Improving Your Operations and Compliance
Solutions for Life Sciences

EMERSON
Process Management

With today's market pressures on biotech and pharmaceutical production, it's not enough to have reliable, repeatable, flexible batch execution. Perfect processing must be matched with complete, error-free batch records for timely product release. Only with a winning production and documentation combination can you satisfy your customers, regulatory agengies, and your investors.

CONTENTS

Efficient, effective and accurate batch record management.

Challenges in Operations and Compliance

Decreasing the cost of goods sold, improving time to market, financing research through operational improvements, and ensuring regulatory compliance are some of the pressing issues facing the industry.

In today's environment of regulations, risk management and PAT (Process Analytical Technologies), there is an opportunity to creatively address these pressures. Now you can effectively manage and change your business to address the challenges long faced by pharmaceutical and biotechnology manufacturers.

Some of these challenges include the following:

- Delayed release of products caused by disconnected batch execution and batch record creation
- Poor yields and extended batch cycle times
- Numerous checks and rechecks due to errors and omissions common to manual processes
- Waste and rework due to quality problems discovered post execution
- Decreased actual operating capacity due to unscheduled downtime and unnecessary preventive maintenance
- Delayed time to market for new products.

"We have arrived at a particular crossroads. Standards are increasing, pressure to reduce costs is increasing, manufacturing science is lagging and the conventional responses to these stimuli have all been exhausted. A paradigm shift in manufacturing is required as the existing model will not be sustainable."

David Pullman
ISPE
President GMS - GSK-Arden House Speech

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An efficient manu-facturer requires precise synchronization between batch execution, work instructions, approvals, people, materials and equipment—all automatically managed and documented in a tightly integrated system with a single batch record.

Only DeltaV and Compliance Suite deliver this real-time, single recipe, single batch record synchronized solution.

With Compliance Suite, you can:
- Know the exact status of every batch and associated record

- Eliminate paper/logbook struggles

- Ensure training compliance while improving execution consistency from batch to batch

- Reduce or eliminate errors, re-work and delayed batch releases that are common with manual processes

- Dramatically improve Right First Time (RFT) metrics for batch records

- Eliminate islands of automation, breakdown department barriers and make important information readily available in real-time

- Decrease deviations due to common manual checking and documenting issues. Ensure better consistency from batch to batch.

With Compliance Suite, tracking down document status, finding people in order to optain signatures, and searching for misplaced documents can be activities of the past.

Lab notebooks, logbooks, paper batch records, and all of the difficulties associated with managing paper can become extinct in your facility. Now you can view real-time records from master batch creation through batch execution to batch approval

You can also ensure training compliance by linking training records to batch scheduling and execution.

And, for existing facilities, integration with existing applications is easy with our platform built on the latest interface technology.

Operational efficiency through synchronized recipe execution, batch re

cord creation.

The advantages of a single recipe, single batch approach are consolidation and tight integration, which can help you avoid duplication and unnecessary engineering.

The challenge

Many existing batch recording solutions are cumbersome due to significant overlap between recipe-centered manufacturing execution systems and batch automation systems' recipe executives.

Manufacturers have struggled to achieve their operational efficiency goals with previous approaches due to:
- Exorbitant amounts of project engineering to map data and synchronize information flow
- Numerous, high-cost experts required to provide ongoing maintenance and support

- Costly efforts required to manage changes due to cumbersome and inflexible islands of information.

The solution

Emerson offers an integrated solution that includes the field level, the process control and plant information level, as well as the manufacturing execution level.

Based on a document-centered approach, the integrated DeltaV Batch Compliance Suite solution avoids unnecessary engineering and maintenance. This integrated solutions provides:
- Seamless integration of the recipe environment including recipe planning, workflow, and execution

- A single plant floor interface for work instructions and execution with complete mobility through secure access, browser-based modules
- Integrated data management via open, interoperable XML data formats
- Open, easy integration with existing infrastructure via XML and OPC including DCS/SCADA, PLCs, ERP, LIMS, etc.

