Preventive and predictive digital maintenance in Pharma 4.0

A journey from data to actionable insights

By Jordi Serrat, Product & Technology Director, and Joan Piedrafita, Digital Development Project Manager, respectively, at Telstar

WHITE PAPER

ABSTRACT

This article outlines the journey of understanding data and its exploitation in the field of preventive and predictive maintenance. Based on a non-intrusive approach implemented in a new digital platform, the authors offer an analysis on how to adapt and improve existing preventive maintenance strategies in manufacturing facilities without incurring an instrumentation deluge and a reformulation of existing processes by using data analysis.

Insights is used to illustrate a model of digital platform that responds to the challenge of how the data generated by the operations of a production line allows to improve the availability of assets. Data collection, processing, and comparison with assets of the same type in similar production situations using analytical and big data tools through a multi-tenant Internet of Things (IoT) platform, provides the ability to generate and, at the same time, manage comparative indicators that allows the industry to improve OEE (Overall Equipment Effectiveness) and move towards predictive maintenance.

Introduction

Pharmaceutical products require, among others, reliability, and confidence in the manufacturing process, so it could be agreed that this requires a high commitment in the performance of the main actors of it. Interactions between people, procedures and methods, and tools and equipment configure the manufacturing process, so they have a direct impact on the production performance as a whole.

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 higher risk of machine failure. Machinery 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 of the production performance.

Machinery maintenance nowadays represents a considerable line in the budget of industrial organizations, that is why enterprises are constantly seeking ways to improve the efficiency and cost of their maintenance activities. The table below identifies current maintenance strategies or approaches, while figures 1 shows when these strategies are executed against a generic PF Curve.

	summary
Reactive	Fix when it breaks
Preventive	Maintenance on a predetermined schedule
Condition-Based	Condition-based monitoring triggers MRO*
Predictive	Model-based (forecasting) triggers MRO*
Prescriptive	Model-based (forecasting) recommends MRO*

* MRO - Maintenance and Repair Operations

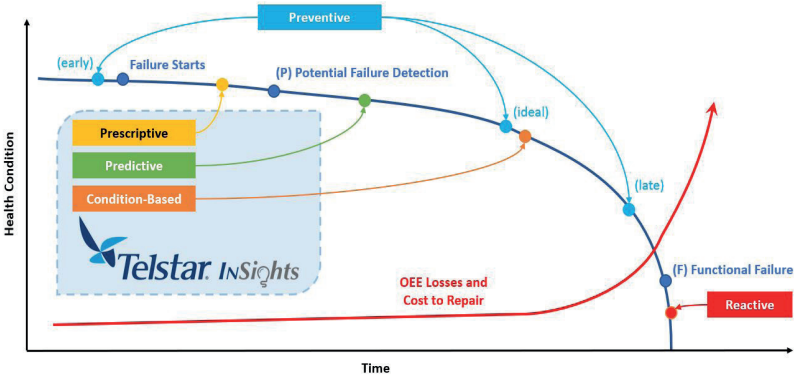

Figure 1 PF Curve vs Maintenance Strategies

There is not a one-size-fits-all maintenance strategy. The best strategy depends on the machine complexity, its own criticality, process criticality, cost to setup and operate the maintenance program, etc. Figure 2 shows a qualitative return comparison defined as the cost of them (setup and operation) against its related uptime improve and repair savings. Figure 3 shows recommended field of application of maintenance strategies.

