CASE STUDY

New trends: optimizing equipment performance and availability by implementing a smart maintenance platform

How acquiring equipment real-time data and defining new maintenance strategies reduce eventual breakdowns and prevent downtime of the final user assets

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ABSTRACT

This case study focuses on a biotech pharmaceutical company that implemented Insights; a smart maintenance platform based on condition-based maintenance (CBM) in their freeze-dryers for sterile production. By leveraging real-time data capture, processing, and visualization, the platform enabled the customer to optimize maintenance operations, improve asset reliability, and reduce costs. The case study highlights successful outcomes, including identifying and resolving equipment deviations, preventing batch loss through condition monitoring, and ensuring proper sterilization processes. The Insights platform's data-driven approach resulted in enhanced operational efficiency, increased equipment availability, and improved safety, empowering the customer to make informed decisions for preventive and predictive maintenance.

Customer

Biotech pharmaceutical company producing vaccines for animal and human health.

Challenge

The production of pharmaceuticals requires, among others, reliability, and repeatability of the manufacturing process, so it could be agreed that this requires a high commitment in the performance of the main stakeholders. Interactions between people, procedures and methods, and tools and equipment configure the manufacturing process, so they have a direct impact on the production performance. It could be stated that production performance is tightly coupled with the functional machinery level, so that a well-maintained machinery is, obviously, more productive than a poorly maintained one that has a higher risk of machine failure. Equipment failures and malfunction can lead not only to a reduction of production time, but also to issues like batch contamination, safety concerns, and in general an overall decrease in production performance. Equipment maintenance nowadays represents a considerable line in the budget of industrial organizations, which is why enterprises are constantly seeking ways to improve the efficiency and cost of their maintenance activities.

Proposal

Telstar has developed Insights, a smart maintenance platform for pharmaceutical industries based on condition-based maintenance (CBM). CBM is a maintenance strategy that involves monitoring the condition of an asset or equipment in real-time to determine the optimal time for maintenance activities. This approach offers several benefits over traditional time-based or reactive maintenance strategies like cost saving, improved equipment availability, extended asset lifespan, enhanced safety, efficient resource utilization, data-driven decision making and reduce reactive maintenance operations.

Customer challenge

The biotech pharmaceutical company produces vaccines in both liquid and freeze-dried presentations. Freeze drying is one of the most critical processes in the entire production line due to the complexity and the risk of losing a batch. The company has several Telstar freeze-dryers and has a contract for preventive maintenance services but wanted to improve the equipment availability and reduce the incident-based maintenance (reactive maintenance).

The maintenance department tried different approaches to collect data from the equipment, but the biggest difficulty was in converting raw data to meaningful insights that could be translated to data driven maintenance operations. After learning about the smart maintenance platform, they decided to do a pilot project with two different case studies.

Project development

Insights is a SaaS platform based on a subscription fee. The upfront investment is reduced to the data connector where the information is captured with it and oversees connecting the user assets to the software backend of the solution. The dataset is mainly composed of machines and production data of equipment, either from raw or generated data by the platform specially for the asset owner. The platform has this segregated dataset of every asset connected that belongs to the owner of the asset and aggregated dataset with anonymous data from all similar assets connected.

Insights provides a unified user platform where real-time and key data, trends, alarms, warnings, reports, and findings are displayed in easy-to-understand formats that enable the user to grasp the data in one look that can foster data-driven management and decision making. It provides a configurable

framework to define rules that drive condition-based maintenance. The platform is not intrusive and will generate alarms and notifications that are sent directly to intended users to allow a proper schedule of related maintenance, repair, and operations (MRO). Finally, the end user could perform a manual analysis of data based on a graphic interface where current and historical data could be compared against the baseline or other cycle data.

Solutions

Case study 1. Optimizing production process and availability of assets due to the aggregated dataset.

The aggregated dataset comes primarily from the safe aggregation process of the asset datasets cited above. It is mainly used to establish a benchmark 'baseline' of the system or equipment in typical or ideal operating conditions.