- The ability to start/stop/modify recipes from Compliance Suite.
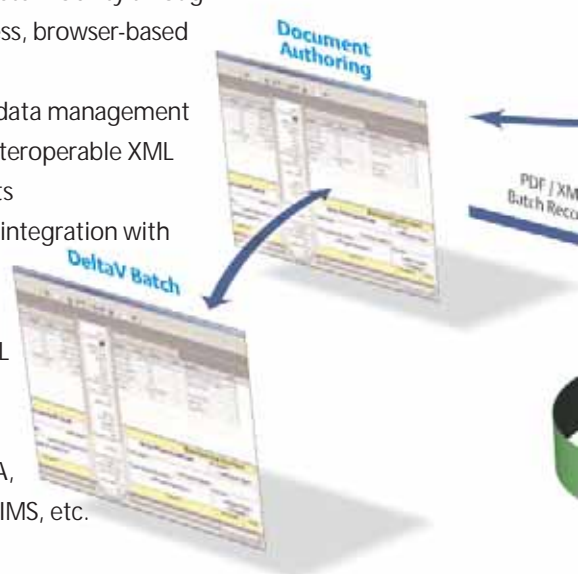
Seamless recipe and work process execu

Component Properties Lookup

Document Control & Archiving

XML Update of Standard BOMs

Orders, Order BOMs, Inventory Transactions

XML S-88 Recipes with Standard BOMs, Weighing Properties, EWI's

Recipe & Order Management

XML /HTML Executed Batch Records

Routing and Approval

Weigh & Dispense

Weigh & Dispense

DeltaV Batch Recipe

Training & Development

ution.

> "The batch executive and the way DeltaV is set up to execute and administer batches has worked very well for us. It's very user friendly and easily traceable from a batch to batch standpoint."
>
> *Ashley Taylor,*
> *Associate Purification*
> *Director, Abgenix*

Achieve best production and manufacturing quality that meets regulatory expectations including Part 11 compliance—with solutions from Emerson.

Here are some of the new ways Emerson's solutions can help you improve operational efficiency while decreasing cycle times and cost of goods sold through:

- Increase percentages by reducing common manual processing errors and omissions as well as calculation and rounding errors
- Decrease waste, rework, and investigations by using structured, verifiable operator instructions, automated data collection, barcoding technology and integrated control
- Improve review and approval process through electronic routing
- Improve process control by utilizing appropriate advanced control techniques
- Increase overall equipment effectiveness through better predictive maintenance techniques
- Improve release process via automatic product release that meets specifications after validation of all othe release activities

- Improve efficiency of the annual product review process with easy access to relevant data and information.

Planning

Planning gets updates on material consumption and movement in real time, minimizing WIP.

Quality Control & Compliance

EWI / EBR eliminates missing data / signatures on batch records. Integrated LIMS ensures potency verification impacts managed in real-time.

Manufacturing

Precision process measurement and device status integrated with advanced control reduces variability and (missing line of text).

Efficiently execute, review and release ba

nent

Does this image work here? If so, please verify images in these two lower right hand boxes. Identify appropriate images if changes are required.

"It facilitates making changes and documenting and justifying those changes. That's a real advantage to us in servicing different customers."

Rick Gray, Vice President, Analytical, Quality & Regulatory Affairs, Cedarburg Laboratories

Plant Management

Plant management has real time access to plant KPFs and can compare current campaign performance to previous runs.

Operations Management

EWI integrated with automated unit operation ensures consistent shift to shift performance and minimizes human deviations

Maintenance

Predictive maintenance practices updated with predictive, real-time equipment status avoid shutdowns and minimizes overtime.

Release and Shipping

EBR with integrated, verified data minimizes batch record review time and facilitates quicker shipments, minimizing inventory.

New image for Release only ????

Release and Shipping

Integrate with ERP or use material management to manage your inventory and shipping process.

For position only - verify position and connection. ????

atches.

The Power to Predict Results

Emerson touches more of the plant with predictive intelligence, providing manufacturers with a consistent well-structured data model to bring your business and decision support systems on-line.