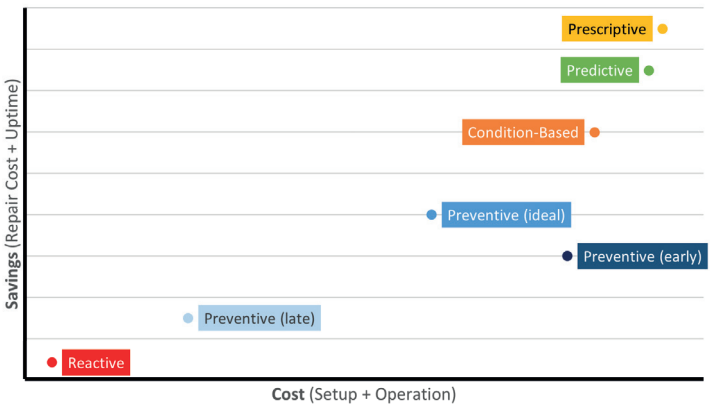

Figure 2 Maintenance Cost vs Return

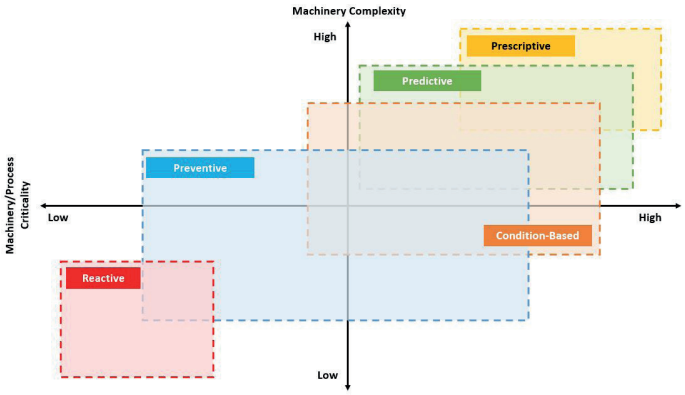

Figure 3 Maintenance Strategy Applicability

Maintenance strategy has evolved through the ages, and today a Preventive model is the dominant enterprise maintenance approach. Preventive maintenance is a proactive maintenance strategy based on estimating the lifetime of a machine or component. It is about scheduling MRO at regular intervals to avoid unexpected failures. Hence, preventive maintenance is as effective as the degree of accuracy of the machinery End of Life (EOL) expectations.

In stable production scenarios, where the risk was practically "non-existent", the benefits of the preventive strategy far exceeded any other, even when it leads to a sub-optimal Overall Equipment Efficiency (OEE) (generally due to over-maintenance). But this has changed in the last few years.

On the one hand, there are the technological factors that are driving the industry 4.0 revolution, such as the cheaper communications and computing, while on the other there are economic-social factors that require changes in established production processes, demanding faster, more flexible, sustainable, and reliable processes. Although this last point was on the rise in recent years, the appearance of the COVID-19 crisis has caused a disruption in society and makes this demand for speed and reliability critical. Because of these, maintenance strategies are changing from existing ones based on hypothetical estimations (EoL) to data-driven ones that allow to fulfil an optimal OEE.

Overall Equipment Effectiveness (OEE)

OEE (Overall Equipment Effectiveness) is the gold standard for measuring manufacturing productivity. It identifies the percentage of manufacturing time that is truly productive. OOE is a metric calculated by multiplying the three factors: Availability, Performance and Quality.

A x P x Q = OEE

- Availability: Considers Unplanned and Planned Stops. An Availability score of 100% means the process is always running Planned Production Time.
- Performance: Considers Slow Cycles and Small Stops. A Performance score of 100% means when the process is running it is running as fast as possible.
- Quality: Considers Defects (including parts that need Rework). A Quality score of 100% means there are no defects (only Good Parts are being produced).

Insights is a digital initiative that, aimed at improving the OEE of customer equipment, incorporates a strategy in its first phase focused on improving Availability and Performance indicators through the exploitation of data.

Exploiting the value of data

In this context, OEE optimization is all about extracting insights and value from all sorts of data related with machinery operation. That's what we do in digital transformation. And with Industry 4.0, IoT and AI/ML the decisions/actions can also be (semi-)autonomous, although everything depends on the nature and purpose of the data.

