



Digitalization for Pharmaceuticals: Safeguarding Product Supply by Ensuring Asset and Process Health

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Many factors impact a pharmaceutical company's ability to ensure supply of end products. One factor could certainly be equipment failures; however, a more comprehensive look must also include continually changing operating conditions and the impact on process health. Both should be addressed enterprise wide in a timely, scalable fashion. Both factors can cause batch quality failures, resulting in costly production losses and disruptions to supply. With single batch values for some drugs surpassing \$3M USD, even one lost batch can deliver a serious blow to profits and supply. So while maintenance costs and capital expenses to replace unreliable equipment can quickly erode margins, this isn't the only impact on security of supply and overall profits.

Digital solutions—particularly advanced analytics—can help pharmaceutical manufacturers prevent equipment breakdowns and ensure process consistency, optimizing production overall and protecting the supply of product to customers. In addition, they can ensure that the selected solutions not only address all facets, but can also be implemented in mere months instead of years.

Advanced Analytics to Maintain Asset Reliability and Ensure Process Health

Predictive maintenance solutions go beyond taking action when a threshold is surpassed. Sometimes misunderstood, these solutions use advanced analytics to identify the signs of pending equipment failure and warn maintenance teams in advance, allowing drug makers to plan repairs, adjust production and avoid unplanned failures that would result in lost product.

Process multivariate analytics further evaluate the complex variables in batch production and determine which are critical to quality, helping pharma producers keep batches on course and, as a result, driving greater consistency and yields.

With these tools in place, pharmaceutical makers position themselves to safeguard security of supply, optimize production and control costs.

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Advanced Analytics to Drive Efficiency

With pharmaceutical companies already facing strict quality and safety regulations, pricing pressure and tighter delivery schedules, many drug makers are focusing more on production costs and efficiency than in the past. For “Big Pharma,” the massive investment in bringing a product to market—including purchasing or repurposing manufacturing assets—often comes with a relatively short useful life due to finite product lifespans before generics enter the market and cut into profits. Similarly, generics and CDMO manufacturers that produce lower value products in high volume must also control production costs to protect the bottom line.

Pharmaceutical and life sciences companies are turning to advanced analytics, artificial intelligence (AI) and machine learning to help them:

- Increase equipment reliability
- Prevent manufacturing losses
- Find the “hidden factories” inside the plant through yield, quality and cycle time improvements, and as a result reduce capital expenditures (CAPEX)

Opportunities to reduce manufacturing costs exist across all stages of the product lifecycle. Advanced analytics can reveal those opportunities,

allowing pharma companies to take informed action to save money. Whether using multivariate analytics to identify process degradation and its impact on quality or predicting final product quality to reduce lab testing lag times, these techniques offer pharmaceutical companies a competitive advantage.

Using predictive maintenance and process multivariate analytics, pharmaceutical companies can position themselves to safeguard security of supply, optimize production and control costs.

PwC suggests “Focusing on specific business issues and sourcing the technologies and talent that can address those issues will help pharmaceutical and life sciences companies move toward the broader adoption of advanced analytics at an enterprise level.” Both predictive analytics for Asset Performance Management (APM) and multivariate analytics for monitoring process behaviors that impact batch quality—ultimately leading to closed loop Process Analytical Technology (PAT) solutions—offer ideal starting points for pharma organizations looking to quickly gain value and reduce costs through digitalization.



Use Advanced Analytics to Avoid Unplanned Downtime, Lost Batches and Off-Spec Product

