InstantGMP™ PRO

Making the case for moving from paper-based systems to Electronic Batch Records software InstantGMP™ PRO

InstantGMP™ PRO is a manufacturing and quality software solution specifically designed for pharmaceutical and biotech companies

INSTANTGMP™

Dr. Richard Soltero created InstantGMP in 2004 because he saw how inefficient systems can affect the largest industry players to the smallest manufacturers. He believed there was a way to demystify compliance and help companies better control their production process through Electronic Batch Records. Many companies still use paper-based systems and spreadsheets for their compliance documentation, despite having numerous solutions available to them. This is in part because companies are concerned about:

- Process disruption
- Internal organizational issues
- Cost
- Quality system change

External Factors Affecting Stakeholders

The FDA has unilaterally increased the number of inspections domestically and internationally. The FDA has added a multitude of new auditors, is opening up industry-specific agencies, and is stepping up their supply chain/vendor investigations.

Manufacturers have learned to stay on top of changing hot-button topics of scrutiny and striving to cut costs and increase profit. Companies are looking to decrease the amount of batch rejections, shorten the time between batches, and increase "right the first time" production while continuing to move towards outlined targets and goals. With an inefficient system, this can be difficult.

Limitations of Paper-Based Systems

- Lack of cross-departmental visibility
- Manual entry and documentation assembly requires time
- Potential problems are not monitored in real-time
- Quality approval delays production
- Many opportunities for mistakes, incorrect data, inventory miscounts, and more
- Costs of paper, printing, issuing, reviewing, archiving, and retrieval of documents
- Opportunities for data and documents to be lost, which compromises traceability

Business Considerations

Many software solutions have quantitative data and statistics to demonstrate how effective they are; with EBR it is ambitious to do so given that each company must outline their goals and Key Performance Indicators (KPIs) ahead of time in order to extrapolate possible Return on Investment (ROI). This is an integral part of evaluating software solutions and requires companies to do their homework and plan ahead before making a decision.

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Your Process, Streamlined

InstantGMP™ PRO is a solution to help manufacturers transition from paper, spreadsheets, and other documentation systems to Electronic Batch Records in order to simplify and streamline the production process. The benefits of InstantGMP™ PRO include:

Affordability: Our software is a fraction of the cost compared to many of the others currently available.

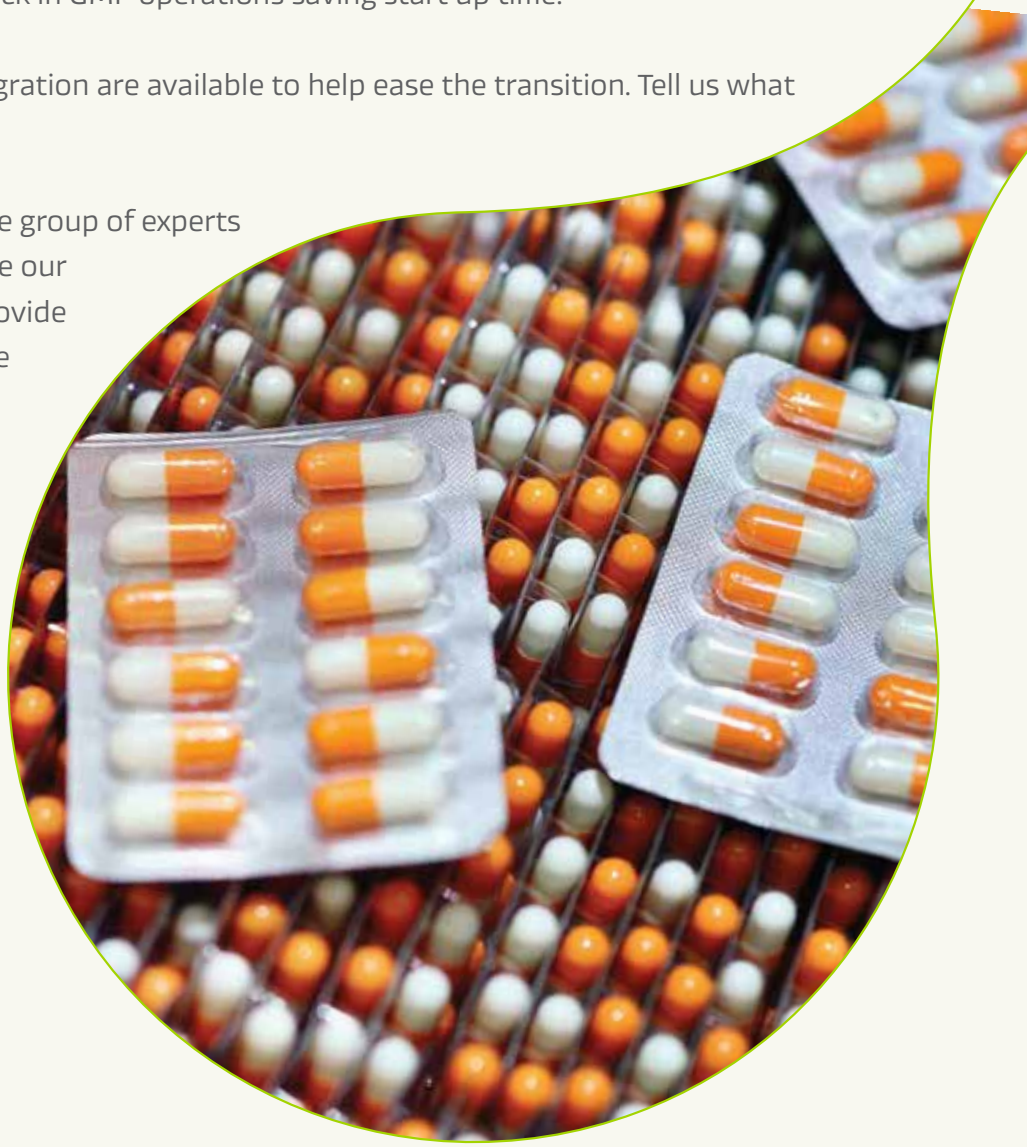
Automation of Work Life: No more hand-delivering documents, hiding behind a wall of paper, or gowning up to read a cleaning log! Using our software, you have 24/7 access to a secured, cloud-based database that houses your documentation.

