LISTEN.
THINK.
SOLVE.®

Beyond Compliance: The Evolution of Pharmaceutical MES

Advances in modern manufacturing execution systems can help you optimize production, speed time-to-market and ease compliance

PharmaSuite™
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Pressures Abound

What does success look like in the highly competitive and strongly regulated pharmaceutical industry? It involves achieving a balance that allows you to be swift and lean in your operations, yet robust in how you respond to changing market and regulatory forces. Finding this balance is increasingly grueling as challenges come at you from every direction.

- Your **speed to market** is more important than ever to reach new emerging markets, compete with generics and get the most out of products before their patents expire.
- Harnessing the power of integrated control and information system is required to build The Connected Enterprise and attain **organization-wide connectivity, and visibility** is needed to align local operations with global requirements and improve efficiencies across plants.
- Maintaining **competitive pricing** is critical as nations around the world undergo varying degrees of health reform aiming to contain costs.
- Achieving **compliant operations** is non-negotiable yet increasingly complex in the global arena.
- Adopting a **serialization strategy** is becoming a necessity to combat global counterfeiting in your supply chain and in the marketplace, and to comply with new anti-counterfeiting regulations.
- **Versatile and responsive operations** are required to serve the needs of an aging global population and the growing number of middle-class households in Asia and elsewhere.

> ***"By 2020, super-aged societies (populations with more than 20% elderly) will increase to 13 globally from three today. By 2030, 34 countries will be super-aged."[1]***

> *"Pharmaceutical companies around the globe continue to be buffeted by blockbuster drug patent expirations, rapidly increasing competition from generics manufacturers, and government and health care industry efforts to control costs – evidenced by price controls, pro-generics policies and patent challenges."[2]*

[1] Moody's: Aging will reduce economic growth worldwide in the next two decades, Moody's Investors Service, Aug. 6, 2014, [2] 2015 Global Life Sciences Outlook, Deloitte, 2014

Part Ways With Paper Trails

Exhaustive paper documentation became the status quo in the pharmaceutical industry to satisfy regulatory documentation requirements. But paper-based systems are time-consuming, which increases your cost per batch and limits your opportunities to be more efficient. They can also introduce risk in the form of human error.

Electronic batch recording (EBR) has changed the game, replacing the age-old method of paper documentation with a more agile software-driven system that can manage work flows and record-keeping for everything from recipe creation to batch qualification.

Today's advanced EBR systems offer far more than an electronic equivalent to paper-based documentation (i.e., paper-to-glass systems). Rather, when integrated with a manufacturing execution system (MES) and deployed within The Connected Enterprise, EBR systems can be transformative to how you operate.

PRODUCE FASTER

An EBR system automates your data collection to help speed up the documentation process and reduce the likelihood of errors. Logged data can also help you reduce cycle times by optimizing every stage of the product life cycle, as well as increase your inventory turnaround times.

CUT COSTS

Greater efficiencies in your production and compliance efforts enable you to lower the cost of your operations. Additionally, improved decision making made possible through EBR data combined with a potential reduction in human errors can help you reduce waste.

MEET COMPLIANCE DEMANDS

A paperless EBR system can simplify your compliance efforts. Deploying a serialization system from the same MES software used for EBR can help meet emerging regulations, including anti-counterfeiting requirements, with significantly greater ease.

What can an EBR system do for you?

- **80% decrease** in batch-review cycle times
- **50% decrease** in investigations
- **70% fewer** manual entries
- **90% fewer** entry mistakes
- **50% increase** in stock turnaround

Faster Time-to-Market

Time-to-market is critical for pharmaceutical makers who want to meet customer demands and maximize profits before patent and product expiration dates.

An advanced EBR system can help improve your time-to-market in several ways.

First, it can help optimize cycle times across the product life cycle. The system can instantaneously retrieve batch protocols and eliminate the need to pass records physically between stations, shortening the time required to produce and ship products.

It can also significantly speed up review times for batch documentation. The system's ability to notify operators of exceptions during the production process can improve batch accuracy and consistency, and allows quality assurance teams to review by exception rather than go through each record line by line to avoid batch-release delays.

Pre-validated recipe building blocks available in advanced EBR systems can be re-used to achieve shorter deployment times. Instead of time-consuming custom programming and validation, recipe authors can use a library of instructions to create new work flows in mere minutes.

