INSTANTGMP™ PRO

Technology is constantly evolving around us, and yet many manufacturers continue using paper-based systems to manage and record their activities while manufacturing. The most forward-thinking, cutting edge manufacturers, especially in pharmaceuticals and biotech, are making the move to Manufacturing Execution System (MES) and Electronic Batch Records (EBR) software. InstantGMP™ PRO is a surprisingly affordable software solution for companies looking to make the guided transition.

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

Dr. Richard Soltero created InstantGMP, Inc. 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 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.

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 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.

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

INSTANTGMP™ PRO

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. This is achieved in InstantGMP™ PRO by:

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 allow for a quicker implementation period versus big-box brands.

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 small, 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!

Master Your Batch Production Records

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

Master Record Automation: Scale up, scale down, copy, and version up your MPRs 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 Records Streamlined: Creation and issuance of BPRs from MPRs has 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:

- **Receipt Tracking**: Each material that is requisitioned/purchased is assigned a unique receipt number that can tie a material to a particular vendor lot.
- **Inventory Status Control**: By default, a received material's status is Quarantine and requires Quality Assurance to verify that this material 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 material is tracked in the system. Users can quickly find batches produced with a material from a specific vendor lot and more.
- **Depleted Inventory:** Users can view materials that fall below a certain stock percentage and plan ahead to requisition/purchase more materials.
- **Bin Locations:** Materials can be added to Bins specified by users. Users can easily switch a material's bin with the click of the mouse.
- **Barcoded Labels:** The system will generate a barcoded label for a material. Each material received will have a label generated to reflect its status. During manufacturing, operators can scan Approved material labels to expedite their process.

System Generated Inventory Reports

- Current Inventory
- Inventory Value
- Low Inventory
- Inventory in Quarantine
- Vendor Lot Traceability
- Production Lot Traceability

Why Invest in InstantGMP™ PRO?

InstantGMP™ 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 211, and GAMP 5 Compliant.

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