InstantGMP Customer achieves successful FDA Audit in under 2 Days with full Product Traceability delivered in 90 Minutes

When the FDA Comes Knocking, Every Minute Counts

CARY, NC, UNITED STATES, June 22, 2026 /EINPresswire.com/ -- InstantGMP™, a leading provider of cloud-based manufacturing, inventory, quality, and lab management software, is proud to announce a landmark customer achievement: dietary supplement manufacturer Ultrabotanica completed a full U.S. Food and Drug Administration (FDA) site inspection in approximately two days, a process that typically consumes an entire week for manufacturers still relying on paper-based systems. At the center of that result was InstantGMP™ PRO, which enabled Ultrabotanica's team to trace a finished product from bottle to raw material in approximately 90 minutes, with every batch record, test result, and vendor lot linked by a time-stamped audit trail.

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>
> *Adam Payne*

When the FDA Comes Knocking, Every Minute Counts

For dietary supplement manufacturers operating under 21 CFR Part 111, the FDA's Current Good Manufacturing Practice (CGMP) requirements for dietary supplements, an FDA inspection is one of the most demanding operational events a company can face. Investigators expect immediate access to complete, accurate, and traceable records: production batch records, raw material identity testing, potency verification, packaging documentation, and the chain of custody connecting every ingredient to every finished unit on the shelf. In a paper-based environment, assembling that evidence trail means days of staff pulling binders, manually reconstructing records, and hoping nothing is missing. That is the reality for many small and mid-size supplement makers and is the very problem InstantGMP™ was built to eliminate.

With InstantGMP™ PRO, Ultrabotanica's team pulled a finished product and traced it end-to-end: from finished bottle through packaging Batch Production Records (BPR), FTIR identity testing, capsuling batch, conjugate batch, and back to incoming raw materials, in approximately 90 minutes. Every step was time-stamped. Every identity and potency test was linked. The finished-good specification matched the bottle in real time.

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What Made the Difference: Electronic Records Built for Inspection Readiness

InstantGMP™ PRO is purpose-built for manufacturers who need FDA inspection-ready documentation without adding complexity to day-to-day operations. The capabilities that drove Ultrabotanica's result include:

- Electronic Batch Records (EBR)- Every production step captured digitally, with automatic linkage between master records, batch records, and finished-product specifications
- Full audit trail- Every data entry, approval, and modification recorded with time-stamps and user credentials, compliant with 21 CFR Part 11 electronic records requirements
- Vendor Management and lot traceability- Incoming raw materials linked to vendor certificates, identity tests, and the specific production batches in which they were used
- Inventory Management- Real-time tracking of material movement from receipt through production and into finished goods, with chain-of-custody documentation intact
- Specifications- Finished-product specifications connected directly to the batch records and test results that confirm compliance, eliminating the need to manually cross-reference separate documents during an audit

For dietary supplement, pharmaceutical, nutraceutical, and health and beauty manufacturers that face FDA manufacturing regulations, this level of integrated traceability is not a luxury, it is what separates a two-day inspection from a two-week ordeal.

A Repeatable Result for Any Regulated Manufacturer

Ultrabotanica's outcome is not an anomaly. It is a predictable result of replacing paper-based documentation with a fully integrated, pre-validated manufacturing software platform. The InstantGMP™ platform is used by manufacturers across pharmaceuticals, biotechnology, dietary supplements, food and beverage, health and beauty, cosmetics, medical devices, and contract manufacturing and can be used for any producer that needs traceable production records and a quality management system that holds up under scrutiny.

"An FDA inspection should not be a crisis. It should be a non-event. Ultrabotanica's result is exactly what we designed the platform to deliver: every record linked, every test accounted for, and full traceability from finished product back to raw material in the time it takes to have a meeting," said Dr. Richard Soltero, President of InstantGMP.

Schedule a demo today to see how InstantGMP™ PRO can make your next FDA inspection a non-event or contact InstantGMP to learn how quickly your facility can be audit-ready.

Debbie Young
InstantGMP, Inc.
+1 704-302-3691
email us here
Visit us on social media:
LinkedIn
YouTube

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