Evaluating the operating conditions of the same type of assets, Telstar subject matter experts (SME) noticed that there was a clear deviation between one of the assets and the others in the duration time of the SIP cycles of the freeze-dryers. Thanks to KPIs visualization and data treatment they were able to compare the average duration and identify this deviation. The affected asset had an average duration deviation of 49 minutes versus the other assets.

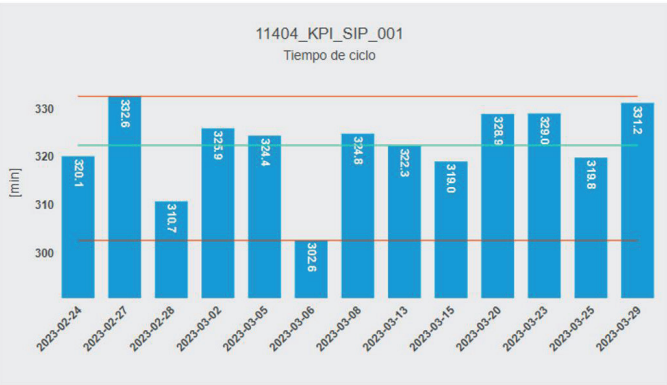

Figure 1. Average SIP cycle duration of affected asset - 323 min

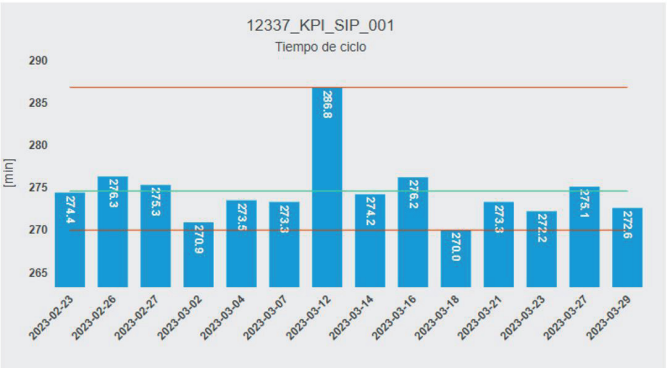

Figure 2. Average SIP cycle duration of non-affected assets - 274 min

The SME, using KPIs visualization dashboard, checked other indicators that can affect the SIP cycle to confirm the different behavior and found the component responsible for this phenomenon. Additionally, when comparing the first pressurization time and the sterilization time to reach the set point, they realized that the affected asset took 26,3 additional minutes for the first pressurization and 10,1 additional minutes to reach the sterilization set point compared to the other assets.

