aizon

SOLUTION BRIEF

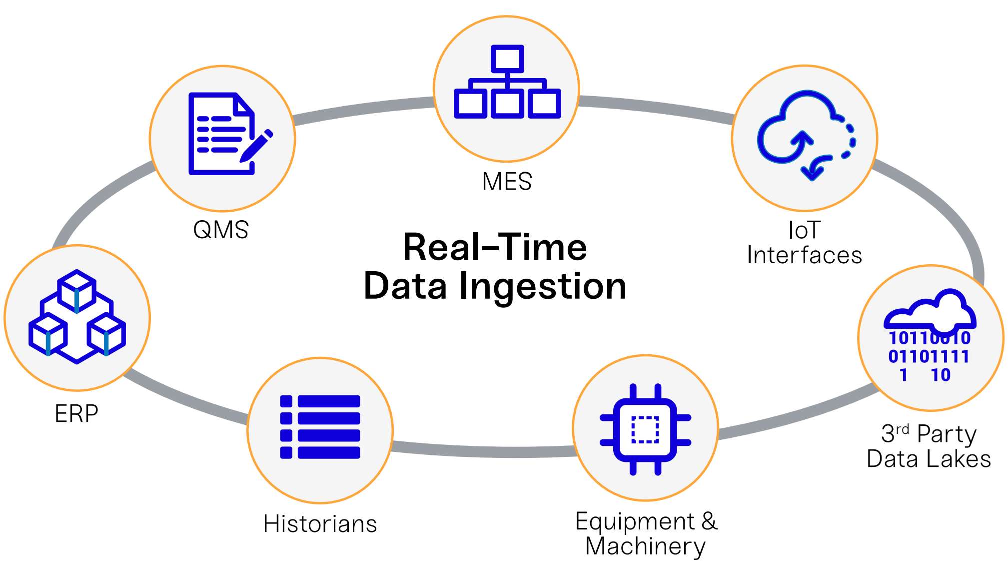
Principal Component Analysis

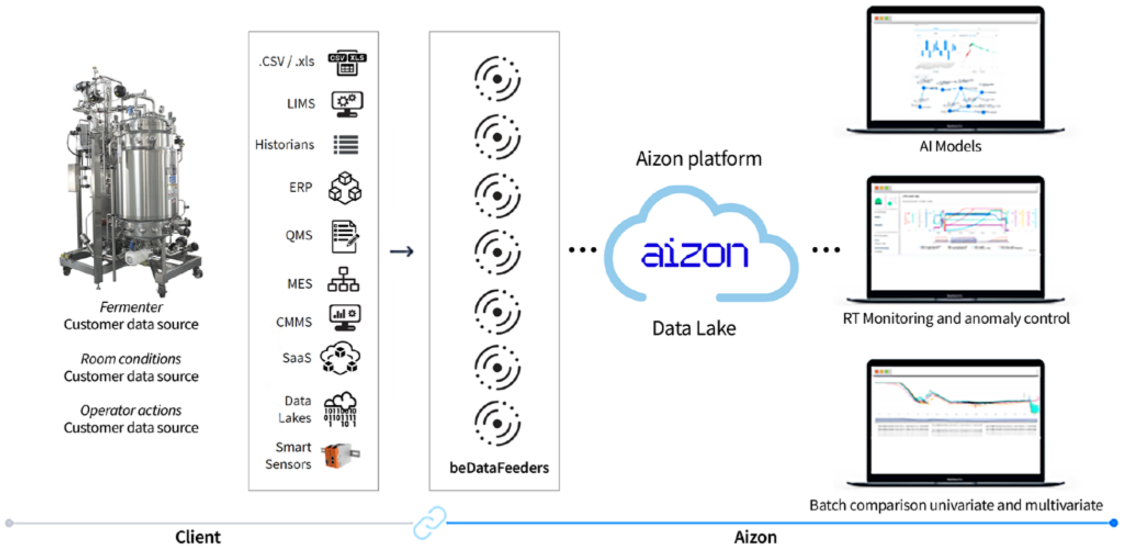
Introduction

Drug manufacturing in the modern pharmaceutical industry has become increasingly challenging to control, especially after the introduction of live organisms in the development process since critical process parameters and critical factors inherently present high variability.

