

# The true impact of machine failure in pharma



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Recent survey reveals gaps in pharma's maintenance and reliability programs — and how they're holding the industry back

█ Today's pharmaceutical industry is facing big expectations — and opportunities.

Tasked with developing and manufacturing effective therapeutics and vaccines for an ongoing global pandemic, the industry's accomplishments have opened the door to next-generation technology. In the future, for example, mRNA vaccines might inoculate against Zika or HIV and the technology could be applied to hard-to-treat diseases like cystic fibrosis or cancer. On top of that, remarkable progress has been made in gene therapy — which holds the potential to transform treatment of debilitating diseases — and it's now the second largest class of drugs in development.

In short: It is truly an exciting time to be in the pharma sector. But as pharma sits on the precipice of great advances, the industry is also facing great challenges.

A recent industry survey conducted by Pharma Manufacturing and Augury confirmed that supply chain disruptions, the workforce skills gap and capacity constraints are still top industry pain points. Respondents who were more

hands-on with asset management, be it through plant floor operations, equipment purchasing, validation or maintenance, put greater emphasis on more specific challenges, such as struggles with forecasting production and new technology adoption (Exhibit 1).

In this complex sea of obstacles,

helping them resolve major machine pain points without a lot of heavy lifting. To that end, our recent survey took a deep dive into the state of machine maintenance and reliability in pharma plants to uncover the true scope of failure and what that means for the industry.

## The right asset maintenance and reliability strategy can move the needle for pharma manufacturers. machine pain points.

zeroing in on the right initiatives that make the largest impact is crucial to meeting goals. For pharma manufacturers, one area that touches all of these challenges is plant machinery. When machines fail or underperform, productivity slows, workers become frustrated, delivery dates are missed, and supply chains suffer.

The right asset maintenance and reliability strategy can move the needle for pharma manufacturers,

### LINK BETWEEN QUALITY AND MACHINE FAILURES

As the pharma industry squares off against well-established challenges, companies are finding themselves evaluating countless new manufacturing technologies and solutions. In these scenarios, what business outcomes are they using to define success? The majority of survey respondents are looking to be more productive and more efficient, without sacrificing quality — in

fact, they expect to reduce quality issues.

Over 64% of respondents specifically define technology success as a “reduction in QA/QC problems.” This was tied with “increase in production capacity” for the top goal.