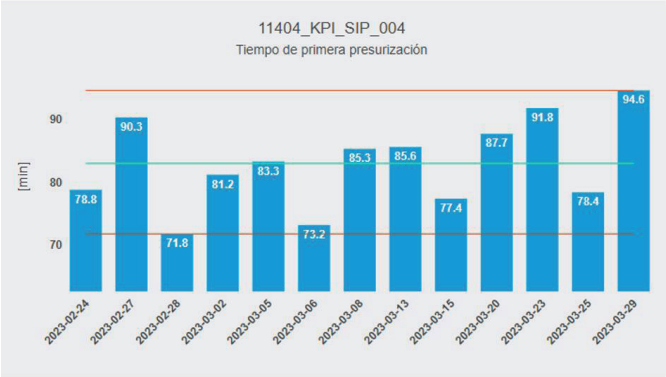

Figure 3. Average first pressurization time of affected asset - 83,1 min

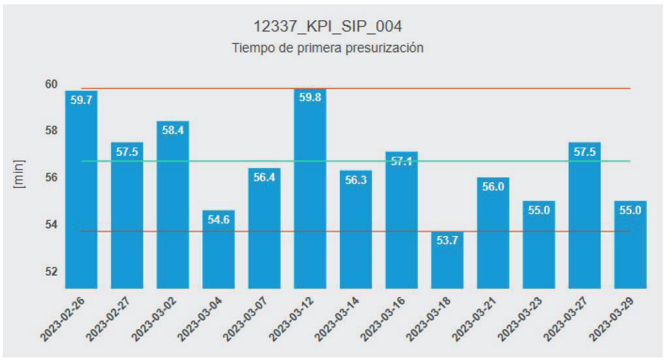

Figure 4. Average first pressurization time of non-affected assets - 56,8 min

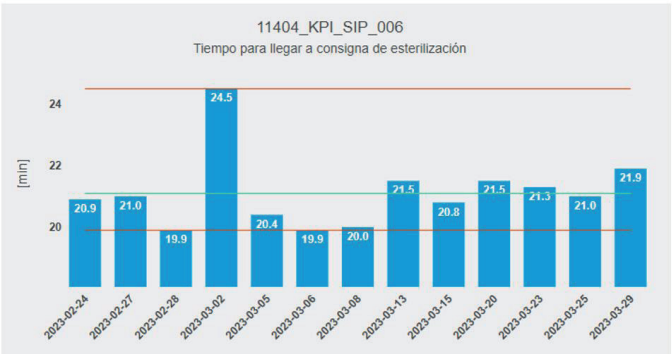

Figure 5. Sterilization time to reach the SP of affected asset - avg. 21,1 min.

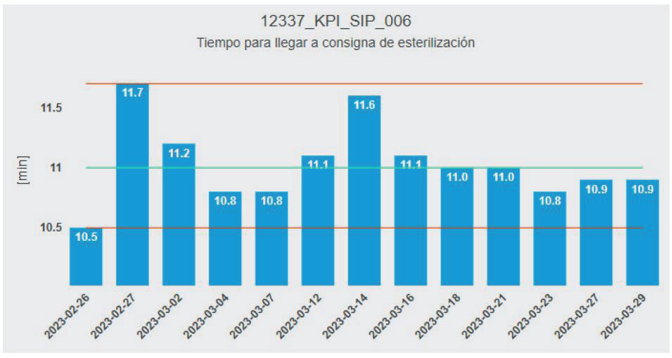

Figure 6. Sterilization time to reach the SP of non-affected assets - avg. 11 min.

After this KPIs analysis, the SME could identify the potential affected components. Checking the P&IDs of similar assets, it was identified that one of the valves in the steam node was not the optimal size for the required process and a change proposal was made.

Once the replacement was complete, the SME analyzed again the behavior of the affected asset during the new SIP cycles. It shows a clear improvement of the cycle duration:

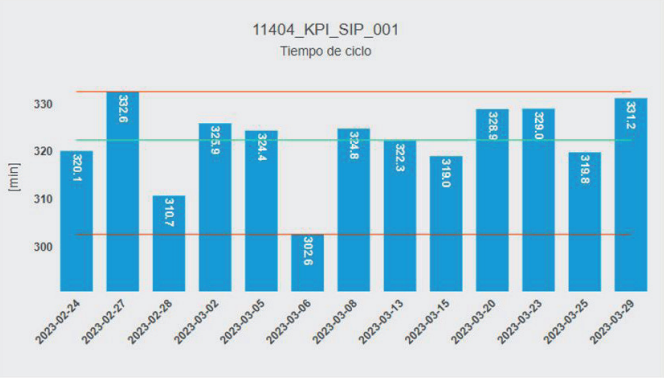

Figure 7. SIP cycle duration of affected asset - avg. 323 min

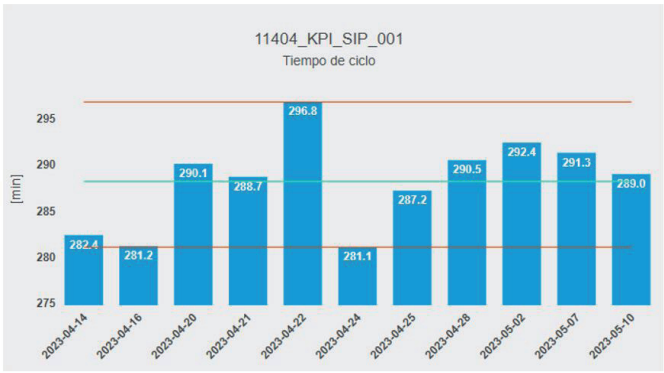

Figure 8. SIP cycle duration of affected asset (correction) - avg. 288 min

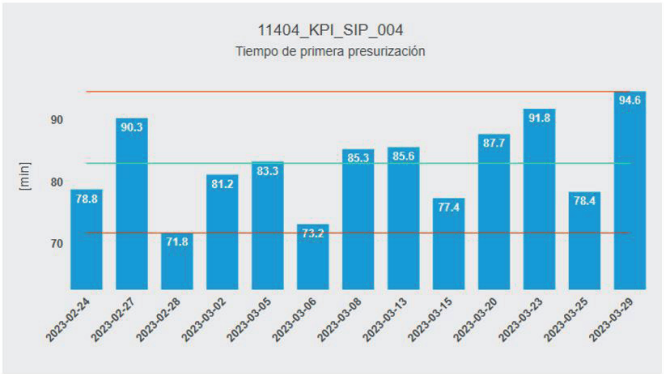

Figure 9. First pressurization time of affected asset - avg. 83,1 min

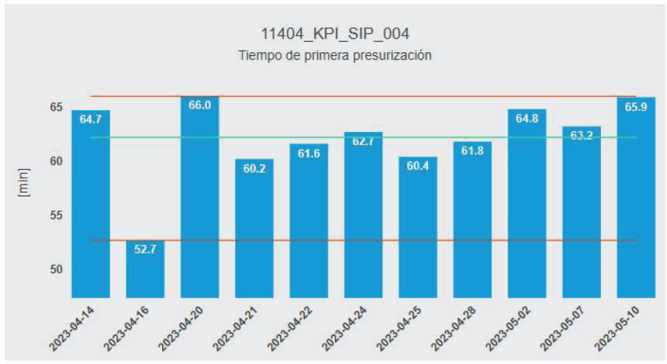

Figure 10. First pressurization time of affected asset (correction) - avg. 61,7 min

Figure 11. Sterilization time to reach the SP of affected asset - avg. 21,1 min.

Figure 12. Sterilization time to reach the SP of affected asset (correction) - avg. 11,7 min.

After the valve replacement the total SIP time improvement was about 15%. On a yearly basis, the total time devoted to SIP was 810,96h, whereas now it is 689,33h. Owing to the improvement using Insights platform, the asset availability for production purposes has increased 121,63 h. In this particular case, this equals to 3 additional cycles per year. Additionally, there has been an improvement in the lifespan of the gaskets and valve diaphragms reducing the number of necessary changes.

Case study 2. Avoiding batch loss and optimizing vacuum performance thanks to a condition-based maintenance module.

During the freeze-drying cycles it is critical to control the vacuum values and ensure its stabilization. Due to the CBM module of Insights platform, the SME can define conditions related with the control of vacuum values comparing different KPIs and tags pre-defined. The system will send a notification once one of these conditions is triggered. In this case study, the operator received two notifications that were related, one of them showed the deviation of the minimum vacuum value during the secondary drying phase vs a set point established in the condition, and the other one, the deviation of the pump set piping tightness during the leak test cycle also, versus a pre-defined set.

This information leads the operator and subject matter experts to analyze other KPIs related to the performance of the vacuum pump set during freeze-drying cycles and leak test cycles with the aim to discard any performance issues with the vacuum pumps.

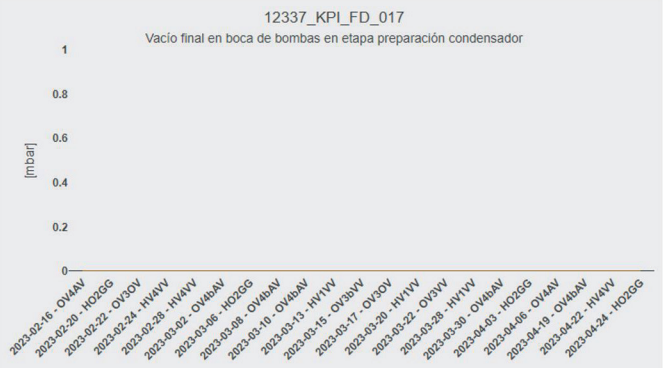

Figure 13. Vacuum pump set performance during FD – Correct (0 mbar)