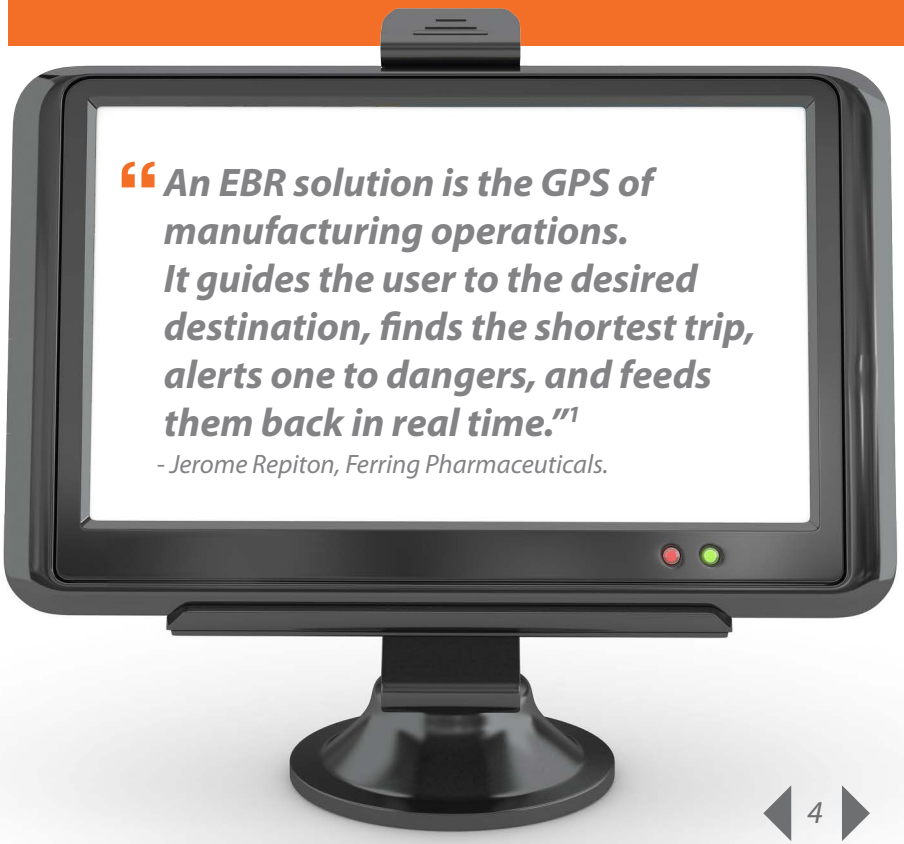
Batch records must be kept for at least one year following a product's expiration. An EBR system electronically archives all records to help you maintain complete batch records.

Lastly, the easy access to key information in an advanced EBR system enables more targeted opportunities for continuous improvement in your operations. For example, it can help you identify and eliminate unnecessary tasks, such as redundant material checks and weight verifications.

Halving Batch-Review Time

Switzerland-based Ferring Pharmaceuticals began implementing an EBR system in 2010 to replace its paper-based system.

Today, the new system has enabled the manufacturer to cut its batch review time almost in half and increase its number of batches processed from 7,000 to 11,000.



[1] A Tale of Two IT Implementations, Pharmaceutical Manufacturing, August 2014

Three Key Cost Savings

Lengthy compliance activities drive up the cost of your production operations while your product sits waiting to be shipped. Additionally, human errors made during the production or documentation processes can result in wasted product or, worse, contamination and potential recalls.

An EBR system can help you reduce costs in three key ways:

SAVINGS THROUGH EFFICIENCY

The efficiencies made possible through an EBR system already discussed can help optimize the total cost of your deployments. For example, automating quality-assurance functions and review by exception capabilities reduces the effort and associated costs of researching process deviations, while electronic logs of batch data eliminate the costs of physically storing paper documents.

LESS WASTE

Reducing the risk of human error combined with EBR features, such as enforceable work flows, can help prevent production or recording errors and reduce wasted product. What's more, preventing these errors can also help minimize the likelihood of expensive, brand-ravaging product recalls.

INVENTORY SAVINGS

Automated data collection and the ability to review exceptions in real time as they happen, rather than after the fact, result in less product sitting in the warehouse and waiting for release. For you, this faster turnover translates to reduced inventory costs.

The average pharmaceutical company holds 180 Days of finished goods inventory on hand.

