Improving Process Efficiency and Business Performance in Life Sciences Plants

by Don Clark

Executive summary

Many chemical and pharmaceutical plants still use manual methods to manage their process operations. As a result, they lack timely information that could prevent cost, quality, or schedule variances. This paper examines how industry leaders are replacing manual processes and guesswork with process automation. This allows for real-time information and data analysis, leading to improved productivity, higher yields, comprehensive compliance, and profitability.
Manufacturers in life sciences face a range of challenges, such as globalization, an aging work force, cost and quality pressures, and regulatory requirements. To remain competitive, these companies are striving to optimize operations in order to accelerate project execution, new product introductions, and production changeovers, and to become more agile and achieve greater sustained business value.

However, chemical and pharmaceutical manufacturers are finding it increasingly difficult to meet these challenges using traditional manual systems to manage workflow, collaboration, and scheduling, as well as many parts of production operations. It’s typical for planning departments to issue monthly production plans that are passed on manually to operations. Since manufacturing rarely goes according to plan, the operations staff is constantly juggling equipment, materials, personnel, and production lines to produce scheduled product volume.

When processes are managed manually, production reports are often weeks old, so plant managers are forced to make decisions without access to the latest information. Instead, they must rely on their experience and best guesses. Thus, the impact of their decisions on profitability is not known until the next financial reports are generated (see Figure 1).

Even enterprises that have adopted some process automation have not done so in a holistic fashion. At the regional or enterprise level, this has resulted in disparate systems and data sources that are poorly integrated, making it difficult for upper management to identify trends, leverage best practices, and grow business value.

To address this challenge, leading manufacturers in life sciences are replacing manual systems with a standardized, automated approach to process operations management. These firms are able to improve decision making at all levels, from the plant floor to the executive suite, by providing accurate and timely information about all plant activities, thereby enhancing a firm’s agility and competitive position.

This paper examines the challenge of operations management in life sciences manufacturing, and discusses how integrating and automating all aspects of production operations can be done.

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1 Based on results reported by Abbot Laboratories; Allergan, Inc., Amgen Inc., Bristol-Meyers Squibb, Celgene Corp, Forest Laboratoires Inc, Johnson & Johnson, Eli Lilly and Company, Merck & Co, Inc., Mylan Laboratories, Inc; Pfizer Inc., Watson Pharmaceuticals, Inc.
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used to achieve higher production yields, lower waste and product variability, and greater business value through improved operations performance.

The business adage, “You can’t manage what you can’t see,” has never been truer than in life sciences manufacturing.

Operating from tradition or inertia, many companies continue to manufacture as they always have, using manual and paper-based systems for operational tasks such as planning, scheduling, quality control, and compliance. As these companies strive to manage multiple plants in an increasingly global environment, they are falling behind. Manual systems simply cannot keep up with the pace of business in the modern world.

This has resulted in a chronic lack of information available at the right time to the right people, leading to myriad problems from the plant floor to the executive suite. It’s estimated that product variability and workflow cost the specialty chemical and pharmaceutical industries millions of dollars per year in lost earnings either through increased costs or lost revenue opportunities. This “cost of poor quality” (COPQ) can represent a significant percentage of sales revenue in even the best plants in this industry\(^2\) (see Table 1\(^3\)).

Table 1
Process improvements can reduce quality costs as a percentage of sales
Source: isixsigma

<table>
<thead>
<tr>
<th>Sigma Level</th>
<th>Cost of Quality as Percentage of Sales</th>
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<tbody>
<tr>
<td>2</td>
<td>More than 40%</td>
</tr>
<tr>
<td>3</td>
<td>25-40%</td>
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<tr>
<td>4</td>
<td>15-25%</td>
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<tr>
<td>5</td>
<td>5-15%</td>
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<tr>
<td>6</td>
<td>Less than 1%</td>
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</tbody>
</table>

Planning and scheduling

A typical life science company issues production plans and target volumes on a weekly or monthly basis. Yet manufacturing never goes according to plan, and soon after a plan is issued, the plant manager and other operations staff must juggle equipment, material, workers, and supplies in an attempt to meet the target volumes on time. Lacking information, they are forced to use best judgment and their expertise, instead of hard data and real knowledge. Such an approach relies almost exclusively on the talent, experience, and training of the people making the decisions. While this may be successful to some degree in a given plant, it is not optimal, nor transferrable to an organization’s plants in other locations.

