Why Electronic Batch Record vs. our Paper-based System?

A primary reason to implement an Electronic Batch Record (EBR) system is to raise profit while meeting cGMP/FDA/EU regulations. Moving away from paper to electronic offers benefits such as:

- Satisfying, documenting and demonstrating cGMP compliance,
- lowering frequency or eliminating rejected Batches,
- drastically reducing labor involved in the QA approval process,
- streamlining inherent inefficiencies with paper-based systems, and
- improving both the consistency and quality of final Batch.

What drives this need to migrate often can often be traced back to the 'human factor'. By this we mean failure to execute, in a sequential and complete manner, signatures, actions, and decision paths in a consistently reliable manner. Employee absence, non-compliance behaviors, and turnover complicate, delay and sometimes even lead to failure with the batch approval process. For example, a cursory review on the FDA's 483 Violations as well as Warnings and Actions histories web site supports the issues with 'the human factor'. Surprisingly, about 70% of all FDA actions are directly tied to activities related to missing paperwork, unsigned paperwork, improperly documented paperwork, poor access to paperwork (i.e. training, SOPs, diagrams, etc.).

These failures ultimately lead to lowered profits from avoidable inefficiencies, higher employee/management stress, less consistent results, and more paperwork. None of these results contribute to a better final result. Worse, these types of inefficiencies create a multitude of other workarounds and problems which further negatively impact results. To review many human-factor issues the EU agencies and the USA FDA routinely identifies, please inspect these FDA resources *(or skip to the next section for a summary)*:

FDA FOIA Violations (filterable types of violations): right-click to open link

FDA Warning Letters 2017, 2016, 2015: right-click to open link

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000174.jsp&mid=WC0b01ac058002708d

To save time from reading through hundreds of violations I have presented an ordered summary of typical FDA violations:

- Missing signatures
- Missing documentation and/or improper version control
- Lack of acceptable control procedures (quality, training, calibration, maintenance)
- Poorly Controlled Access to cGMP paperwork

Further, other industry and regulatory segments are actively migrating to electronic systems either to realize efficiencies or meet regulatory deadlines (electronic health care records, drug filings, food & beverage, etc.). Industry experts predict the FDA may soon issue draft mandatory electronic record systems guidelines for the drug manufacturing industry as it has already done in other areas. The forthcoming Serialization requirements (E.U. and U.S.) will be yet another step in the direction of a

paperless-system. *If 70% of all FDA violations can be traced back to the human factor, and you can profitize existing business by simply migrating away from paper-based systems, isn't it logical to immediately implement an EBR system?*

To address many aspects of noncompliance behaviors InstantGMP™ PRO automatically 'hardwires' GMP compliance by . . .

- ✓ Automating record capture such as signatures and other data,
- ✓ Providing document version control, training materials, images, diagrams,
- ✓ Directing *in-process* approvals and/or options rather than 'post-batch',
- ✓ Securely stores all this data at your fingertips.

What benefits does InstantGMP™ PRO offer my organization?

- **Stakeholder Visibility/Accessibility** (interact, manage from anywhere, anytime *securely!*)
- **Batch Review Approval done in seconds** (not days, weeks, or months)
- **Fast ROI** (<3 months implementation – results are near-instantaneous!)
- **Versatile** (integrate with other systems like SAP, QuickBooks, Data Loggers, Environmental Monitoring Data, IoT, Email)
- **Improve Batch Results** (remove bad decisions using "if-or-and-then" functions)
- **Easy to use** (Confirm Inventory and issue Batch Production Records in less than 7 seconds!)
- **Compliant & Validated** (21 CFR Part 11, 211, EU GMP, ISPE GAMP5, ISO 9001/13486)
- **InstantGMP™ use has passed FDA Inspection for 100% of our customers!**

Everyone agrees and understands efficiency is often tied to profitability. Thus, in a nutshell, can you present what your software does in 30 seconds or less? Yes! See here please . . .