The use of univariate tools monitoring single variables still is a common way of controlling the limits of key process parameters to maintain the process under control. However, process knowledge is limited when parameters are studied individually. For such reasons, multivariate analysis may help to better understand the processes and discover hidden relationships between variables. As ICH guideline Q8 on pharmaceutical development (2017) recommends, monitoring and analyzing the data from just one data source is no longer an option.

The variety of information to be managed and the need to understand the sensitivity of the biosystems suggest that manufacturing in this area could benefit from advanced statistics capable of interpreting complex reactions with multiple factors.



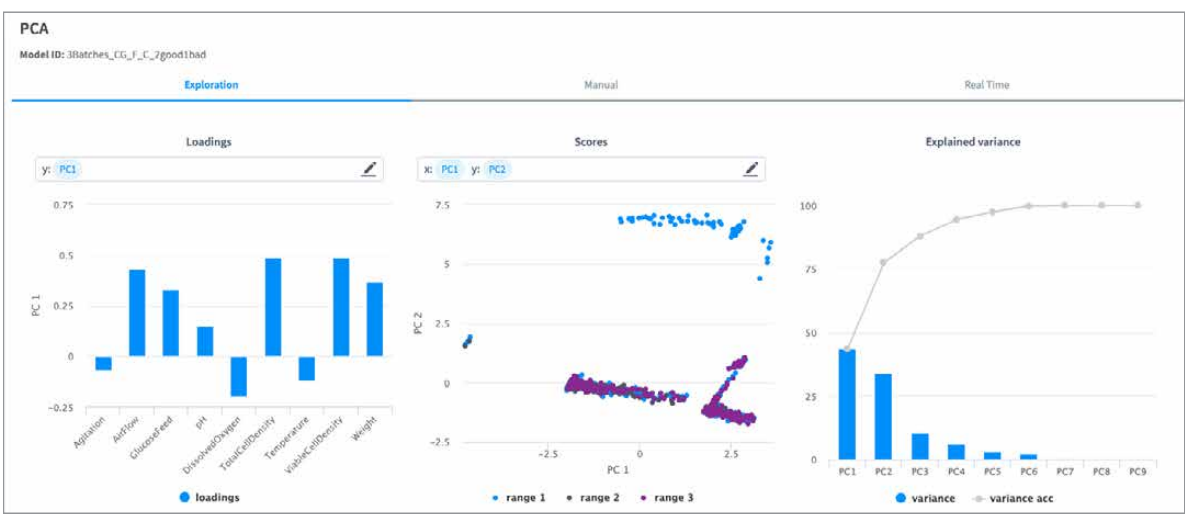


What is a PCA?

The Principal Component Analysis (PCA) is a powerful multivariate exploratory tool that transforms a number of possibly correlated variables into a smaller number of uncorrelated variables called Principal Components (PCs).

PCA is a fundamental tool to analyze manufacturing processes which present a high amount of parameters. PCA can reduce the dimensionality of high-complexity data, while retaining trends and patterns.

In Aizon, the PCA provides multiple ways of exploring data, including both historical and real-time rendering of up to 3 Principal Components. The PCA widget allows users to understand which variables present higher variance and consequently those that may have a more significant impact on the process.

