

A View to Performance Management

Pharmaceutical companies are under enormous pressure to streamline manufacturing. Not only must the FDA be satisfied that systems are compliant, but companies need to meet changing business and financial drivers as well. More and more frequently, pharmaceutical manufacturers are looking for ways to improve operational performance in the production environment – with many companies moving toward producing on demand and devising new ways to increase their manufacturing throughput. Additionally, initiatives like Process Analytical Technologies (PAT) strive to not only improve product quality but to reduce manufacturing cycle time and drive waste out of the system.

In order to address these manufacturing issues, companies need better visibility into manufacturing operations. There's an old adage: "You can't improve what you don't measure," and by the same token, you can't measure what you can't see. More and more life sciences companies are heeding these sentiments. Organizations are demanding better ERP system and plant floor connectivity. In an effort to drive real-time visibility and intelligence and identify plant efficiency metrics, companies are implementing systems and processes to move toward real-time production performance management.



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Can You See Me Now?

Process and quality improvement initiatives can come under many banners – Right First Time, Process Excellence, Lean Manufacturing, TQM, and the list goes on. The growing trend toward better visibility into manufacturing operations requires not only technology but effective processes. Technology applied to a bad process results in an automated bad process. Process improvement efforts rely on an adequate system to measure people and results – and to hold them accountable.

Once an effective process has been put in place and personnel understand and support that process, enabling technology can be layered on top to help drive improved operations and global visibility in a pharmaceutical manufacturing environment.

An effective system to help enable and sustain a lean initiative, for example, and drive performance management should begin by having the ability to collect plant data from a variety of disparate sources close to the manufacturing environment. Data should be transported into a secure repository that centralizes record keeping. Centralized record keeping helps to enable regulatory compliance by storing data in one secure environment. A central repository can also provide information to generate an Electronic Batch Record (EBR) and is an enabler of PAT. Each of these initiatives is aimed at speeding release of product to distribution; reducing errors, review time and Work-in-Process (WIP); and decreasing regulatory risk.

The system should then digitize plant operations in a “virtual plant” and transform plant data into meaningful information using business rules and analyses. More and more companies are tracking metrics like Overall Equipment Effectiveness (OEE), Overall Asset Effectiveness (OAE), sales effectiveness, finished goods inventory and WIP inventory.

As pressure continues to build on pharmaceutical companies, they need to determine better ways to utilize plant assets, including people, equipment, and materials. A comprehensive view of overall equipment efficiency allows them to achieve better results from less production effort. In addition, companies can identify and improve areas that are causing operational inefficiencies and make data-driven decisions on capital expenditures and process improvement investments.

Better Visibility, Better Quality

While efficiencies in the operation increase, companies can also achieve higher quality production from enhanced real-time visibility. A major driver for life sciences companies is avoidance of product recall. The wave of recent major product recalls echoes the need for a quality management system as part of production management. Detailed, easily accessible tracking and genealogy capabilities limit the scope of recalls and quarantines while offering quick response to customer issues, and an effective quality management system will enable faster time-to-market with higher success rates.

Furthermore, managing production can drive an increase in schedule execution and accuracy, resulting in a reduction of overruns/shortages, lower inventory costs and faster, more accurate changeovers. This last point is especially salient as new drug pipelines decrease, and life sciences companies move toward fewer blockbusters – with large production runs – and instead more batches of small runs targeting smaller patient populations.

A comprehensive performance management system can also increase batch process consistency and reduce variability. Utilizing batch analysis tools, life sciences companies can compare cycle times, parameters, and variables across batches. In addition, they can trend, report on and summarize batch data, resulting in faster, more accurate product changeovers.

Finally, through a performance management system, companies can gain web-based visibility and analysis for real-time decision-making. The system should securely supply information to operations, the business, customers and suppliers for continuous process improvement. All of this helps to drive waste out of the process and requires that the system track and control production for improved agility.

By establishing effective processes and utilizing the correct enabling technologies, pharmaceutical companies can streamline operations – and help to relieve business pressures.

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