InstantGMP™ PRO

FOR FDA REGULATED INDUSTRIES

InstantGMP PRO is the all-in-one manufacturing and quality system that delivers both efficiency and GMP documentation... GMP-by-design...

INSTANTGMP™

Our Electronic Batch Record centered system design stands out.... why?

- **Real-Time Resource Control** facilities, equipment, inventory, and cost production info within the EBR framework
- **Make-To-Order Capability with New External User Batch Approval** provides product and process design-as-you-produce within the operation... ideal for both contract manufacturing and R&D development
- **Room and Equipment Log/Equipment Task Scheduler integration** provides high-ticket resource control within the EBR
- **Two Level Configurability of EBRs** 1. the order and logic of the batch steps, and 2. user control of dynamic fields and formulas
- **Project Level Operation in Real-Time** dedicates EBRs and Production Teams to individual clients for white label/ private label manufacturing
- **EBR's for Intermediates** allow a completed batch to be used as an ingredient to another, for packaging operations, or further work in progress
- **Quality Signoffs** provides quality with the ability to issue, monitor and co-approve all EBRs to support GMP in the production process
- **EBR at the Center of the Design... by Design** establishes a vantage point to allow better overall useability to optimize batch completion time, events and costs

Why Invest in InstantGMP PRO?

- Manage and Reduce Batch Time and Cost
- Generate GMP data Efficiently
- Work with a Team of Experts to fulfill a successful GMP Journey and Destination
- Minimize Batch Rejects and Reworks
- Secure, Manage, Stage, Track, Trace, and Ship Inventory End-to-End
- Track Costs Accurately with Configurable Costing and Inventory Cost Adjustment
- Reduce Errors with an Integrated System Footprint
- Streamline A Full Range of Quality Tasks with Included CFR Quality Workflows
- Execute all processes with a fully GAMP5, Part 11, ISO13485 Validated System
- Create Documents Interactively
- Version, Approve, and Deploy Documents and other files to Support a Full Range of PRO Operations
- Schedule periodic equipment tasks and report completion status to select users

GMP Inventory by design and detail

Material Planning makes it easy to procure ingredients by planned production times

Cost the batch your way to roll up materials with incoming costs, configure labor and departmental time, and price it

Configurable screens and powerful inquiries secure and export real-time inventory data as you demand

State of inventory color coding identifies expired receipts or those needing retest

Choice of inventory use (barcode swipe, picklists for staging, selection form all approved receipts) includes a max-min window to ensure correct quantities

System Generated Inventory Reports for Better Inventory Decisions

- Current Inventory
- Inventory Value
- Low Inventory
- Vendor Lot Traceability
- Production Lot Traceability
- Alert Level
- Reorder Level
- Materials Near Retest/Expiry

Inventory Designed Bottom Up for GMP

- Supplies specifications for materials configurable for vendors, linked to Material Receipt for convenience
- Provides a built-in GMP role-based inventory status approval workflow
- Provides a system-wide audit trail
- Ensures validation per GAMP and FDA standards for any type of GMP regulated product
- Provides a Shipping Manifest to close the GMP loop to the customer or end user

Document Management

The InstantGMP™ PRO Electronic Document Management System provides easy document approval, tracking, and versioning to support the GMP activities throughout the PRO system.

- **Document Control** permits document managers to upload, version up, and send documentation for review and approval
- **Document History** maintains all superseded documentation alongside the comments and changes made during an activity cycle
- **Documentation Integration** allows key documentation to be attached directly to a Batch Record, Room or Equipment Log, or a Material Specification
- **Wide variety of file types supported**

Documentation Included with Purchase:

120 Template GMP Policies and Procedures for areas like:

- Quality Systems
- Materials
- Facility & Equipment
- Safety
- Packaging and Labeling
- Production

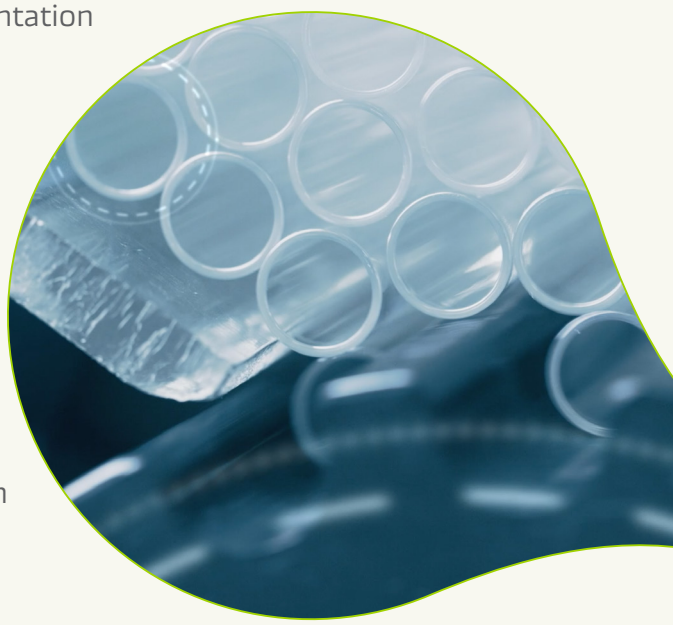
18 GMP Forms and Templates:

- Audit Plan
- 2-Way CDA
- Deviation Report
- Serious Adverse Event Report
- and much more!

Quality Management

InstantGMP™ PRO can also help your quality team manage a complete set of tasks in a cGMP operation.

- **Quality Logs** manage the **Deviation**, **Incident**, **CAPA**, **Change Control**, and **Audit** quality logs with pre-built workflows that make navigation and completion flow easy
- **Integration of EBR and Deviation Workflow:** Save time in documentation and resolution
- **Vendor Management** supports collaboration on key documentation with vendors in "data room" mode to complete and expedite vendor qualifications, agreements, etc.
- **Training Log** issues and stores training activities completed by your personnel. When used in conjunction with the optional **Learning Management System**, it organizes online curricula (presentations, videos, documents) for all approved system users
- **Vault:** Gives the end-user an internal file database and organizer separate from the Document Management System to secure the hierarchy of non-versioned information



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