Figure 4, depicted as a hierarchical model in the shape of a pyramid is known as the DIKW model. DIKW allows us to understand the potential value of data and information and gives us the ability to capitalize upon it all.

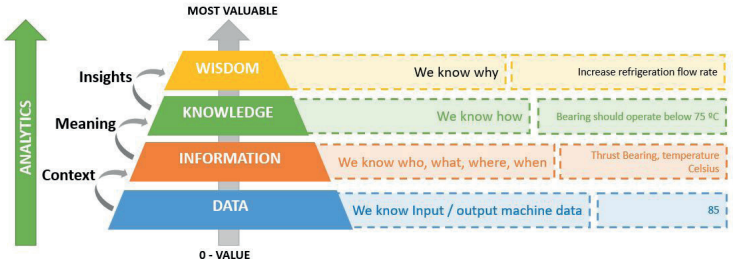

Figure 4 DIKW Pyramid

The foundation - (D) data

At the foundation of the pyramid is data and is what everything else is built upon. These days we are flooded with various types of data: big data, small data, smart data, fast data, slow data, unstructured data, it doesn't matter. Making sense of this data is necessary to drive strategic growth decisions, but understanding, cleaning, and

updating this data is difficult to do and requires a tremendous amount of focused, dedicated effort. It's also critical to make sure you are asking the right questions of the right data, a prevalent issue that often goes unaddressed.

In the Insights Platform, data capture relies on a dedicated gateway / connector, that oversees connecting the customers assets to the backend of the solution, and is responsible:

- for data capture (real-time and non-intrusive).
- temporal storage (Store & Forward).
- processing (if necessary).
- subsequent secure delivery to the backend.

To avoid the risk of using out-of-date or inconsistent data, the platform automates all the data capture process on an asset type defined template basis, as can be seen in figure 5. This data conforms to what is called Customer Dataset.

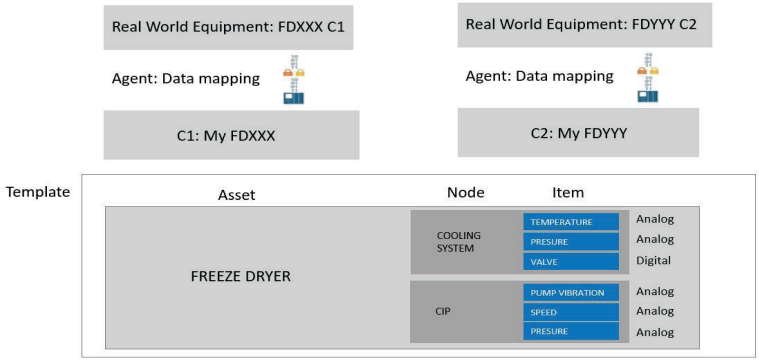

Figure 5 Templated Based Organization

Customer dataset - owned by a specific customer. It is mainly composed of machine data and production of customer equipment, either from data capture or generated by the platform specifically for this customer.

As integrity and privacy of the data is an important concern, the platform guarantees:

- the non-alteration of captured data by the platform.
- data isolation between customers (multi-tenant platform).
- complete management of the same by their respective owners

Contextualization – Obtaining Information (I)

Information sits on top of the data foundation and is attained by providing context to data. All data capture has no value unless it is structured, contextualized, and with an appropriate meaning. To give meaning and purpose to the data, several different approaches could be implemented, from more human based methods as Subject Matter Experts (SME) analysis to (semi-) automated methods based on data analytics and AI.

Insights approach is based on a predefined organization of data capture based on a SME experience and analytics methods. When data has been uploaded into the platform in its rawest form, it is then arranged into different organizations to make it more valuable. The new platform 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 and ease data-driven management and decision making.

Approach as stated before is a data collection arrangement based on templates, data is first organized depending on process steps / machine nodes. The platform provides a front end to allow real-time visualization of defined tags/variables. This provides a more meaningful framework; data classification allows better compression of machine data. But numerical representation is hard to understand and doesn't provide quick information, that's why the platform has a SME based approach for the arrangement and grouping of data in contextualized charts, graphs and calculated KPI and report generation.