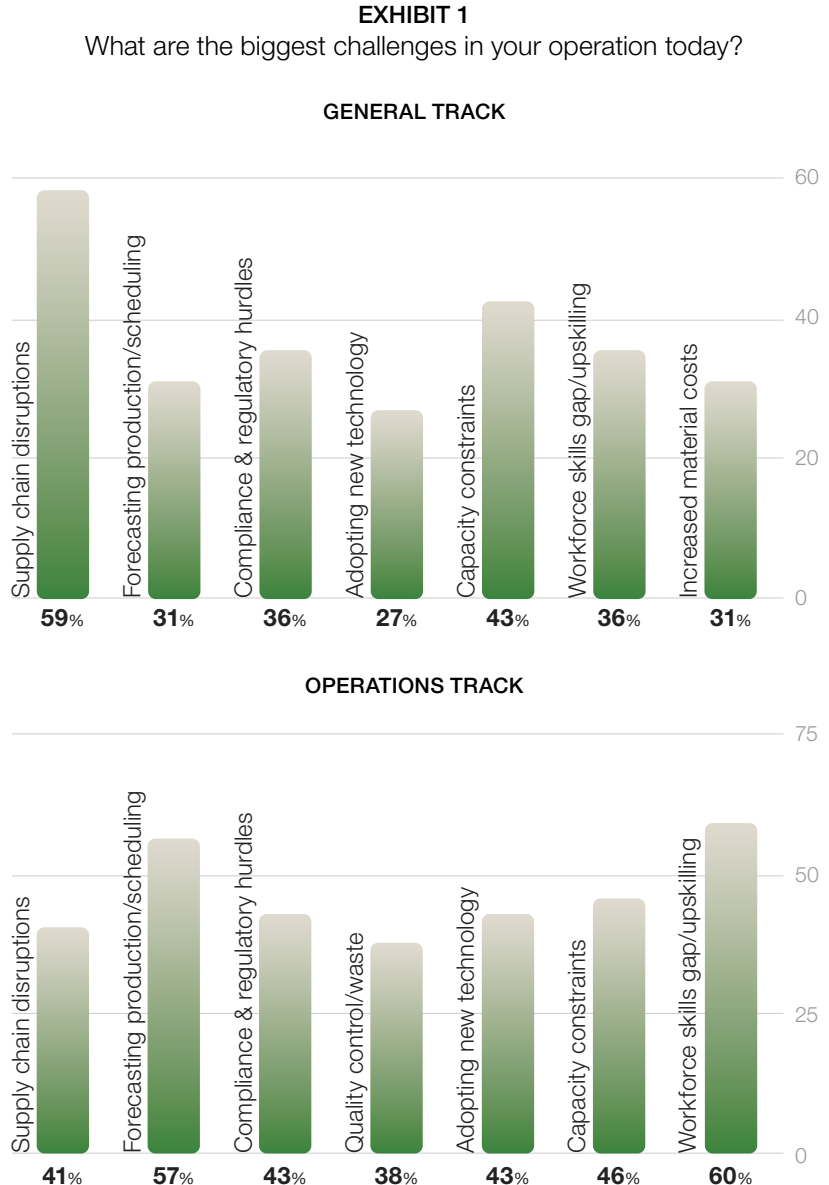
As the pharma industry races to get products to market, quality remains a high-stakes area. Quality issues could have serious regulatory and financial repercussions, and in a worst-case scenario, could lead to loss of human life. Even with consistent, time-consuming quality checks, issues persist — hence the ongoing search for a way to reduce QA/QC problems.

Our survey found a notable connection between quality issues and machine failure. In fact, over 80% admit that there is a link between quality issues and asset malfunctions or failures. And 28% of respondents are seeing a high correlation, admitting that quality issues at their plants are “often” or “very often” caused by machine failures.

So: Reduce machine failures and you can reduce the incidence of quality issues. But before we get into how pharma is accomplishing this, it’s important to examine the true scope of the problem.

## HOW BIG IS THE ISSUE?

A critical machine failure can



bring an entire production line to a halt — a condition referred to as unplanned downtime. Our survey revealed concerning numbers when it comes to disruption frequency and duration.

A shocking 63% of those working in equipment-related pharma jobs report that their sites

experience unplanned downtime because of an issue with a critical asset at least once per month. What’s worse is that over 40% say the disruptions are happening on a weekly or *daily* basis.

Unfortunately, these aren’t fleeting disruptions either. Over 73% of respondents say that disruptions

persist for longer than just a few hours. And almost half of respondents claim disruptions last for several days or even, weeks.

What is causing these machines to fail so frequently and extensively in pharma plants? Respondents overwhelmingly attribute it to two types of problems — mechanical and operational. Half of respondents say they attribute unplanned downtime to physical deterioration of machines due to age or usage. Meanwhile, 42% point to issues caused by operator error.

## BRINGING PHARMA'S MAINTENANCE STRATEGIES UP TO TASK

A strong maintenance and reliability program — especially one that includes real-time monitoring of assets — can reduce both mechanical and operational errors, thereby greatly cutting back the incidence of machine failure.

Interestingly enough, 56% of those surveyed believe their company has the ability to visualize the real-time condition of critical assets across all production sites.

But is this real-time visibility into machine conditions being utilized in plants' maintenance and reliability strategies?