Optimization: Pre-set workflows lock in GMP operations saving start up time.

Flexibility: Customization and integration are available to help ease the transition. Tell us what you need and we'll build it!

Personalization: We're a passionate group of experts that regularly use feedback to drive our software development. We also provide training that covers how to use the software and consultation to help a company map their process in InstantGMP™ PRO.

Simplification: Our software helps companies organize, centralize, streamline, and automate their GMP records. It also provides process controls and thorough traceability so that your business can focus on increasing production volume and expanding your brand!



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Master Your Batch Records

InstantGMP, Inc. assists businesses in many facets of their production and quality processes; here's how we have helped our customers:

Master Batch Record Automation: Scale up, scale down, copy, and version up your DMRs with only a few clicks of the mouse.

Compliance Checklist: The software notifies users through color-coded alerts about missed steps, deviations, unused inventory, and much more.

Batch Production Records Streamlined: Creation and issuance of BPRs from MPRs have never been so efficient! Information auto-populates from previous data entry via dropdowns and smart fields.

Cross-Departmental Communication: Our software cross-references each step and all input data to keep you on track. InstantGMP™ PRO provides a holistic and real-time vantage point for all users across multiple departments and multiple facilities.

Streamlined Quality: Quality will love having all compliance documentation in one place and being able to digitally sign everything to prevent post-batch chaos that delays product release.

Decreased Risk: Before, during, and after production; quality and compliance checks have already addressed potential issues. Reports, logs, system tracked numbers, and more provide extra traceability for peace of mind.

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Inventory Management

InstantGMP™ PRO not only provides cGMP compliant workflows, but doubles as an Inventory Management solution:

Material Requirements Planning (MRP): Users can easily calculate which materials should be ordered to maintain steady production.

Receipt Tracking: Each component that is requisitioned/purchased is assigned a unique receipt number that can tie a component to a particular vendor lot.

Inventory Status Control: By default, a received component's status is Quarantine and requires Quality Assurance to verify that this component conforms to established Specifications. Users can add attachments such as an MSDS or COA.

Inventory Management: This extensive view of all on-hand inventory is available with real-time use updates.

Inventory History: Every use of a component is tracked in the system. Users can quickly find batches produced with a component from a specific vendor lot and more.

Shipping Manifest: Users can organize and trace final goods shipments to the client.

Bin Locations: Components can be added to Bins specified by users. Users can easily switch a component's bin with the click of the mouse.

Barcoded Labels: The system will generate a barcoded label for a component. During manufacturing, operators can scan approved component labels to expedite their process.

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Quality Management

InstantGMP™ PRO can also help your quality team manage the quality aspects of a cGMP operation.

Quality Logs: Manage the many different quality logs such as: Deviation, Incident, CAPA, Change Control, and Audit. with pre-built workflows to make navigation and completion easier for the user.

Vendor Management: Collaboratively work on key documentation with your vendors to complete vendor qualifications, deviations, and agreements.

Training Log: Issue and store training activities completed by your personnel. Use in conjunction with the Learning Management System, supplied by Entrenar.se, and you can begin organizing curricula that can include presentations, videos, or documents for operators to quiz on.

Vault: The Vault gives the end-user an internal file database separate from the Document Management System. This is used to store stability data, CMC documentation, regulatory agreements which are critical for due diligence investigations.

System Generated Inventory Reports

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

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Document Management

InstantGMP™ PRO can help you manage your documents and make sure they are always visible to your team, no matter the task.

Document Control: Document managers can upload, version up, and route documentation for reviewing and approval.

Document History: The system maintains all superseded documentation alongside the comments and changes made during its cycle.

Document Placement: The DMS 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.

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!

Why Invest in InstantGMP™ PRO?

InstantGMPTM PRO provides a holistic approach to cGMP manufacturing. It was built by veterans of the Pharmaceutical Industry with decades of Quality and Manufacturing experience. The benefits of using the software align with the business drivers that companies desire:

- Fraction of the cost of other solutions
- Pre-set modules for easy, organized implementation
- Affordable customization and integration
- No Additional Need for IT Hardware or IT Personnel
- Increased Productivity Through Controlled Processes
- Reduction in Rejected Batches, Reworks and Review Times
- Reduction in Risk of Adulteration, Contaminants, Recalls, and Operator Error
- Fully Validated, CFR 21 Part 11, Part 820, ISO 13485, and GAMP 5 Compliant

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