Unexpected events

Manufacturers can expect the unexpected to happen: A supplier runs out of a crucial ingredient. A natural disaster disrupts the supply chain. A flu epidemic depletes the workforce. Whatever the unexpected event may be, it will impact business performance, and with only manual systems and paper records to guide them, decision makers will struggle to find an effective solution or work-around.

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\(^3\) Arne Buthmann, “Cost of Quality: Not Only Failure Costs,” isixsigma.com, Feb. 2010
Problem identification

There can be long-lasting problems in production that can go unidentified for weeks or months, simply because there is not enough data to recognize that there is a problem. As noted by isixsigma, "When key parameters in manufacturing are not being monitored real-time in control charts, deficiencies in process are often hidden until final inspection, greatly raising the exposure to process waste and the potential for scrapped product." \(^4\)

Even when a problem is suspected, and experts are dispatched to isolate it, root-cause analysis can be slow when records are incomplete or lagging weeks behind production runs.

In either of these scenarios—where a problem is not recognized, or the source of the problem cannot be accurately identified—the manufacturer is essentially throwing away profits.

Corrective action

In addition to “You can’t manage what you can’t see,” is the fact that “You can’t correct what you can’t identify.” Corrective action requires precise problem identification in order to be both effective and cost-effective. For example, lacking data-based analysis of a problem, a pharma manufacturer might be forced to destroy entire production runs even though only part of one shift might be involved. In other instances, it might be necessary to recall all products from a region, because the specific plant at fault cannot be isolated.

In cases such as unnecessary product recalls, the cost of “failing to correct” will obviously be quite high, possibly even catastrophic. Less obvious is the cost of minor problems that go undetected. Minor but persistent waste in production—such as inefficient materials movement or excess inventory—can be difficult to identify and correct without detailed production records, and thus can go on for long periods of time at a large cumulative cost to the company. In some facilities, the cost of waste can run as high as 40% COPQ.\(^5\)

Compliance

Compliance is an ongoing challenge for life sciences companies. That challenge is heightened when production operations are partly or completely manual. Enforcement is difficult to maintain, and if reports are required to prove compliance, they are costly and take a long time to produce. Noncompliance becomes costly if root causes cannot be identified and companies are forced to quarantine, destroy, or recall larger-than-needed quantities of product.

Of course, the need for safety and compliance in life sciences is absolute. But that does not mean compliance must be inefficient, if there is a better way to achieve it. As noted by isixsigma, "Safety, no matter how costly or inefficient, in particular has driven a high level of operational waste within many business units of life sciences companies."\(^6\)

Best practices across plants

From the perspective of the executive suite, lack of information and standardized metrics prevents optimum decision making for the enterprise, and puts a roadblock in the way of achieving uniform best practices. Production operations are difficult to standardize and compare across plants when some or all of the plants are managed manually. Lacking real data, plant managers make decisions based on experience and best guesses, which is not a model that can be exported to an organization’s other plants around the world.

\(^5\) Based on Schneider Electric’s experience

“One company making over-the-counter drugs had a COPQ of more than $100 million for their three largest-selling drugs alone.”
Cost of poor quality

Quality is a key metric for life science companies. In the absence of automated production systems, manufacturers have developed a testing approach to quality control, which means high levels of scrap and waste. Product variability and workflow costs the specialty chemical and pharmaceutical industries millions of dollars per year in lost earnings either through increased costs or lost revenue opportunities.

Some studies estimate the COPQ within life sciences at 25% or more of sales revenue. A Pharma Manufacturing article reports that one company making over-the-counter drugs had a COPQ of more than $100 million for their three largest-selling drugs alone.

Best-in-class life sciences companies are beginning to standardize, integrate, and automate their production operations across the enterprise. This is accomplished by using computerized information systems to plan, deploy, control, monitor, and report on production details in the plant. Automation can support virtually any operation related to manufacturing, from production line processes themselves (whether conducted by machines or people) to plant conditions such as temperature and humidity that could affect product quality.

Although systems and implementations will vary across companies, automated production provides several key capabilities that enable better, faster decision making and more efficient operations of both the production line and the overall business (see Table 2).