Performing maintenance activities based on machine's real-time condition (rather than less reliable indicators like age) can eliminate

unplanned downtime. However, when asked about maintenance approaches, the vast majority (over 84%) of survey respondents say they are still implementing preventative maintenance at their facilities, indicating that they are not fully taking advantage of the benefits of real-time condition monitoring (Exhibit 2).

A more traditional method, preventative maintenance aims to catch problems sooner by having workers perform maintenance tasks on a time-based schedule. The issue though, is that most machine failures are difficult to predict solely using data such as operating

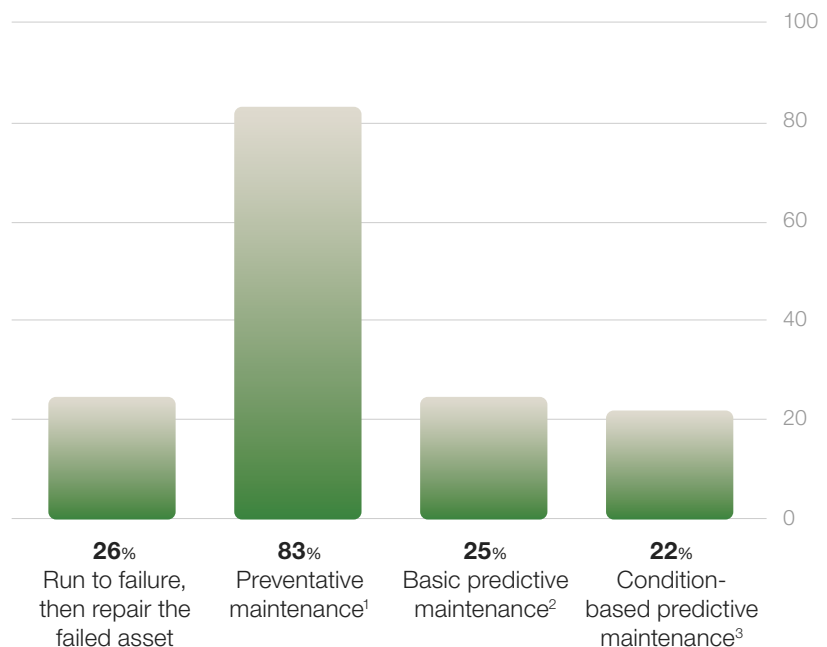
hours or life cycles as a determining factor of when machines need maintenance.

Hence, plants that stay in this preventative state may continue to run into obstacles when it comes to deriving deeper insights from machine data. According to our research, the biggest challenge faced by pharma manufacturers when collecting data about assets is understanding what action to take from that data (Exhibit 3). This is closely followed by concerns over accuracy of data and the time it takes to collect data.

In recent years, however, the manufacturing world has seen an

EXHIBIT 2

What maintenance approaches does your company use?



1. Some scheduled, but mostly reactive, manual maintenance. Typically time-based, route based, or threshold based

2. Periodic data and sensor analysis that allows some predictive maintenance capabilities

3. Real-time monitoring of asset condition used to detect malfunctions and plan maintenance

increase in a newer type of maintenance strategy focused more on catching problems ahead of time: predictive maintenance. In a true condition-based predictive model, internet-connected sensors are attached to equipment to monitor key machine health data in real time. That data is fed into a predictive maintenance platform that applies data analytics to identify red flags as soon as they appear so that technicians can be alerted.

Our research indicates that less than one quarter of pharma plants have integrated a condition-based predictive method into their maintenance strategy (Exhibit 2).

It is only by implementing this condition-based strategy that plants can take their predictive maintenance to the next level — machine health.

A more holistic approach, machine health uses IOT and AI to predict and prevent machine failures, and improve machine performance, so that manufacturers can reduce

downtime, maximize production capacity and optimize the cost of asset care. This enables maintenance and operations teams to eliminate emerging issues, either by optimizing production process and control parameters, or by intelligently performing the correct maintenance activities around the production schedule.