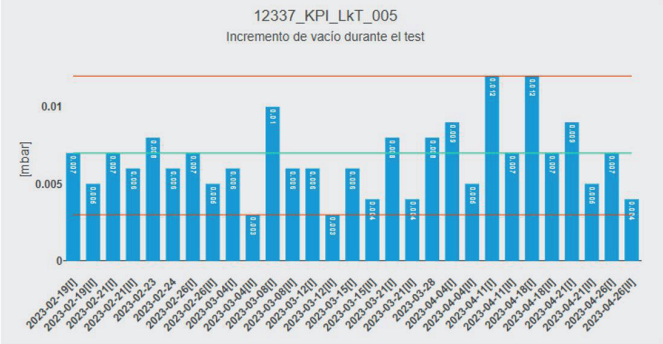

Figure 14. Vacuum pump set performance during LkT - Correct

The analysis discarded any performance issue, so the remaining point was to check the KPIs dashboard, where an important deviation of pump set tightness during leak test could be identified.

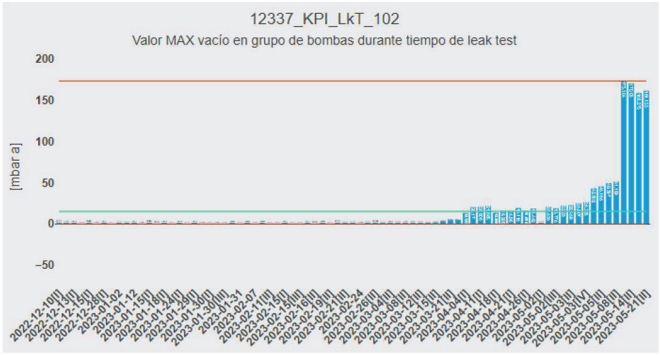

Figure 15. Pump set circuit tightness during LkT.

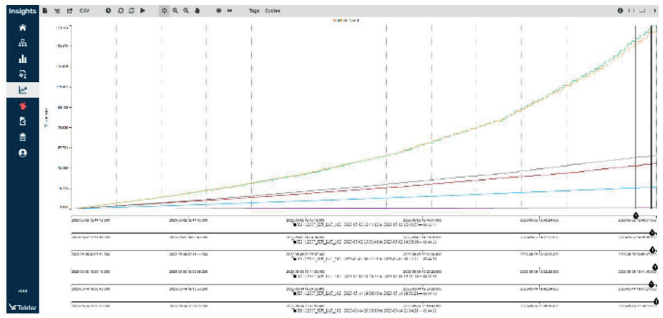

Figure 16. Pump set circuit tightness deviation.

The leak could not be identified during normal operation or leak test cycles as it was small, and the vacuum pump set was still capable of performing the cycles. After an on-site inspection with a helium detector, a leak in a flexible hose between the roots pumps and the fore pumps was identified. The replacement of the flexible hose solved the issue and a second one was also replaced as a preventive measure.

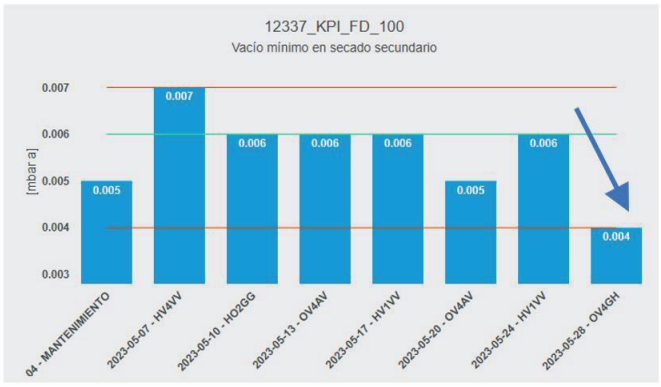

Figure 17. Minimum vacuum value during secondary drying

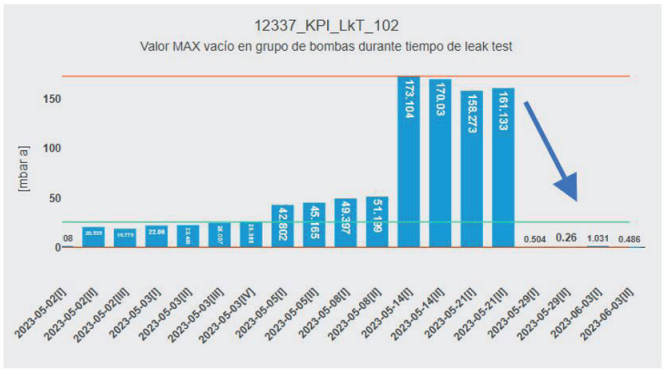

Figure 18. Pump set circuit tightness during LkT.