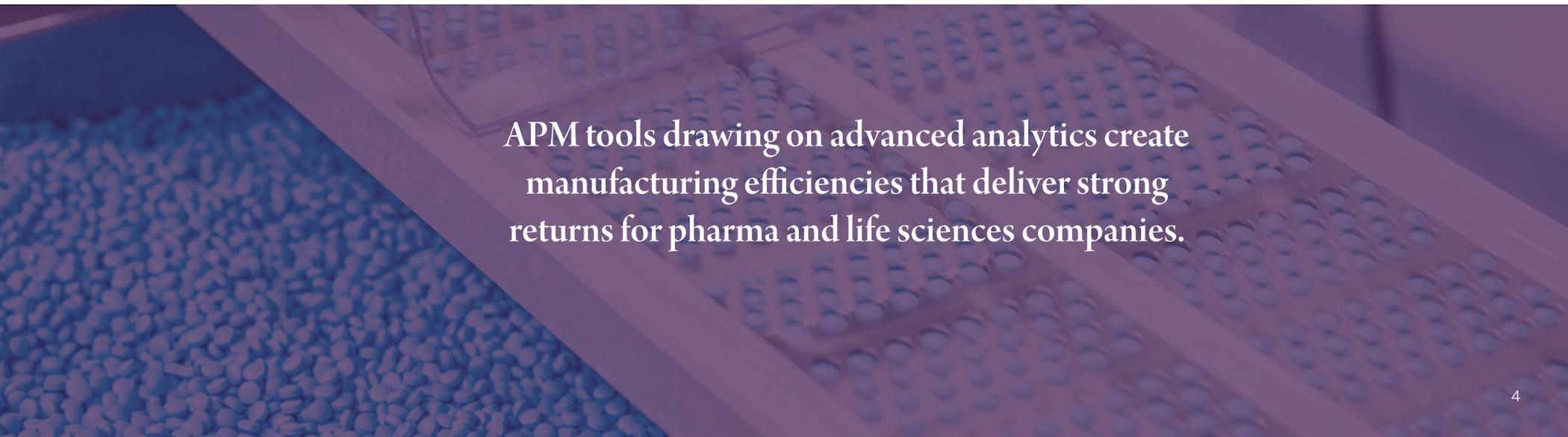
APM tools drawing on advanced analytics create manufacturing efficiencies that deliver strong returns for pharma and life sciences companies. Deloitte calls out, “With technologies like IoT-based sensors and machine learning—a common component of AI—a biopharmaceutical manufacturing organization can put these data to work toward smart process monitoring, advanced operator solutions, condition-based maintenance, and other advanced capabilities.” These advanced capabilities create substantial manufacturing efficiencies and offer superior control of the production process, eliminating unexpected events that result in losses. Saving even a single high-value batch offers payback on the investment in the software.

Analyzing Precise Failure Patterns

Predictive maintenance solutions analyze precise failure patterns to provide anomaly alerts and advance warnings of pending equipment

failures. With weeks or even months to plan for repairs, drug manufacturers can avoid unexpected shutdowns, reducing maintenance costs and preventing production losses. Predictive maintenance tools offer faster implementation and shorter time to value than many other digitalization investments, making them a strong choice for pilot projects in what Deloitte calls “digital incubators.”

Easy-to-use predictive maintenance software captures and analyzes data quickly, making best use of all knowledge and skill sets within an organization. Drawing on data history, past work orders and known failure modes, plant staff can develop Agents that identify anomalies and signs of pending failure. The Agents provide alerts that allow operators to investigate anomalies to determine whether they indicate a potential problem or schedule maintenance before a breakdown occurs.



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Multivariate Analytics Monitoring

Using existing sensors, data and infrastructure, multivariate analytics software analyzes and continually monitors for how discrepancies in material properties, variations in procedures and process anomalies such as sensor drift and changing environmental conditions impact the final product. These tools can help identify and troubleshoot process and product quality issues, increase yields and reduce off-spec product. Multivariate analytics monitoring can be especially valuable when applied to the complex chemical and biological processes prevalent in many pharmaceutical manufacturing processes; not reacting to small variations can steer a high-value batch off course.

The latest sophisticated tools support data scientists executing deep analysis while also being accessible to the operational teams most familiar with the process and helping them make sense of the available data. Without creating a need for dedicated staff, software that quickly diagnoses batch deviation to enable informed and timely action pays for itself many times over. Moreover, because these solutions can draw conclusions from sparse data, additional sensors or physical inspection rounds are not required to reap the benefits of reduced downtime.