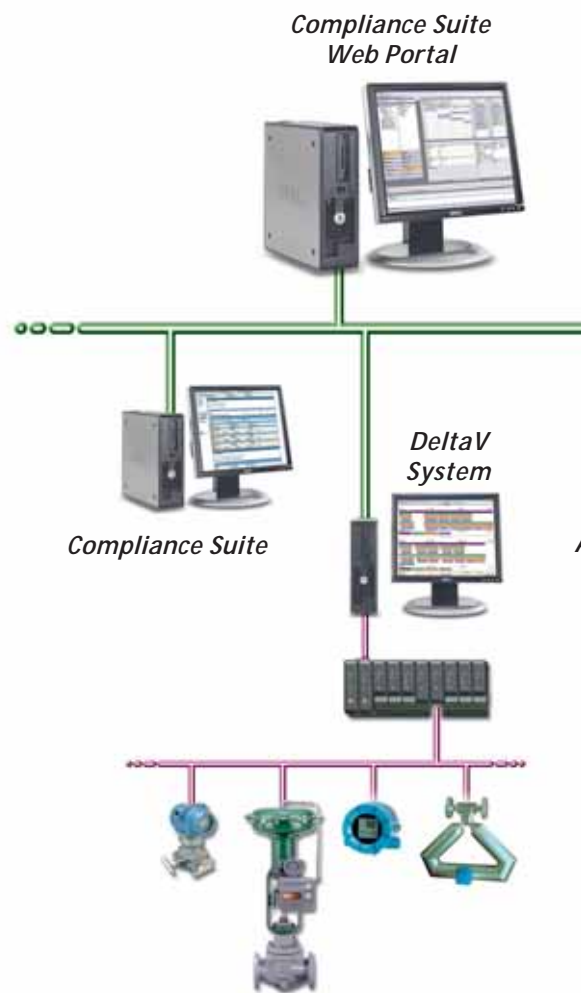These real-time solutions improve process understanding, organize data, identify disturbances, and increase yields.
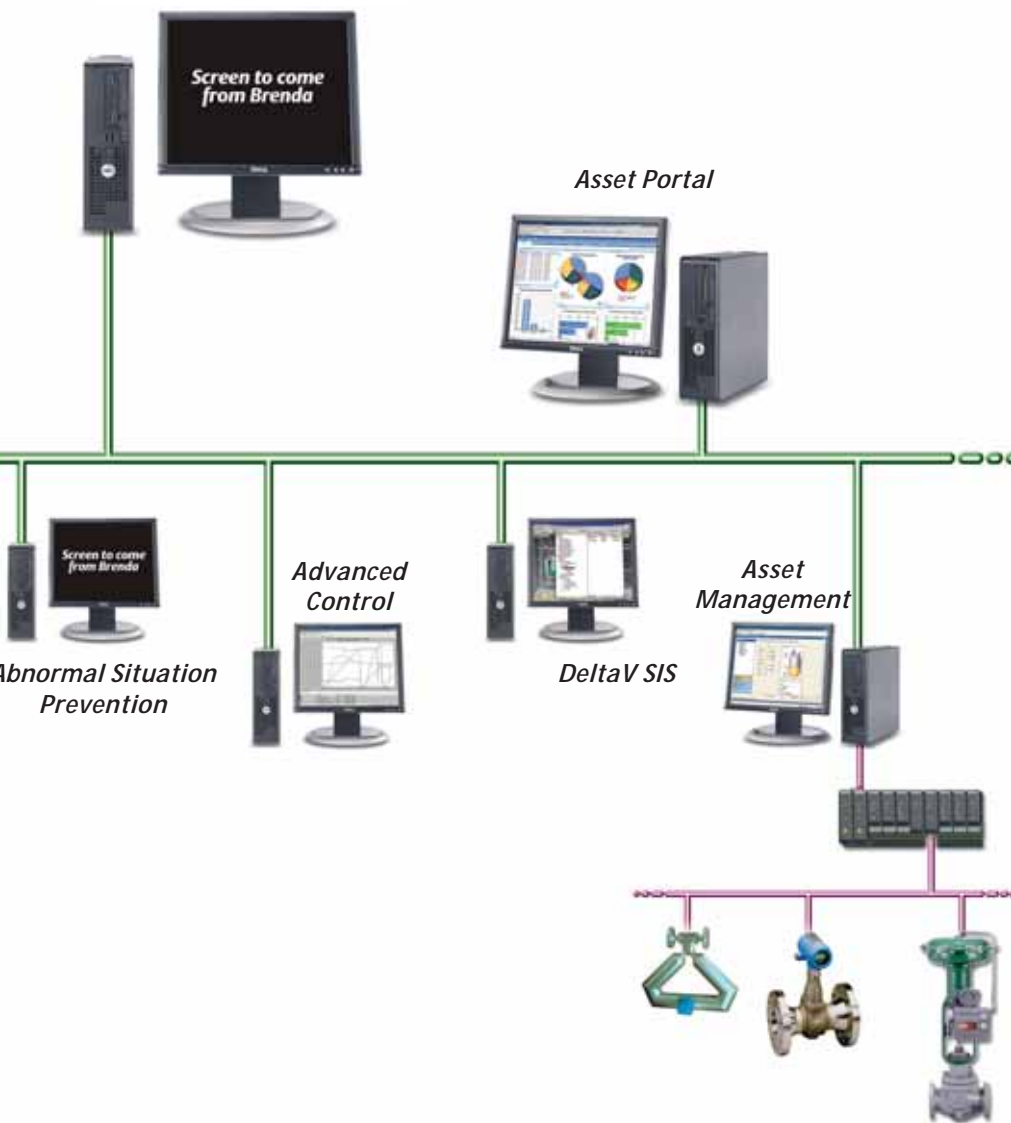
With Emerson's PlantWeb architecture you can predict failures before they occur and significantly reduce unplanned downtime in operations. What's more—you can predict process upsets and manage your process more effectively.