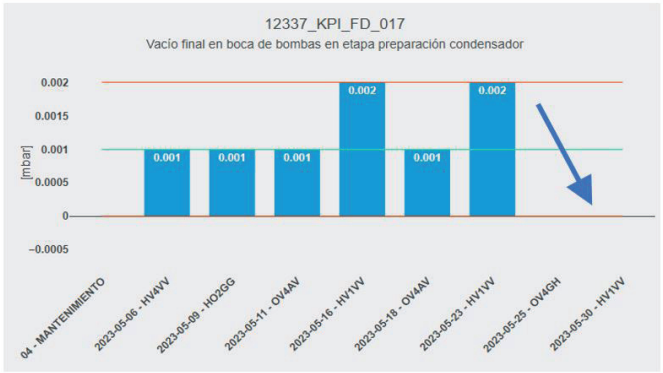

Figure 19. Vacuum pump set performance

In this case, the importance of having meaningful data is well reflected as otherwise the flexible hose would have further deteriorated to a point where an alarm would stop the leak test cycle or even worst during a production run with the consequent loss of production time or even worst losing a batch.

Results

Overall, condition-based maintenance offers numerous benefits by optimizing maintenance activities, improving asset reliability, and reducing costs. By leveraging real-time condition monitoring and data analysis, organizations can achieve better operational efficiency, increased equipment availability, and improved safety.

Platforms like Insights could capture data from existing controlled and supervised equipment to establish a baseline of current process, and then propose improvements and evaluate its performance impact for the established process. These improvements could stand for condition-based parameters to be tuned or new instrumentation to be set up. This is a technological non-intrusive application that provides the ability to make the assessment of these actions based on the mentioned baseline. The customer could prioritize the return of investment based on the data and given predictions by the platform.

In the case studies cited above, the smart maintenance platform with a few minutes of data analysis by the customer or SME, is able to give a prediction of a possible anomaly thanks to CBM, being able to plan the components changeover without altering the production plan, increasing the asset availability.

This scalable and extended approach allows the customer to adapt its current maintenance strategy based on the increasing knowledge of its equipment, avoiding expensive solutions whose return is unknown or could not be clearly defined. To summarize, the ability to set up a base line of the current maintenance strategy performance over existing assets, as well as the capacity to evaluate the impact of proposed actions over it, constitute one of the top features of the smart maintenance platform for preventive and predictive maintenance.

The author

Joel Nuñez, Product Manager at Telstar, holds a degree in Chemistry from Universitat Autònoma de Barcelona (UAB). He has collaborated with the 'Group of Sensors and Biosensors' of the UAB to develop a microfluidic analysis instrument for the European Space Agency (ESA). He has extensive experience in different sectors such as electricity, where he worked as Senior Corporate Product Manager at the Simon company, and the construction sector, where he worked first as R&D manager in an international research group, and secondly as Product Manager in Spain for different lines of business at the company Saint-Gobain. In his current position, he is responsible for providing new solutions and value-added services addressed to facilitate the development and production of freeze-dried pharmaceuticals in GMP environments.

About Telstar

Telstar, part of the azbil Group, is a company specialized in the development of engineering & construction projects, integrated process equipment and GMP consultancy solutions, including turnkey projects and critical installations, for companies associated with Life & Health Sciences (pharmaceutical & biotechnology, healthcare, cosmetic, veterinary and food & beverage industries, hospitals, laboratories & research centers). Acknowledged as one of the 10 major suppliers for the pharmaceutical industry, Telstar is one of the few international manufacturers able to offer integrated process solutions for the biopharmaceutical industry with in-house sterilization, freeze drying, containment, clean air and cold storage technologies.