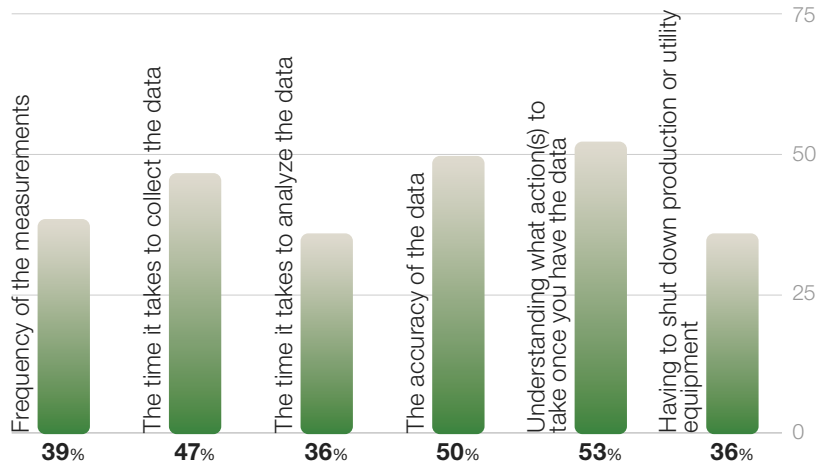
Not only can machine health reduce unplanned downtime, it can also help make planned downtime as quick and efficient as possible so machines can get back up

and running. Our survey found that 42% of pharma plants have planned shutdowns more than once per year. An additional 36% have shutdowns on a yearly basis. The majority of plants use these shutdowns for major equipment maintenance, equipment check-ups and general facility upgrades.

Machine health monitoring systems with advanced AI capabilities can diagnose machines in real time and provide predictive insights about what exactly needs to be fixed and when

### EXHIBIT 3

What are the biggest challenges you face when collecting data about your assets?



**Machine health uses IOT and AI to predict and prevent machine failures and improve machine performance.**

— enabling equipment experts to work smarter and faster during planned shutdowns.

## PRIORITIZING MAINTENANCE AND RELIABILITY IN PHARMA

When it comes to making true improvements to maintenance and reliability strategies, both site-level buy-in and adoption across the enterprise are essential.


In this regard, our survey found encouraging feedback from those on both the general corporate level and those working in more operational-based roles. Almost everyone surveyed noted the importance of standardizing a global maintenance and reliability program across all sites. On the corporate end, 79% flag this mission as “critical” or “very important” while on the operations-side, 70% say the same.

The industry now has the technology to use data from machines to get better insight into what’s

going on in specific plants as well as across an entire enterprise. Standardizing a maintenance and reliability strategy is important, but standardizing the *right* strategy is even more crucial.

Leaving a preventative state in favor of a conditions-based predictive maintenance strategy can

have a big impact — eliminating unplanned downtime, reducing quality issues and even speeding up planned shutdowns.

The pharma industry is sitting on the cutting edge of medical treatments – shouldn’t their maintenance and reliability strategies keep pace? 

## SURVEY DEMOGRAPHICS

Survey results were fielded among Pharma Manufacturing readers in August 2021 using a web-based survey tool.

The survey received 150 total responses. Based on respondents’ self-reported core job responsibilities they were separated into two different survey pathways: One specific to those in operations-based roles and one more general to industry. 56 respondents indicated core responsibilities involved the following: digital transformation; equipment validation; equipment evaluation or purchasing; plant floor manufacturing/operations; facility or equipment maintenance; asset or facility management. 94 respondents indicated core responsibilities involved the following: corporate management; QA/QC; packaging; plant engineering; IT; vendor management; regulatory compliance; consulting. In total, the breakdown of how respondents characterized their companies was as follows: 36% generics; 18% biopharma; 17% traditional pharma; 13% contract manufacturing; 6.5% APIs/excipients; 6.5% fill/finish; 3% vaccine-makers.