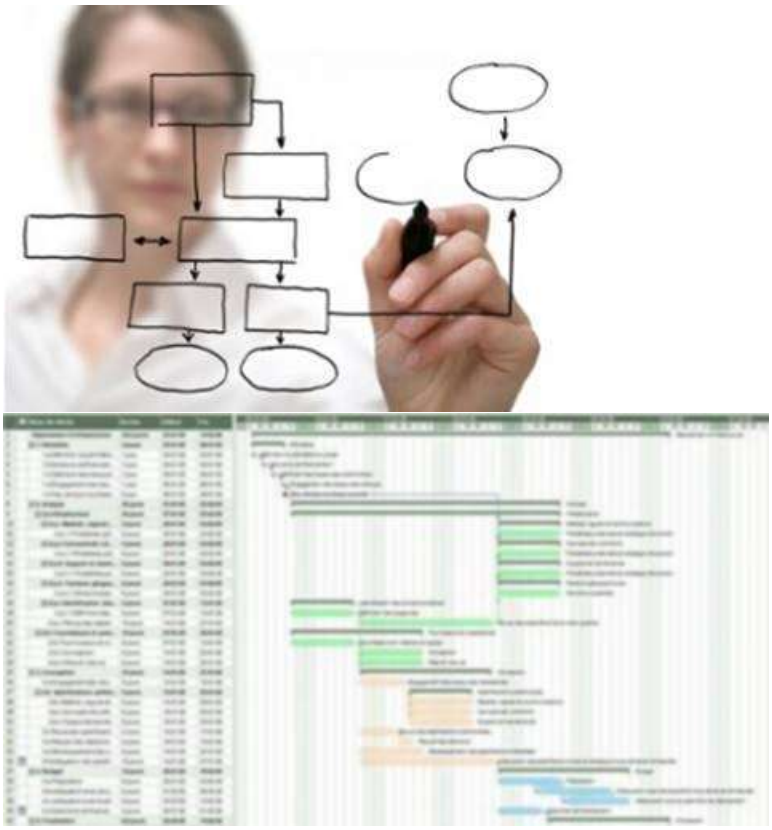
https://www.instantgmp.com/instantgmp-on-line_2 or https://youtu.be/e9DbKzZcUK4

How do we migrate from our current process to InstantGMP™ PRO?

First, your organization must decide if it is best for internal Trainers to lead the training and implementation or if you desire an external Trainer. InstantGMP, Inc. offers both choices. Our software is so intuitive all training and consulting occurs online with both live and archived video training available 24/7/365. The system was designed to be inherently intuitive so that Operators and Facility Staff will be able to easily navigate your complex and critical tasks.

If external training is desired, we offer the Implementation Program. This program assigns a dedicated and experienced Pharmaceutical Project Manager to lead the entire effort. Our PM team has over 50 years of hands-on successful project management and knows how to keep the effort on-track. Typically, the size of your organization does not determine the need for our Implementation Program; rather, your culture, resources and timeline are greater factors. Implementation overview includes:

- Process Evaluation and Consulting – *review of your company's current production workflows*
- Map company specific batch production related work flows (Gnatt Chart Format)
- Plan out the transition from manual systems to electronic batch records
- Create company specific Master Production Records (MPR)
- Guide the implementation and roll out to all users



Second, if integration is required from/to existing Inventory or Manufacturing systems, the requirements of this interaction needs addressing through a Scope of Work submittal. Most InstantGMP™ PRO data is exportable in Excel as a default, (or PDF in the case of Batch Production Records) as well as to QuickBooks and IoT devices. Additionally, we offer included software tools to help migrate data from your existing inventory system.

If you use an existing ERP or MES system (i.e. SAP, Evolution, Oracle, etc.) the Scope of Work issued by your company will outline the API software requirements, (data type, data exchange mechanism, frequency, format requirements, query guidelines, process requirements, etc.) InstantGMP, Inc. utilizes APIs but we will need to provide you a quote based on your unique Scope of Work.