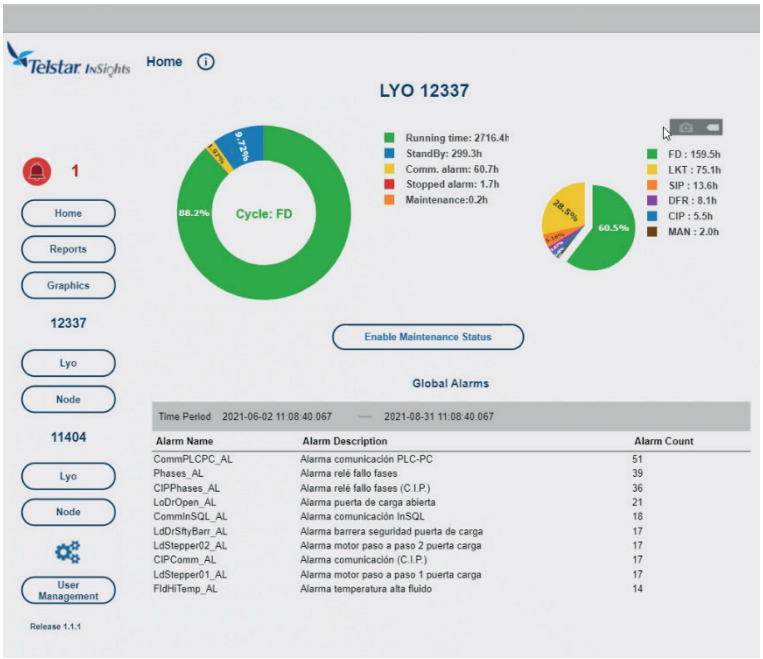

Figure 6 Telstar Insights Screen Capture

Knowledge (K) Generation

Knowledge exists above information and represents the synthesis of multiple sources of information over time. Knowledge often comes

in the form of frameworks, theories, and potential solutions for the problems or decisions at hand. To allow knowledge AI/ML methods foster knowledge generation and value increase.

One of the main issues with AI/ML methods are quality and quantity of underlying data, to perform accurate predictions, data needs to be correct, and this means that needs to be representative for the intended purpose. That implies that an application whose purpose is to predict something, as the more samples of data and scenarios we have, less biased, and more accurate should be the prediction. The same happens in maintenance, the predictions generated for a particular type of machine based on only single equipment has lower value than generated from a huge set of equipment. As more data is provided from different scenarios, uncertainly decreases.

To address this need, Insights is based on a multitenant platform to exploit a large dataset of information, and it is based on the presence of an Aggregated dataset.

