InstantGMP Outlines AI Governance Approach for GxP Electronic Records Ahead of EU AI Act's Delayed High-Risk Deadline

CARY, NC, UNITED STATES, September 15, 2026 /EINPresswire.com/ -- CARY, N.C., September 2026 – InstantGMP™ is an ISO 9001 certified manufacturing software and Global Manufacturing Platform (GMP) detailed its approach to AI governance for GxP (Good Practice is an umbrella term for the manufacturing, laboratory, and clinical practice regulations that govern life sciences records) electronic records. The announcement is timed to the 2026 PDA/FDA Joint Regulatory Conference and addresses how AI-assisted quality management and electronic batch records can be deployed without compromising validation rigor for pharmaceutical, biotechnology, and medical device manufacturers.

> A delayed deadline is not delayed responsibility,"
> *Dr. Richard Soltero*

The timing follows a significant regulatory shift. In May 2026, European Union institutions reached a provisional political agreement on the European Commission's "Digital Omnibus" package, postponing the European Union Artificial Intelligence Act's (EU AI Act) high-risk compliance deadline for standalone AI systems up to December 2, 2027, and pushing the deadline for AI embedded in already-regulated products, such as medical devices, to August 2028. The delay has fueled debate across the life sciences industry about how AI Features inside quality systems, from anomaly detection to automated root cause analysis, reconcile with 21 CFR Part 11 data integrity requirements that predate the AI Act by more than two decades. For manufacturers, the extra runway doesn't change the underlying question regulators will still ask: can an AI-generated observation, deviation flag, or trend analysis hold up under FDA or European Medicines Agency (EMA) inspection?

InstantGMP Isn't Waiting on the Deadline

InstantGMP's regulatory affairs team began an Annex IV-aligned gap analysis and technical documentation effort for its AI-enabled features well ahead of the original 2026 deadline. That is a head start most competitors in the manufacturing software space have not yet begun. Annex IV of the EU AI Act specifies the technical documentation a provider of high-risk AI systems must maintain, covering system design, data governance, risk management, and human oversight.

- Annex IV-aligned technical documentation: Gap analysis and technical-file preparation are already underway, positioning InstantGMP customers ahead of both the original and the newly extended compliance timelines.

• Risk-tiered AI scoping: Consistent with the FDA's draft AI credibility framework, InstantGMP scopes AI features narrowly, including flagging anomalies or deviations for human review; so that lower-risk, human-in-the-loop applications stay proportional to their actual stakes rather than carrying the validation burden of a fully autonomous decision-maker.
• Native, unified audit trail: AI-assisted entries in InstantGMP™ QMS and InstantGMP™ EBR flow through the same audit trail as every other record; no bolt-on tool with a disconnected data trail to reconcile during an inspection.
• Human-in-the-loop validation: AI outputs support the record; they don't replace the reviewer, preserving the accountability structure inspectors expect to see.

Why Data Integrity Still Comes First

AI outputs used in GxP records remain subject to the same 21 CFR Part 11 electronic signature and audit trail requirements and ALCOA+ data integrity principles that govern every other entry in a batch record. Because InstantGMP™ natively integrates Electronic Batch Records (EBR), Quality Management (QMS), Manufacturing Execution System (MES), and Laboratory Information Management System (LIMS) functionality in a single pre-validated platform, AI-assisted entries stay attributable, legible, contemporaneous, original, and accurate, with full traceability back to the source data and the operator who entered it. This all-in-one cloud-based manufacturing platform approach benefits manufacturers across pharmaceutical, biotechnology, dietary supplement and nutraceutical, and medical device production who are beginning to evaluate AI-enabled tools inside their quality systems, as well as contract manufacturers managing GxP records on behalf of multiple clients.

InstantGMP has been publishing its analysis of these questions throughout 2026, including:
• FDA's 7-Step AI Credibility Framework, Decoded for GMP Manufacturing
• Annex 22 Excludes LLMs from Critical GMP Applications. Where Does That Leave Your Agentic AI?
• AI Took a Shortcut and the FDA Noticed. Here's What Purolea's Warning Letter Really Tells Us.
• AI in GMP Manufacturing: What Nobody Tells You About Validation
• Agentic AI and InstantGMP: What Works Now
• Root Cause Analysis Used to Take a Year. AI Changes That.
• AI Quality Management Starts Where Data is Entered

"A delayed deadline is not delayed responsibility," said Dr. Richard Soltero, President of InstantGMP. "Manufacturers don't need to wait until December 2027 to figure out whether an AI feature belongs in a validated record. We built our AI governance work into the platform itself so that it is natively connected to the same audit trail, the same electronic signatures, and the same data integrity principles our customers already trust. That's the approach we're bringing to the conversation in Washington this month."

Manufacturing Software Built for the AI Governance Conversation

InstantGMP is a global manufacturing platform that provides electronic batch records, inventory management and LIMS for manufacturers across pharmaceutical, biotechnology, dietary

supplement, food and beverage, and medical device industries. The GMP in InstantGMP stands for Global Manufacturing Platform, reflecting the system's ability to serve any manufacturer that needs traceable production records and quality management. As AI capabilities move further into quality management and batch documentation, InstantGMP's position is that governance needs to be a part of the platform, not layered on top of it.

Schedule a demo today to see how InstantGMP keeps AI-assisted GxP records validated and audit-ready, or contact InstantGMP to talk with the team ahead of the 2026 PDA/FDA Joint Regulatory Conference.

About InstantGMP™, Inc.

Founded in 2004 by Dr. Richard Soltero, InstantGMP, Inc. is a Global Manufacturing Platform, cloud-based software company delivering affordable, all-in-one manufacturing solutions for producers across pharmaceuticals, biotechnology, dietary supplements, food and beverage, health and beauty, cosmetics, medical devices, and other regulated and non-regulated industries.

InstantGMP is pre-validated to 21 CFR Part 11, GAMP 5, ISO 13485, and EMEA Annex 11 standards, and supports electronic signatures and full audit trail compliance across all modules. The platform is purpose-built for small, mid-size, and growing manufacturers who need inspection-ready quality systems that are practical, affordable, and fast to implement.

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