How do we measure ROI?

Whether you choose internal training or hire us to do this for you, the average 'zero to hero' training and implementation process for generic pharma organizations is about three months. This integration may be ongoing as not all products may be migrated initially. Each company is unique in this manner. For example, we have had customers implement in one week (dedicated single-focus effort) but more typically, a three-month window is more reasonable. Your Return on Investment (ROI) timeline will vary but we typically see this period measured in months – not years! Easy metrics to gauge ROI will be batch approvals vs. rejects, 'surprise' inventory depletion, and improved production cycle times though these are just the tip of the iceberg. VSM programs can real-time monitor; however, most customers tell us they can point to highly visible financial benefits without complicated VSM measurements such as avoiding failed batches or missing signatures holding up shipping or packaging creating havoc for production scheduling! Think in terms of:

- ✓ improved production efficiency,
- ✓ better quality of final batch results *are inevitable,*
- ✓ elevate Suppliers who consistently support your objectives and isolate underperformers,
- ✓ reduced/elimination of failed batches due to incorrect decision making,
- ✓ lowered employee turnover due to poor training and communication gaps,
- ✓ fewer outages and downtimes from incorrect or missing documentation including maintenance,
- ✓ avoid crippling mistakes of utilizing outdated equipment calibrations,
- ✓ higher confidence in tasks reinforces positive outcomes,
- ✓ better overall inventory-to-product shipping support & communication,
- ✓ bottlenecks from inventory through to packaging quickly identified and rectified,
- ✓ fewer missed shipment deadlines, on and on.

How do Employees and Management interact with the system?

Data is entered via a web browser as InstantGMP™ PRO offers you a reliable, secure (Amazon Server System) cloud-based service. You can interact with your data, approve documents or steps, or simply update progressions from anywhere using the Internet and your web browser! Further, each User is Role Based meaning certain approvals, access and interaction is restricted. This avoids manipulation which bypasses company SOPs.

How the data entry occurs is in one of three ways:

1. Standard computer login by password authentication,
2. Barcode trigger (employee badges printed for each User), or
3. Internet of Things (IoT) actions.

Additionally, the designer of your batch production records may elect Observer signature/authorization to confirm an Operator action step was completed properly, or a training guideline was followed (SOP, video, diagram, PPT). This prevents skipped steps to help insure the right outcome! Again, this type of electronic signature must be made by traditional log in/password or barcode scanning their authorized employee badge. Additionally, facility depository of temperatures, valve positions, tank levels, atmospheric pressures, relative humidity, airflow, etc. can be integrated manually or automatically into discrete actions or simply logged as supporting data during the Batch Approval Final Step. Regardless of granular customizations, the result remains GMP compliant!

What are the hardware types and requirements?

The software was designed to work with minimal hardware requirements running Windows 10x and web browsers such as Mozilla, Chrome and others. In concert with computers, bar code wands are an excellent and preferred method for signature authorization, scanning inventory or material codes, and other data actions to enhance and facilitate accuracy!

Typically, most any budget laptop, tablet or desktop running Windows 10x is more than sufficient. Safari and other non-Windows 10x (W10x) web browsers will work though some functions are not supported. If you have a preferred browser, please let us know so we can test critical functions.

Data can be entered while moving around your facility with hand-held devices like Windows-based tablets, 2-in-1, touchscreen, or laptop. Wireless data repeaters and redundant access points will provide a more reliable and robust signal or where transient operations impede signal. Zip-lock clear poly baggies for devices like tablets and laptops work well for cleanroom/restricted area movement.

Typically, computer devices are mounted on stands, attached to walls or equipment, are worn using special clothing holders or simply reside on a nearby bench or desk. Your IT Department may have requirements and considerations for types of hardware based on its use operating environment, access for repair or maintenance, charging, powering considerations as well as explosion hazard risk. For example, the IT department may want the computer outside of the cleanroom so it can be physically accessed without the need to enter/exit the cleanroom or disrupt production staff. A simple solution is a touch-screen remote display tethered to the computer located outside of the cleanroom.

