

LEVERAGING PREDICTIVE ANALYTICS FOR PHARMACEUTICAL INNOVATION



Innovation in the Pharmaceutical Industry

Pharmaceutical companies aiming to develop innovative new therapies and treatments face many challenges. Without proper processes and systems in place, it is very difficult to replicate successful results, mitigate failures, reduce product variability and ultimately deliver a new therapy to market. Having competent control and visibility over each step of the development process, from early stage ideation through scale up and production, is becoming increasingly important in modern laboratory facilities. This includes not only having total control over laboratory operations but also the proper documentation to prove process control for quality and regulatory compliance.

A critical factor in optimizing efficiencies and control is to ensure that a life science laboratory is both safe and predictable. Safeguarding a state-of-the-art, innovation-based laboratory is no easy task and requires foresight, experience, and attention to detail. With this in mind, many pharmaceutical companies opt for a proactive, rather than reactive, approach to monitoring and protecting valuable life science facilities, assets and equipment.

Leveraging predictive analytics is an emerging, popular method for cultivating a proactive approach to optimizing life science facility operations, ambient conditions, and equipment maintenance schedules. Predictive analytics derives valuable information

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on probable future events based on past data trends. This ranges from visually examining patterns in measurements and extrapolating possible outcomes, to building, testing and implementing sophisticated statistical algorithms based on robust datasets gathered from myriad sources.

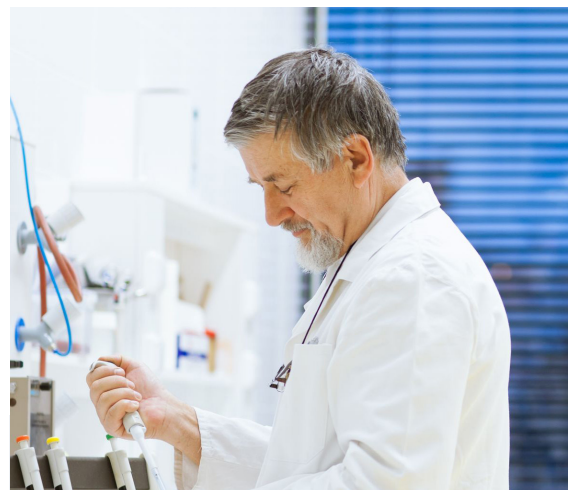
The growing presence of Internet of Things (IoT) devices in the lab—such as pharmaceutical lab equipment and sensors working holistically in a virtual environment—enables pharmaceutical researchers and lab personnel to perform experiments and gather digital data almost instantly, a task that historically took hours or days to complete manually.

The pharmaceutical industry is often conservative in the adoption of emerging technologies, but has been a prominent proponent in implementing IoT technology. There are many life science organizations using IoT to connect disparate laboratory devices, equipment and instruments. This real-time monitoring data can be used for root-cause analysis, quality reporting and preventative maintenance. With some additional manipulation and analysis, this data can also be used to optimize processes, derive predictive algorithms, improve cost efficiencies, and save significant time.

PREDICTIVE ANALYTICS FOR PHARMACEUTICAL LAB EQUIPMENT

There are many modern advances in predictive analytics that help apply these practices to pharmaceutical organizations. Leveraging IoT solutions that integrate data from disparate laboratory devices, equipment, systems and facilities on a homogenous, cloud-based platform helps organizations improve efficiencies, gather new insights and innovate faster than competitors. By using predictive analytics platforms on laboratory assets and equipment, organizations can actively monitor and anticipate equipment malfunctions in order to proactively schedule calibrations or repairs. Predicting potential failures and optimizing maintenance schedules ensures operations are safeguarded from downtime and potential costly catastrophic failures.

A recent report substantiating the use of predictive analytics for preventive maintenance indicates that the overall benefits of implementing solutions that enable such analysis is immediately evident. Reductions of approximately 25% in the overall frequency of repairs for equipment when leveraging predictive analytics, as well as a 30% decrease in overall repair costs, are just some of the benefits gained. To put this in perspective, the average cost of a repair for a cold-storage device, such as a refrigerator or freezer—valued at approximately \$15,000, is 30%-40% of the cost of the device, roughly \$4,500-\$6,000. On top of this, companies found a three day average reduction in equipment and device downtime, per device, by leveraging predictive analytics for preventive maintenance, which results in additional savings. For organizations that operate tens, hundreds or even thousands of devices, the ROI of adopting these technologies increases exponentially.



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BENEFITS OF PREDICTIVE ANALYTICS

Pharmaceutical companies with integrated sensors, devices and equipment can develop a competitive advantage in the industry. By enabling laboratory operations and facilities teams to remotely access, manage, and track all lab devices, organizations enhance equipment and process productivity while mitigating risks from error-prone, manual tasks. For pharmaceutical researchers, using sensors to monitor room conditions such as relative humidity, temperature, differential pressure, VOC's and particle counting provides reliable data on real-time laboratory conditions to ensure experiments are conducted within optimal parameters. The ability for lab devices and equipment to integrate with other systems, such as Laboratory Information Management Systems (LIMS) or Electronic Laboratory Notebooks (ELNs), allows automated recording of important data and increased visibility over the entire pharmaceutical process.