### Table 2

Automated Production Capabilities

- Automatic process change for rapid adjustment of production plans
- Continuous information capture, providing key metrics to management
- Automatic “out of spec” alerts for batches or other processes
- Early identification and correction of problems, reducing product variability
- Process optimization for additional capacity and yields
- Accessible product history to aid in analysis and regulator reporting

Production automation can be extended to and integrated with HVAC controls, especially where strict environmental requirements exist, such as in laboratories and cleanrooms. For example, exhaust systems merit particular attention for labs and clean manufacturing facilities, because they comprise up to 40% of the ventilation system's energy use in the typical facility, and as much as 30% of the total energy consumption.

Better control of exhaust systems and how they function in production operations will both ensure proper conditions for manufacturing and optimize energy use and costs. (To learn more about lab- and cleanroom-specific energy and control issues, download the Schneider Electric white paper, “4 Steps for Improving Energy Efficiency in Laboratories.”)

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8 Bikash Chatterjee, “Quality Circle: Profitability, Integrity and the Cost of Poor Pharma Quality,” pharmamanufacturing.com, Feb. 15, 2012
Production operations can also be integrated with a facility's building management system, to provide a still higher level of control and visibility. Very few facilities exist in a sealed environment. Air flow in the plant is affected by air pressure and conditions in the building where the plant resides. Best practice today is to integrate lab and production systems with other building automation systems, to optimize both overall air flow performance and energy use.

There are multiple benefits to automating production operations as shown in Table 3. This section highlights three benefits that are worth emphasizing, as they provide the foundation for all the other benefits that flow out of a fully integrated production operations and automation solution.

**Benefits of Automated Production Operations**

<table>
<thead>
<tr>
<th>Improved batch execution</th>
<th>Closer integration of operations with scheduling</th>
<th>Improved access to meaningful business information</th>
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<tbody>
<tr>
<td>Increased yields</td>
<td>Less variability in process performance</td>
<td></td>
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<tr>
<td>Improved workflow &amp; collaboration</td>
<td>Increased capacity &amp; reduced waste</td>
<td></td>
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<tr>
<td>Reduced inventory &amp; need to stockpile</td>
<td>Easier &amp; faster data analysis &amp; knowledge</td>
<td></td>
</tr>
<tr>
<td>Improved agility &amp; response to operational variances</td>
<td>Improved traceability &amp; compliance</td>
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</table>

**Improved batch execution**

Batch production is the primary manufacturing activity for many life science companies, and improving its efficiency and accuracy can be fundamental to business performance. Automation improves batch execution through:

- better control and lot-to-lot repeatability of batches
- faster, more informed response to changing conditions
- supervisory ability to manage the batches and report on the production operations.

The degree of improvement in batch production will depend on the current level of automation. In some fine chemical and API (Active Pharmaceutical Ingredient) plants that are currently using entirely manual batch operations, full automation could improve economic performance by reducing waste as much as 60%, increasing yields by 5 to 10%, and lowering lot-to-lot turnover times by as much as 25%. For plants with some level of automation, the economic value of fully automating will be less but still significant.

**Closer integration of production operations with scheduling**

Scheduling is by nature static, while batch production is highly variable and subject to many complexities. Integrating operations helps bridge this gap, eliminating the hassles of trying to coordinate outdated schedules. This can have a major impact on business, in terms of improving plant efficiencies and meeting customer expectations.

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10 Based on Schneider Electric's experience
Typical improvements that life science companies report in this area include:

- better information for the scheduling department, leading to more realistic and optimized schedules
- faster indication of when schedules and production are out of alignment
- the ability to make changes in operations that ripple automatically into the production schedule process, simplifying change and improving agility.

**Improved access to meaningful business information**

Enterprise resource planning (ERP) information is usually outdated by the time it becomes available. For optimizing operations, decision makers need to know what *is happening*, not just what *has happened* weeks in the past. Integrated production operations automation provides the ability to access the correct information when it’s needed, in real time and in a meaningful way, for improved decision making.

This empowers plant engineers, operators, and management to take corrective actions based on real-time information of the KPIs of their critical processes. It also enables drill-down into the running process to determine the root cause of variances, allowing rapid corrective action before variances become costly.

Production information can be aggregated from plants worldwide, packaged and presented in a way appropriate for corporate-level decision making. For example, executives can monitor plant performance metrics across plants and regions, or view supplier performance in areas such as quality and ability to deliver on schedule. This kind of visibility into operations provides a clear competitive advantage versus companies that are only “guesstimating” or using old information.