Top performers average about

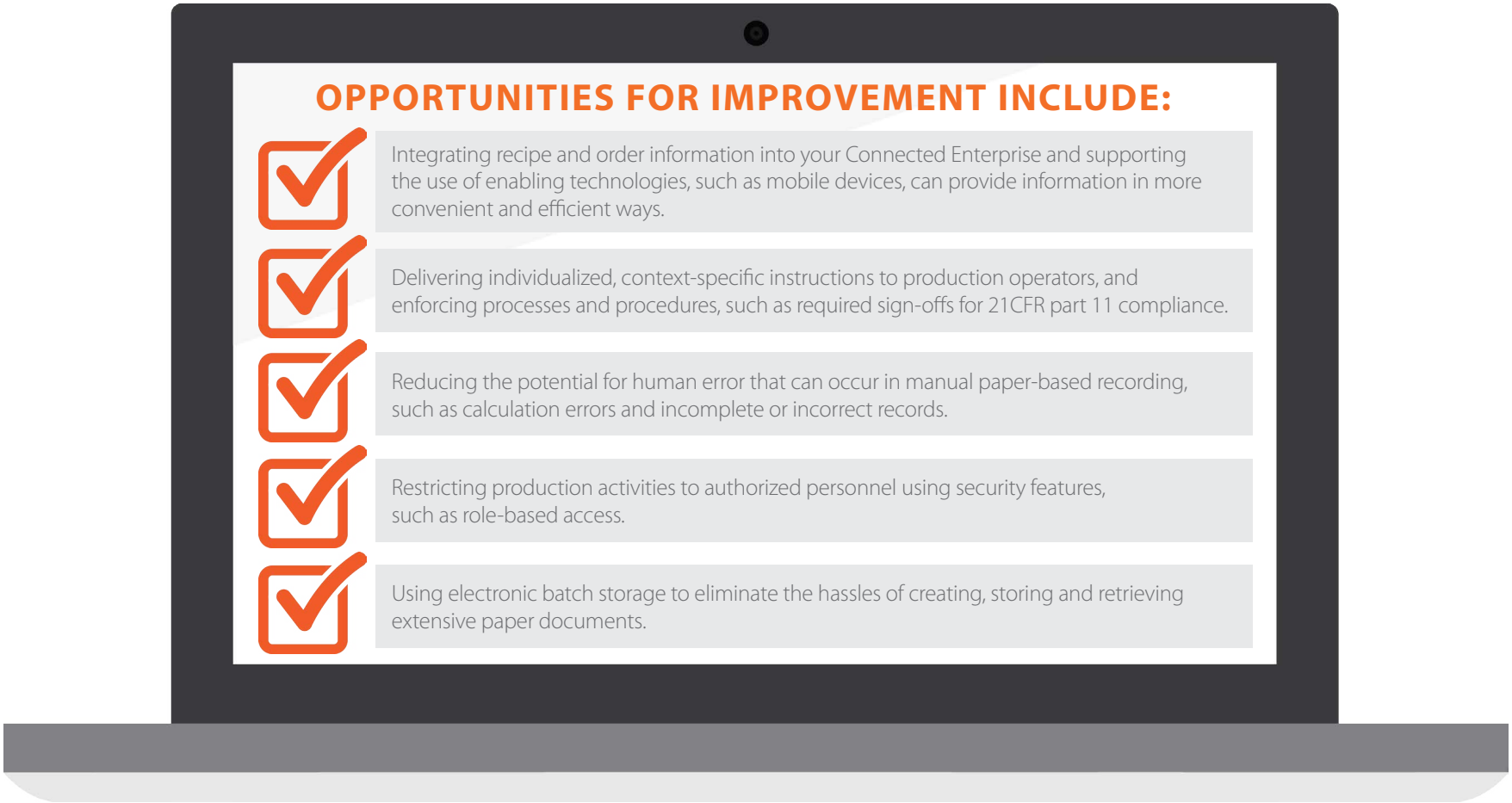
100 Days[1]

[1] Outlook on Pharma Operations, McKinsey & Company, 2010

Compliance Support

Compliance is compulsory – but it doesn't have to be painful. A paperless EBR system harnesses the power of automation and greater connectivity to help ease and even improve your demonstrated compliance.

> *"Rather than inspect facilities on a set schedule as was the case in the past … the [FDA] now determines which facilities to inspect based on the overall level of risk they pose, which is determined using a model that takes into account inherent risk, outbreaks, recalls, adverse events and compliance history."* [1]



[1] FDA Steps Up Foreign Inspections, Pharma Exec Magazine, April 2, 2015

Conquer Counterfeits

Governments around the world are designing and implementing anti-counterfeiting regulations. While the regulations each have their own unique flavor, they share similar approaches in requiring manufacturers to use serialization systems for product traceability and/or authentication.

Complying with these regulations will be critical, especially for global manufacturers operating in multiple countries. For example, those serving the Brazil market, the second largest in the developing world[2], must begin limited serialization by December 2015 and full serialization in 2016[3].