Some customers prefer all-in-one computer monitors on wheeled stands (commonly used in hospitals), hinged to equipment or mounted on a convenient wall. Touch-ball mouse control, pen and tablet, traditional wired and wireless mouse, touchpads, etc. are all common options for software interactions. For ultra-sterile or harsh computer environments options are available for hardened Windows computers.

For high moisture environments there are a variety of sealed touch screen computers available for purchase as well as rugged tablets. See resources here:

Dual-Mode Clean Room Tablet.
https://groupmobile.com/xplore-xc6-dual-mode-clean-room-dmcr.html

19” Waterproof PC
https://yourcleanroomsupplier.com/cleanroom-product/1677/19-full-ip65ip66-waterproof-pc-with

Here is a link to a rarely used but viable option:
http://www.banthrax.com/compudome

What if I want to install the software on my local servers?

InstantGMP, Inc. offers a Cloud-based service including responsibility for validation, updates, and version changes. If you desire to move your license from the Cloud, we offer a program to migrate your instance from our Amazon-based Cloud Service System to your own local servers. There is a one-time fee for this migrations service. Our software engineers will oversee this transfer. Next, once you move the software to your own Servers you will be responsible for validation going forward. This process takes us about six weeks to conduct but for an additional fee we will supply you with step-by-step template instructions to perform required validation. This fee also includes web/phone-based training guidance for your first solo validation. If you have an experienced QA staff already in place, this may be a viable option for your organization; otherwise, leaving the software in the Cloud will be attractive.

If you are concerned about uptime, availability or security, we can address those now. For the ultimate security of uptime, I recommend you simply include, as part of your SOP, a printing step of the Batch Record at time of initiation. This way, should weather events disrupt incoming internet service, or during times of local construction events (backhoe/excavator digging machine cuts incoming Internet Service), you can use paper until internet access is restored. Once restored, you may start at the current appropriate batch record step and attached previously completed paper-based steps into the final record as a scanned or imaged version. This optional process is covered under FDA and International guidelines. Also, if someone is inputting data and Internet connection is interrupted, previous data is not affected. Finally, your data is 128-bit encrypted then 256-bit encrypted and double-verified utilizing Amazon's servers, the leading standard in reliability, security, and uptime.

Do you offer SOPs?

Yes. We offer two types: Full Set and CORE Set. The CORE set are the SOPs that parallel our software. At a minimum, you will need to consider purchasing the CORE Set with your License. The Full Set offers ~110 SOPs that cover cGMP guidelines for the entire facility. This represents a better value and is helpful to make sure all your basis are covered. Learn more about the Full Set of SOPs here: https://www.instantgmp.com/solutions/sops/full-set

What is the cost?

The system is based upon a minimum of 5-User license with annual renewal. Users may be added at any time. Your software license purchase will include the following:

- Electronic Batch Record
- Inventory
- Specifications
- Test Methods
- Document Management (optional purchase)
- Dynamic Fields Functions
- Online live training (2 hours Orientation of workflows, a section-by-section tutorial given to two users who will become trainers. Training is done in 3 two hour meetings via web sessions.)

Optional Services

Validation Package and Updates (Summary reports, Operational qualification protocol and test scripts, interim operational qualification summary reports)
Customization or Integration (ERP, VSM, Accounting, MES systems, etc.)
Scale Integration (for Internet of Things including scales, valves, and other data devices)
On-site Server Installation
SOPs (Full and Core Sets)
Additional Training
Consulting
Implementation Program: Includes process evaluation and consulting, mapping workflows and specific process flows, plan-out the transition to InstantGMP, create Master Production Records, guide rollout to all Users. For most Generics Manufacturing Plants, running multiple shifts, this optional service is always purchased.

Best Regards,
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