Protecting All Your Critical Assets

Pharmaceutical manufacturing incorporates a wide variety of equipment and processes. Here are a few examples of the types of equipment that predictive maintenance solutions have been proven to effectively protect:

Primary equipment and systems	Secondary production and packaging equipment	
<ul style="list-style-type: none">▪ Air compressor▪ Boiler▪ Centrifugal compressor▪ Mixer dryer▪ Pump▪ Vacuum pump▪ Water purification system	<ul style="list-style-type: none">▪ Autoclave▪ Bead mill▪ Centrifuge▪ Chiller▪ Conveyor▪ Freeze dryer▪ Fluid bed dryer	<ul style="list-style-type: none">▪ Granulator▪ Plastic welder▪ Plate dryer▪ Roller press▪ Spray dryer▪ Spray head▪ Tablet press



Examples of Asset Performance Management Solutions Delivering Value for Pharma

Explore some of the value and savings asset performance management has delivered for drug manufacturers that have applied it to different types of equipment and processes:

Secondary Milling Mechanical Seal

One company was replacing the mechanical seal in its bead mill every eight batches to prevent batch loss—at an equipment cost of \$25K USD per replacement. Each batch was valued at between \$250K and \$300K USD. While the company tried to avoid batch losses, frequent shutdowns to replace seals limited capacity. The company needed to ramp up capacity and purchase two additional mills. Adopting Aspen Mtell® for predictive maintenance allowed it to reduce supply chain disruption from seal replacements and cut lifecycle maintenance costs by 60 percent. In addition, the company reduced CAPEX and associated lifecycle maintenance costs by 50 percent.

Water Purification System

Many pharmaceutical plants rely on water purification systems to support multiple products and manufacturing lines. Breakdowns in these systems can cause major losses. In 2019, one global pharma company suffered purified water system failures that shut down entire sections of the plant for as long as a week, resulting in the production loss of 15 batches.

Using Aspen Mtell to predict pending breakdowns in the enterprise-wide system provided the company with 35 days advance warning of a deionizer failure, allowing staff time to schedule maintenance and prevent production losses.

Formulation and Process Development

A Canadian research university was challenged to design a polymer for an ophthalmic application. The medication's properties needed to change with both temperature and light. Liquid at room temperature, the polymer needed to form a gel upon injection into the eye—without suffering from exposure to UV light.

When 23 trial-and-error formulations failed to meet one or more of the design goals, researchers turned to Aspen ProMV™. Using data from existing products as well as the previously failed design formulations, the team used Aspen ProMV to run offline experiments, varying formulations of new sets of ingredients and reaction conditions. As iterations of polymer formulations failed to meet all the objectives, the new data was added to a database, and the model was updated. Adding different formulations made for a “smarter” model with more combinations of ingredients and process conditions to test.

The second iteration of the Aspen ProMV Optimizer framework identified a successful formulation. The research team was able to determine which ingredients and components of the process were critical to quality, ensuring consistency in production.

Accelerate Your Digitalization With Advanced Analytics

Pharmaceutical and life sciences companies that embrace the power of advanced analytics solutions gain a significant competitive advantage by reducing maintenance costs and eliminating production losses to ensure security of supply. Tools that can easily scale create greater agility—and deliver greater value—while at the same time leveraging all existing process and data science talent effectively.



Predictive maintenance and multivariate analytics tools offer fast return on investment and quick wins for pharmaceutical companies at all stages of the digitalization journey.

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Summary

As the pharmaceutical market becomes ever more complex and competitive, agility will be imperative. Rapidly identifying ways to increase overall equipment effectiveness, reliability and throughput while maintaining product quality offers pharmaceutical and life

sciences companies a formula for success. Take the first step to investigate this strategy's potential using utilizing AspenTech's Process and Asset Performance Management solutions.





About Aspen Technology

Aspen Technology (AspenTech) is a leading software supplier for optimizing asset performance. Our products thrive in complex, industrial environments where it is critical to optimize the asset design, operation and maintenance lifecycle. AspenTech uniquely combines decades of process modeling expertise with machine learning. Our purpose-built software platform automates knowledge work and builds sustainable competitive advantage by delivering high returns over the entire asset lifecycle. As a result, companies in capital-intensive industries can maximize uptime and push the limits of performance, running their assets safer, greener, longer and faster.

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