InstantGMP Modernizes Software Validation with FDA Computer Software Assurance-Aligned Approach

CARY, NC, UNITED STATES, December 15, 2025 /EINPresswire.com/ -- InstantGMP™, a provider of cloud-based GMP and FDA compliance software for pharmaceutical and other regulated manufacturers, announced it has aligned its software development and validation practices with the FDA's Computer Software Assurance (CSA) for Production and Quality System Software guidance.

By applying FDA CSA principles, InstantGMP has adopted a risk-based validation framework that focuses testing and documentation efforts on features that present the highest process risk, those that could affect production, quality systems, data integrity, or regulatory decision-making. Because InstantGMP's software is not classified as a medical device or part of a device, this approach centers specifically on process risks.

> "Adopting FDA Computer Software Assurance principles allows us to reduce unnecessary documentation while keeping validation where it matters most," said Dr. Richard Soltero, President of InstantGMP."
>
> *Dr. Richard Soltero*

InstantGMP categorizes software functions into low, moderate, and high process-risk groups. Low-risk features, such as equipment, room, deviation, and CAPA logs, primarily collect or tabulate data. Moderate-risk features, including inventory adjustments, batch record data-entry steps, and quality reviews and approvals, always require human oversight and authenticated signatures. High-risk, fully autonomous decision-making features are not present in the InstantGMP platform, further reducing process risk for customers.

A core design principle of InstantGMP is that no regulated action occurs without user intervention. Role-based access control, electronic signatures, and comprehensive audit trails

ensure traceability and help prevent unauthorized changes, directly supporting FDA CSA's emphasis on human review as a risk mitigator.

While CSA guidance encourages the use of less burdensome assurance activities for low- and moderate-risk features, InstantGMP intentionally maintains a high level of rigor. The company's validation approach includes scripted qualification testing for all features, automated test execution using GXtest, full requirements traceability, validation summary reports for every release, and documentation managed through a controlled document management system (DMS).

For customers, this combination of CSA principles and comprehensive testing offers:

- Stronger compliance assurance for GMP and FDA requirements.
- Reduced validation burden and faster implementation on a hosted platform.
- Improved traceability and audit readiness through electronic links between requirements, tests, and approvals.
- Greater confidence in the reliability of production and quality workflows.

"Adopting FDA Computer Software Assurance principles allows us to reduce unnecessary documentation while keeping validation where it matters most," said Dr. Richard Soltero, President of InstantGMP. "Our customers benefit from a risk-based approach that supports compliance, shortens implementation timelines, and helps them stay ready for audits."

To learn more about our all-in-one manufacturing, inventory, and quality software, contact our sales team today to schedule a demonstration.

About InstantGMP™, Inc.

Founded by pharmaceutical industry veteran Dr. Richard Soltero, InstantGMP, Inc., offers affordable all-in-one manufacturing, inventory and quality software. The company develops cloud-based electronic batch record software and standard operating procedures specific to industries that are required to follow FDA manufacturing regulations and Good Manufacturing Practices ("GMP").

As a manufacturing software company, InstantGMP™ pioneered accessible, easy-to-use electronic batch record software for products manufactured using GMPs. The Company's updated software simplifies the documentation and approval procedures for quality processes that keep all quality documentation organized in electronic format while providing for quality checks and workflow processes to make compliance with FDA requirements easy.

Debbie Young
InstantGMP
+1 919-645-1073

email us here
Visit us on social media:
LinkedIn
Facebook
YouTube