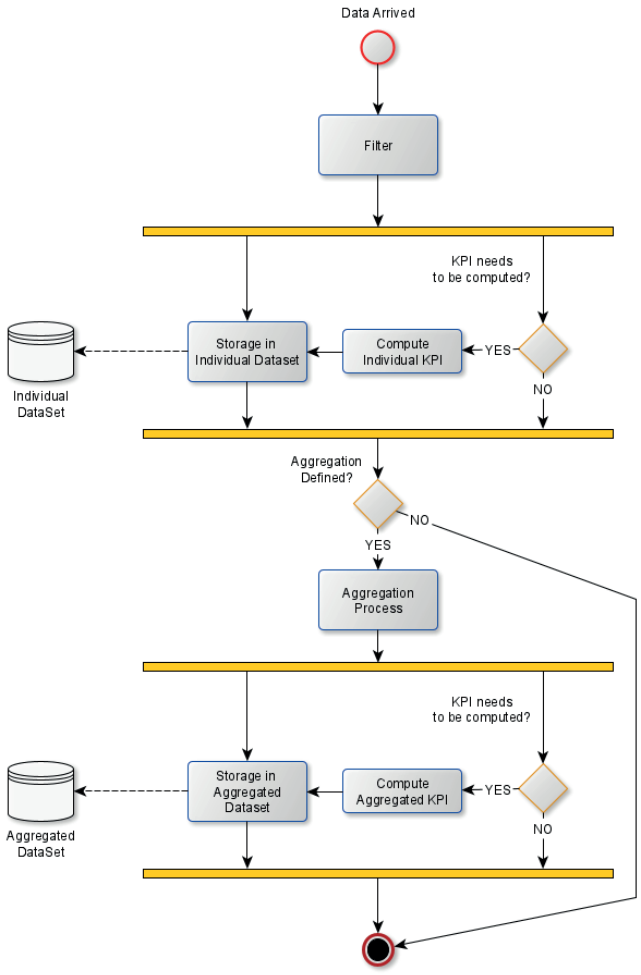

Figure 7 Aggregated dataset generation process

Aggregated dataset – Is owned by the proprietary company -in this case Telstar- and comes primarily from the safe aggregation process of the customer datasets cited above. It is mainly used to establish a "baseline" evaluation of the system or equipment in typical or ideal operating conditions. This is performed by a hybrid approach that combines human supervision and AI/ML techniques.

This approach fosters a knowledge increase of the end user about its production equipment, mainly because it allows owners to access predictions based, not only of its owned equipment but in a huge amount of equipment all around the world. By this approach, the company takes in consideration the ownership of data, and provides a secure framework where integrity, privacy and confidentiality play a key role. Figure 8 depicts architecture of the solution, and the different kind of datasets are represented.

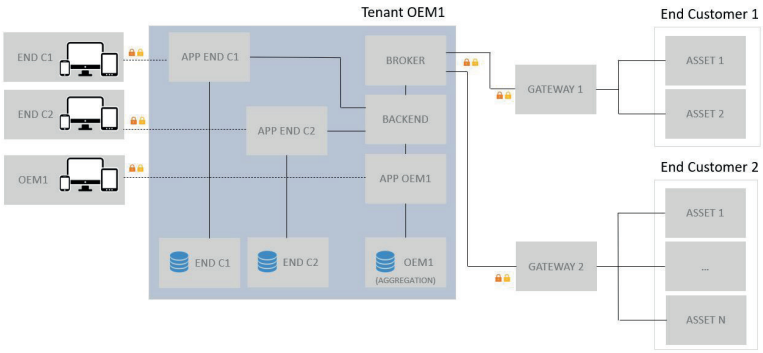

Figure 8 Proposed Architecture

Insight platform approach provides two kinds of outcomes.

- Base Line generation.
- rediction Model generation.

Both methods, as already said, are Human Supervised and provides the core capabilities for condition-based maintenance and predictive maintenance.

- **Condition-Based maintenance** relies on real-time monitoring of machine data. A supervising module is constantly monitoring machine provided data or status and in case of an anomaly, MRO is triggered. Anomalies occur when exceeding the predefined threshold over a single or a set of defined variables (generally machine related). As can be understood, this strategy appears to be more optimal than the preventive one since the maintenance actions are launched closer to the failure without

overcoming it. But this process doesn't consider other situations that could be more optimal, because of the lack of forecasting capacity.

- **Predictive maintenance** is in essence an extension and improvement of condition-based monitoring, but more diagnostic analysis is performed to predict future events. The objective of predictive maintenance is to calculate the remaining useful life of a component and schedule MRO during normal operation downtime, thus leads to a higher level of optimization of OEE than Condition-Based Strategy.

This platform 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 directly sent to intended users. Additionally, the platform provides a prediction model to determine criticality of the occurrence to allow a proper schedule of related 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, other cycle data or other customer machine data.

