, Quality Management logs (deviations, CAPAs, complaints, change controls, incidents, and audits), Inventory Management, Document Management, Equipment Log entries, and training records —

giving quality teams AI-accessible change history across every module of their manufacturing quality system.

Inspection Readiness Reaches a New Level
Combined with InstantGMP's existing AI access to QMS, EBR, and inventory data, the new QC and audit trail connections give manufacturers a complete, on-demand view of inspection readiness. A single query — "Give me an inspection readiness summary" — can now surface:

- Open deviations with age and resolution status
- Overdue CAPAs and their blocking action items
- Batch production records in quality assurance (QA) review beyond 30 days
- Personnel with overdue training assignments
- Equipment with overdue calibration entries
- Pending QC tests without results, organized by batch and material
- Anomalous data modification or access patterns from the audit trail

What previously required a multi-day coordination effort across quality, production, and lab teams now takes seconds — and can be run at any time, not just in the weeks before an inspection.
Compliant by Design for Regulated and Non-Regulated Manufacturers

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