By utilizing today's advanced digital control techniques like DeltaV's embedded advanced control and abnormal situation prevention, you can decrease variability in your process and gain better quality, consistency and higher throughput.

Connecting the Intelligent Life Science Manufacturing Plant

PlantWeb—Emerson's proven digital plant architecture, uses the power of real time analysis, predictive intelligence and electronic workflow compliance solutions to optimize your plant's performance with:

- Standards-based architecture based on Intelligent field devices
- Unified scalable and modular software and hardware platform
- Tools to optimize plant performance
- Design that supports 21 CFR Part 11

Compliance Suite Web Portal

DeltaV System

Compliance Suite

A

Real time analysis optimizes plant perfo

Integrated View of
Operations

Screen to come
from Brenda

Asset Portal

Advanced
Control

Asset
Management

Abnormal Situation
Prevention

DeltaV SIS

Screen to come
from Brenda

rmance.

Industry-experienced Emerson resources can help you apply the appropriate technology to your unique production while uncovering and solving operational issues and challenges.

With decades of experience serving the pharmaceutical and biotech industries, Emerson's expert engineers, project managers and industry-experienced consultants are uniquely qualified to partner with your organization to deliver manufacturing productivity.

By combining automation systems with workflow and compliance management software you can maintain a parallel flow of a single recipe with its single batch record in real time.

Emerson's consultants use an operational excellence methodology to identify your business opportunities and drivers, justify improvements, and implement solutions to meet your needs, expectations and budget.

Examples of benefits include:

- Reduced delay in product release with tightly linked batch execution and batch record creation.

- Predictive, preventive measures can remedy defects before they occur.

- The product and its batch record are produced simultaneously and interactively so both are right the first time.

- Error-fraught manual processes are automated with operator prompts and acknowledge-ments to reduce opportunities for errors and to streamline approvals and authorizations at each step.

- Barcode printers and scanners can be used to make materials or equipment use checks and associated data entry error-free and simple.

Emerson's OpX advantage

Emerson's OpX Advantage program is a proven, data-driven methodology with a structured approach that can be tailored to meet your operational improvement initiatives. Tools from Six Sigma, Lean Manufacturing, or any other appropriate technique can be incorporated in the overall process. This structure includes:

Initial Assessment: What problems need to be solved? Areas of opportunity can include throughput improvements, cost reduction, and increased availability.