Top value exploit – Wisdom (W)

The final state is known as Wisdom. Wisdom is the ideal state and exists at the top of the pyramid. Ultimately, this brings everything together and is the most important state of understanding and it is generated by insights. Predictive analytics are one thing, relying on past data and decisions-making. Actions to be performed are another.

At this level, the decision maker should be able to teach or explain to others what is happening and why it's happening. Prescriptive analytics falls at this level.

Prescriptive maintenance, sometimes used interchangeably with predictive but is not the same, takes this analysis to a higher level, not only by predicting failure events, but also by recommending actions to be taken. The prescriptive strategy allows us to perform what-if analysis and provides recommended actions based on them. It can therefore incorporate fault diagnostics to lead to intermediate treatment and prolong life.

To have a successful prescriptive maintenance program, you need to be able to correlate specific signatures in the raw data and trends to specific root causes. It is not so easy. The following is required:

1. To be able to find these signatures after the fact (representative and detectable).
2. To be able to find a Root Cause (feasible).
3. To be able to determine the suitable actions to overcome that situation.

Prescriptive maintenance provides even further improved machine uptime compared to the previous strategies as failures are detected even earlier. However, to get the most out of this strategy, and to achieve a massive increase in savings, depends on the capacity to tell maintenance teams exactly what to fix (and what parts to bring with them), without needing them to do onsite evaluations.

The Insights platform, at this stage, provides some basic prescriptive maintenance functionality based on an SME supervised approach to provide a semi-automated environment based on AI/ML technologies for a non-intrusive prescriptive functionality, by setting up a hybrid development team composed of Data Engineers and Customer Service Experts.

Conclusion

This document has outlined the main strategies in equipment maintenance, how these are implemented in a real digital platform and its relation to a well-established model for data analysis, like the DIKW model.

The adoption of the above framework, together with the non-intrusive approach, provides Telstar Insights with the ability to adapt and improve current preventive strategies without incurring an instrumentation deluge and a reformulation of existing processes, by using data analysis.

One of top values provided by the Insights platform is the ability to capture data from existing controlled and supervised equipment to establish a baseline of current process, and then to propose improvements and evaluate its performance impact for the established process.

These improvements could stand for condition-based parameters to be tune or new instrumentation to be setup. Telstar Insights 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.

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 advanced digital platform for preventive and predictive maintenance, as these allow the customer to evolve, in a paced way, towards prescriptive maintenance as a superior strategy.

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About the authors

Jordi Serrat, Product & Technology Director at Telstar, holds an electrical engineering qualification from Terrassa School of Industrial, Aeronautical and Audiovisual Engineering (ESEIAAT) at Polytechnic University of Catalonia (UPC). He also has a master's degree in Functional Areas Management from the Chamber of Commerce and Industry of Terrassa, and a master's degree in Project Management for directors from IESE Business School. In his current position, he manages R&D and industrialization of new developments, focusing on new digital technologies to develop added value services associated to the Telstar portfolio. Previously, he has held the position of Technology Manager, both in Engineering and R&D Management at Telstar; General Manager of the joint venture IMA-TELSTAR SL for Freeze Drying Equipment for the Pharmaceutical Industry, and Head of Engineering and Manufacturing of Special Projects in Telstar Industrial SL.

Joan Piedrafita, Digital Development Project Manager at Telstar, holds a Computer Science Engineering qualification from the Autonomous University of Catalonia (UAB). He also has a European master's degree in Computational Science and Engineering from UAB and combines this with his Telstar membership in an Official Research Group, HPCA4SE. Joan has experience in development of e-mobility, IoT, and smart and advanced manufacturing projects as well as his specialism in integration of information technologies in the industry sector. In 2019, Joan joined Azbil Telstar Technologies SLU as an Industrial IT Architect participating in a wide variety of projects related to life science industry digitalization, from robotized lines to smart platforms related to architecture, software security and quality.

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, process water & waste treatment, clean air and cold storage technologies.