A Single Platform

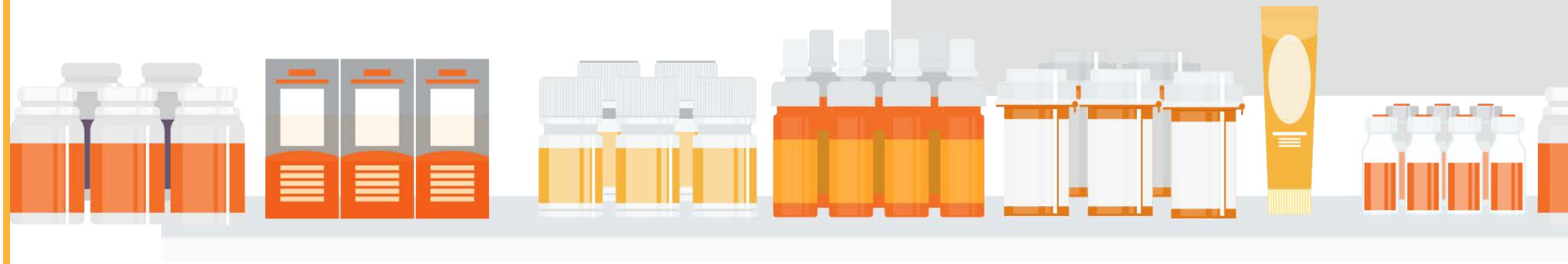
The same software used for your MES and EBR system can also form the core of your anti-counterfeiting serialization system. This can help you meet the data-collection and data-management requirements for emerging anti-counterfeit laws, such as DQSA, and eliminate the burden of designing, implementing and maintaining multiple stand-alone systems.

> *"Counterfeit drugs represent less than 1 percent of medicines sold in developed countries to as much as 10 to 30 percent of those sold in developing countries."*[1]

KEY CONSIDERATIONS

When evaluating serialization system options, keep these key issues in mind:

- Data-management capacity is critical to meeting your UID creation, printing and verification demands, both today and in the future.
- A system designed at the MES level – instead of at the machine or enterprise levels – enables seamless integration up to ERP systems and the cloud, and down to the production line.
- A commercial out-of-the-box system is less likely to result in production interruptions and validation burdens during integration compared to a custom-developed system.
- Availability of a common serialization data thread offers benefits beyond serialization, including consumer authentication and the ability to conduct more accurate recalls.
- A global support provider can ease troubleshooting and repairs to help minimize potential downtime wherever problems may arise.



[1] Counterfeit Drugs, Centers for Disease Control and Prevention, April 7, 2014, [2] Capturing the Brazilian pharma opportunity, McKinsey & Company, April 2012, [3] New Serialization Guidance Published in Brazil, Outsourced Pharma, Sept. 10, 2014

Getting Started

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Advances in EBR systems represent a new future filled with opportunities for pharmaceutical manufacturers that are still reliant on paper-based reporting systems. Opportunity to be more productive. Opportunity to be more cost effective. Opportunity to be compliant, even as new regulations emerge.

But where do you begin?

Rockwell Automation recommends a four-phase approach to implementation:

PHASE 1: PRE-ASSESSMENT REVIEW

Actions: Define the opportunity, your overall readiness and the project's scope

Time Required: Two to three days

PHASE 2: PROOF OF CONCEPTS

Actions: Begin initial design changes and develop documentation guidelines

Time Required: Eight to 13 weeks

PHASE 3: RE-DESIGN AND HARMONIZATION

Actions: Re-design and harmonize remaining documents; begin pilot testing, change control and implementation

Time Required: 13 to 16 weeks

PHASE 4: ADDITIONAL OPPORTUNITIES

Actions: Add complementary MES modules, such as a serialization system; begin interfacing with business systems

Time Required: Open

Contact a Rockwell Automation sales representative or visit

http://www.rockwellsoftware.com/pharma

www.rockwellautomation.com

Power, Control and Information Solutions Headquarters

Americas: Rockwell Automation, 1201 South Second Street, Milwaukee, WI 53204-2496 USA, Tel: (1) 414.382.2000, Fax: (1) 414.382.4444
Europe/Middle East/Africa: Rockwell Automation NV, Pegasus Park, De Kleetlaan 12a, 1831 Diegem, Belgium, Tel: (32) 2 663 0600, Fax: (32) 2 663 0640
Asia Pacific: Rockwell Automation, Level 14, Core F, Cyberport 3, 100 Cyberport Road, Hong Kong, Tel: (852) 2887 4788, Fax: (852) 2508 1846

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