Detailed study: What are the main obstacles and limitations? Emerson can help you identify specific process problems while uncovering best work practices, systems and process capabilities. Current state maps are developed, potential operational improvement benefits are developed, and possible future state plans are introduced.
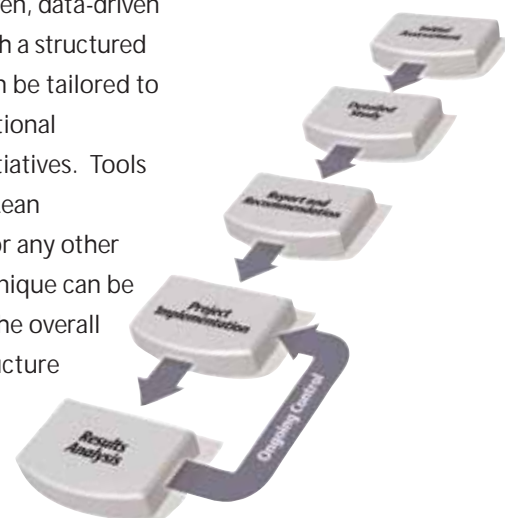
Increase productivity with the right combination of resources

and Technology Drive Productivity

Report and Recommendation: How will modifications to business processes and systems deliver benefit? How will changes impact the organization? All of the data gathered in the detailed study is thoroughly analyzed, benefits are quantified, future state maps are developed, training and change management needs are formalized, and ROI is estimated.

Project Implementation: How will the project be managed with project planning and execution that will efficiently and effectively realize benefits? Emerson blends industry expertise, tools, technology, and effective project managers together to deliver the projected benefits.

Results Analysis: How do the results compare with the initial baseline? Improvements are measured against the measurements from the initial assessment and detailed study.

On-Going Control: What work practices can be put in place to sustain or even increase the improvements? Processes, procedures, and performance indicators are established to maintain the benefits. Continuous improvement can also be a part of this phase.

Add OpX guarantee: Based on experience, Emerson has developed the Operational Performance Guarantee problem to help you assess and realize operational improvements. Tailored to meet your individual needs, the program follows a structured methodology from initial performance study through project implementation, and offers a guarantee of predicted gains.

"With regard to the PAT initiative, I feel that the ability to conduct real-time monitoring of process parameters and abnormal operations is the key to achieving the process understanding that leads to improved process control."

Mel Koch
CPAC Director
University of Washington

- ■ Improved capital efficiency through increased investment life as new products and technologies become available.

Doing business with Emerson Process Management also gives you the confidence that the products, services, and solutions you buy are backed by our unmatched global support.

The advantage: We're everywhere you are. The information and support you need can be as close as your telephone or web browser —or right around the corner.

Innovative Support Service

Guardian sets a new standard in services for Emerson customers. This innovative support service enables real-time visualization and management of Lifecycle Support requirements. The results:

- ■ Better decision making with data from many sources combined, analyzed and turned into user-personalized and actionable information

- ■ Improved staff productivity through global collaboration across systems and sites

- ■ Lower operations and maintenance costs by shifting from a reactive/preventive strategy to predictive/proactive maintenance

- ■ Better operating performance as new features and maintenance fixes enable improvements in plant control operations

With Guardian Support's secure content management website you can review and configure information so that it best serves your individual needs.

- ■ User interface language selection

- ■ Actionable KPA's (Knowledge Based Articles) —tracked and rematched to the most recent captured system content information

- ■ Examine technical support calls history

Emerson—Consider it solved.

ce and Support

- Send/reciew call status updates
- View your specific system lifecycle states
- Share system content changes with others to narrow the focus

Wrap up paragraph describes Emerson's track record of being the number one choice for pharmacuetical customers worldwide. Wrap up our commitment to helping customers reach their potential with the technology and solutions that only Emerson can provide.

"Emerson's project execution capabilities were a critical part of our project's success."

— David Whitehead
Clough Engineering

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Customers who have requested this brochure have also requested the following brochures:

As a core element of the PlantWeb digital architecture, the DeltaV systems makes controlling your process easy.

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