PROTECT AGAINST ERRORS AND FAILURES

It is imperative for pharmaceutical laboratories to remain in constant control of processes and parameters. Consistent checks on variations, deviations or anomalies in equipment and conditions are paramount in maintaining critical processes and quality parameters. Leading technologies enable predictive analytics, provide real-time notifications, and deliver insights on laboratory equipment conditions and ambient parameters. With these technologies, organizations can closely monitor for any anomalies and maintain continuous control over laboratory operations.

Certain solutions enable researchers to access equipment data through an online portal and generate automated reports for quality and regulatory compliance. These systems send real-time alerts and notifications if deviations occur from preset parameters, keeping a pulse on laboratory devices and equipment operations, while enabling lab staff to respond effectively and efficiently to any adverse events. Data aggregation from myriad machines, lab equipment and devices provides profound levels of insight and a holistic view of pharmaceutical research, development, and manufacturing operations. Without proper monitoring and protection of laboratory devices, equipment and facilities, organizations find it challenging and costly to maintain optimal conditions. This has an adverse effect on experiment results and increases the potential for catastrophic failures.

According to a recent report on facilities and operations management, the average cost of an equipment failure is over \$300,000 and there is a 60% chance that such an event occurs during a 10-year span. This entails a weighted average cost of over \$500,000. Most facilities can expect to face a catastrophe every 2 years, with exponential increase in the likelihood of failures for facilities that operate multiple buildings in multiple locations.

Equipment failures carry their own significant cost, but for pharmaceutical organizations aiming to protect valuable samples and experiment assets in various devices and equipment, it is often the livelihood of the entire organization at risk. Protecting reputation and Intellectual Property (IP) is another key aspect to consider. Implementing the right solutions to protect against errors and failures becomes an important factor for any pharmaceutical company that aims to lead industry innovation.

IMPROVE QUALITY MANAGEMENT

Implementing any new technology or solution entails inherent difficulties. Associated costs can be a deterrent for many companies. Most technologies require a large capital investment that can be difficult to justify to key stakeholders. There is often hesitancy from researchers and staff when adopting technologies due to the burden of learning and implementing a new process into their routine. This can also be time and resource intensive. However, the potential improvements to quality, quality processes and standard operating procedures (SOPs) can far outweigh the costs and challenges of implementation.

Documenting and adhering to procedures during day-to-day activities involving interaction with laboratory devices and equipment is critical for mitigating risks, losses and failures. Pharmaceutical organizations also benefit by using predictive analytics to understand trends that affect device and equipment operations, enabling subsequent corrective action. A common instance is when various researchers utilize certain equipment, such as a freezer or incubator. Each researcher that accesses samples within the unit opens the door for varying lengths of time. This usage may be outside of manufacturer specifications and make it difficult for the device to recover properly. Each door opening can create spikes in temperature or CO₂ levels, and if door openings are too long or too frequent, improper storage conditions can lead to adverse consequences, such as sample damage or misleading research results.

Improving quality management and SOPs allows pharmaceutical organizations to protect against errors, losses and failures. Utilizing automated reports and data analysis also assists in proving compliance with quality and regulatory standards in the event of an internal or external audit. The resulting efficiencies and quality improvements contribute to creating a competitive, innovative organization.

PHARMACEUTICAL INDUSTRY INNOVATION ADVANTAGES

There are multiple advantages gained in the pharmaceutical industry when implementing solutions that leverage predictive analytics for laboratory equipment and facilities. Seamlessly integrating data from disparate devices, equipment and systems, automating tasks in quality management, improving standard operating procedures, and allowing for predictive maintenance are all ways predictive analytics improves organizations today. Additional advantages include risk mitigation and better overall operational procedures. Pharmaceutical companies with solutions to support robust data gathering and predictive analytics gain competitive advantage and are better equipped to adapt in this constantly evolving industry.

ABOUT XILTRIX

With over 30 years of experience and expertise in life science industries, XiltriX provides an autonomous, 24/7 monitoring solution that operates as a Safety Net for any research laboratory, storage facility, or manufacturing site. All day, every day, XiltriX acts as the pulse of your laboratory infrastructure.

The system can be fully validated and is compliant with all appropriate quality and regulatory standards: GMP, GLP, GxP, FDA 21 CFR part 11, CAP, CAPA, HACCP, JCAHO, USP 797, etc. The subscription-based pricing includes all hardware, any necessary maintenance, repairs, and support. In addition, the XiltriX Safety Net team ensures that any alerts are quickly addressed, 24/7, 365 days a year.

Utilizing XiltriX will provide improved compliance and complete peace of mind. XiltriX protects your science and helps you sleep at night.