InstantGMP™ PRO

FOR ˄ REGULATED INDUSTRIES
FDA

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?

- ~~It Provides~~ **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 and D~~ development
  R&D

- **Room and Equipment Log/Equipment Task Scheduler integration** for high-ticket resource control within the EBR

- **Two Level Configurability of EBR's…** *1.* the order and logic of the batch steps, and ~~with our included Dynamic Fields~~
  2. user control of dynamic fields and formulas.

- **Project Level Operation in Real-Time** for white label, private label, etc. Dedicates EBR's, ~~Resources~~ and Production Teams *to individual clients.*

- **EBR's for Intermediates…** a completed batch can be an ingredient to another, for packaging operations or further work in process

- **Quality ~~EBR~~ Signoffs:** Quality has ability to issue, monitor and co-approve all EBR's to support GMP in the production process

- **EBR at the Center of the Design… by Design.** This vantage point allows better overall useability to optimize batch completion time, events, and costs

Page Break - start GMP inventory on new page

GMP Inventory by design and detail

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

Cost the batch your way Roll up materials with incoming costs… then configure labor, departmental time, etc… then price it!

Why Invest in InstantGMP PRO?

- Manage and Reduce Batch Time and Cost, while
- 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
- ~~Use this~~ Fully GAMP 5, Part 11, ISO 13485 Validated System ~~with Confidence for all your regulated products~~
- Create Documents Interactively
- Version, Approve, and Deploy Documents and other files to Support a Full Range of PRO Operations
- ~~Supported by an CBD/Hemp/ Cannabis Experienced Regulatory team, top to bottom~~
- Schedule periodic equipment tasks and report completion status to select users

919.657.0950

Configurable screens and powerful inquiries for securing and exporting 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...all with max-min window for ensuring correct quantities

Inventory Designed Bottom Up for GMP

- Specifications for materials ~~vendor~~ configurable for vendors, ~~flexibility,~~ linked to Material Receipt for convenience

- GMP role-based inventory status approval workflow built in

- Complete audit trail systemwide

- Validation per GAMP and FDA standards for any type of GMP regulated product

- ~~Configurable FG costing provides accuracy and even creativity for a variety of cost types~~

- Shipping Manifest closes the GMP loop to the customer or end user

System Generated Inventory Reports for Better Inventory Decisions

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

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:** Document managers can upload, version up, and ~~route~~ *send* documentation for review and approval.
- **Document History:** The system maintains all superseded documentation alongside the comments and changes made during an activity cycle.
- **Documentation** ~~**for Active Support**~~ *Integration***:** The EDMS is integrated into most of the software. This means key documentation can be attached directly to a Batch Record, a Room or Equipment Log, or a material specification.
- **Wide variety of file types supported**

Quality Management

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

- **Quality Logs:** Manage the many different quality logs such as: **Deviation**, **Incident**, **CAPA**, **Change Control**, and **Audit**. ~~With~~ *with* pre-built workflows to make navigation and completion flow easy
- **Integration of EBR and Deviation Workflow** ~~to save~~ *: Save* time in documentation and resolution
- **Vendor Management:** Collaborate on key documentation with your vendors in "data room" mode to complete and expedite vendor qualifications, agreements, etc.
- **Training Log:** Issues and stores training activities completed by your personnel. Used in conjunction with the optional **Learning Management System**, ~~supplied by Entrenar.se,~~ organizes online curricula that can include presentations, videos, or documents for all included users on the system.
- **Vault:** ~~The Vault gives~~ *Gives* the end-user an internal file database and organizer separate from the Document Management System to secure the hierarchy of non-versioned information.
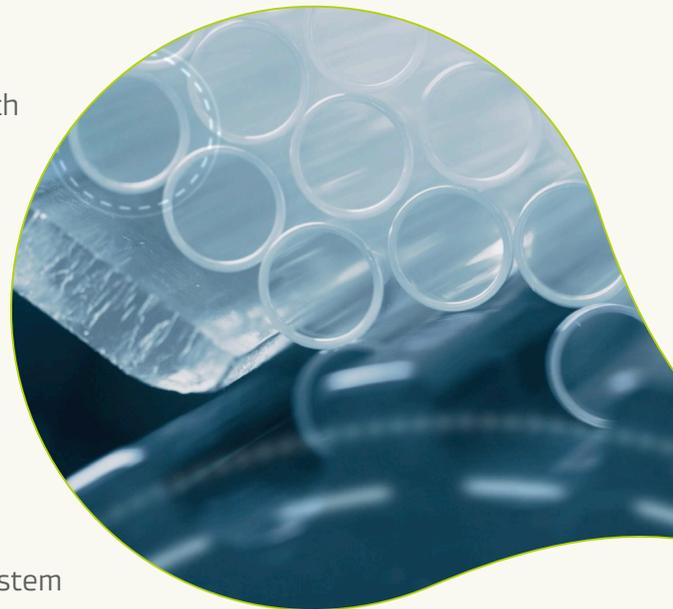
BIOTECH & PHARMA

Contact Jeremy Hall at **(919) 657-0953**.

.

HEMP/CBD & DIETARY SUPPLEMENTS

Contact Robert Pochadt at **(215) 968-5414**.