There are several capabilities to look for in choosing a vendor for automating process and production operations. These will be based on an organization’s needs and goals. Following are some of the key capabilities that should be considered.

**Integration of production systems**

As much as possible, process automation should be able to be tightly integrated with other information systems related to production, such as ERP, product lifecycle management (PLM), inventory, and quality control. Such integration allows companies to leverage production information to gain deeper insights into business operations. Big data can be used for enterprise-level analysis that can uncover otherwise hard-to-see problems and trends that are crucial to business success.

For example, imagine that a drying oven burner inspection door has been inadvertently left open during a plant maintenance turnaround. Following start-up, the burner control system may be quite capable of compensating for the dramatically increased burner load (cold, outside air), and the product is just fine. But a huge cost deviation is accruing, unseen by plant personnel and undetected until the ERP reports come out two months after the fact.

Now imagine the same situation, but with tight integration of the control and production reporting systems. The variances to forecast costs—now available in real time—can be detected immediately and alerts sent to production staff to investigate “adverse gas consumption” well before it can become a significant problem.

The greater the integration of systems and data, the more these types of problems can be recognized and solved, and the greater the benefits become across the organization.
Predictive modeling

Another benefit of automation is that it can be used proactively. Some vendors provide predictive modeling capability as part of their solution, along with other data analysis services. Historical data can be analyzed to create predictive models that suggest alternate pathways to achieving specific goals such as volume, quality improvements, or profitability. To give one example, a modeling program might analyze production records and predict that a change in suppliers and scheduling could reduce inventory by a given amount, without affecting volume. The company could then implement the changes with a high degree of confidence in the return on investment that could be expected.

Scalability

While automation can be worthwhile in a single plant, its real benefit is realized when systems are standardized across the enterprise: The larger the “scope” of the applied solution, the greater the potential for economic impact to the company. To achieve this, it’s essential to have a system that is highly scalable, not only to handle the facilities in operation today, but also new facilities that may be opened in the future. In addition, scalability supports a “start small and grow” strategy of implementation, allowing companies to prove results in one plant before extending the investment across the enterprise.

Global support

Related to system scalability, global support is a requirement if a company is to have a unified solution for manufacturing across regions. A single robust provider of systems and support will simplify implementation as well as ongoing operations and can use scale of operations to help reduce costs.

Integration with building systems

Some life science companies have extended integration beyond production, to include building management and utility management systems. This type of integration provides yet a higher level of control and a truly holistic vision of automation. For example, it enables a company to correlate production runs and facility energy usage, and develop optimum schedules that reduce costs and result in more sustainable operations. According to an article in Industry Week, a single platform for building management, process automation, and environmental monitoring in life sciences “will ease validation efforts, improve product quality, reduce total cost of ownership and improve time to market.”

“A single provider of systems and support will simplify automation implementation.”

A process operations automation solution empowers plant personnel to identify potential problems before they become serious by accessing and integrating data from multiple disparate systems. By replacing manual systems with a fully integrated production operations solution, enterprises can take greater control over their plant floors and drive higher yields, reduced waste, and greater profitability. When deployed on a global scale, a life sciences manufacturer can drive best practices and continuous improvement across all facilities, and provide upper management with the information needed to make better decisions that grow business value.

For companies that are interested in pursuing the automation of all aspects of their production, several providers exist. Many vendors offer webinars on their websites, and these can be a good source for gaining a high-level understanding of process automation and how it can be applied to a company. Live webinars offer the opportunity to ask questions about specific situations. The next step is to develop a short list of vendors based on the issues that are most important to a company (those outlined in this paper, and others that may be unique to an organization).

By understanding requirements, and asking hard questions of prospective solution providers, life sciences manufacturers can achieve a production operations solution that not only optimizes operational performance and agility while improving yield and quality, but also enhances other information systems as well as corporate management’s ability to sustain and grow business value over the long term.

Don Clark has nearly 40 years of experience in process operations IT for life science and specialty / fine chemicals companies, including Honeywell, 3M, and Rohm & Haas Chemical Company. He is currently VP and Schneider Fellow at Schneider Electric. A member of ISA and IEC, Don holds a B.S. in Chemistry from California State University, Fullerton, and an M.S. in Chemical Engineering from the University of Houston, Texas.