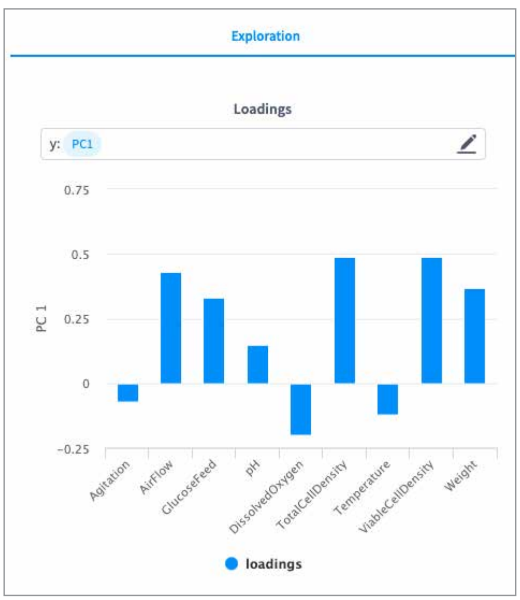


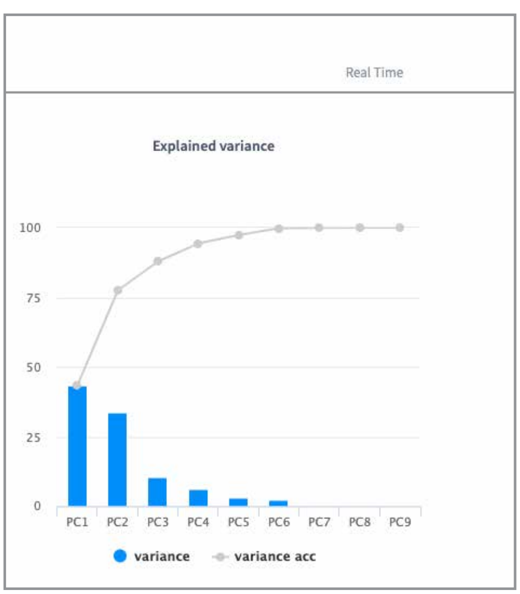
Benefits of the PCA in Aizon

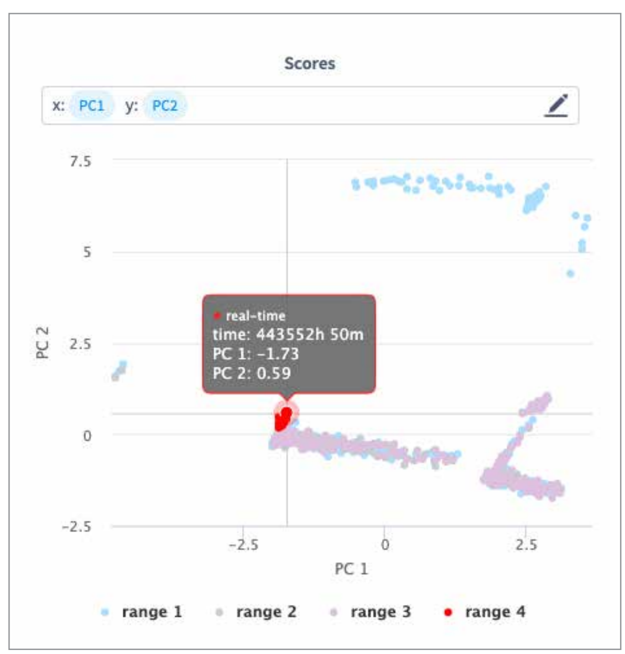
Aizon's AI-powered, GxP-qualified platform offers a range of analytic and exploration functionalities, ranging from classic statistics to more advanced tools like artificial intelligence widgets, that allow users to obtain deep knowledge of the process and the data. A better understanding of the process can guide the initial Design of Experiment as well as the identification of relevant factors.

With the PCA widget, users can reduce the dimensionality of the process and identify the parameters that explain most of the variability.

In addition, since it is a real-time PCA, it is possible to monitor the current batch's development with relation to a golden or failed batch in the past. This is due to the fact that the PCA widget allows users to graphically represent the pattern of a process, simplifying significantly the way we understand and identify batch outcomes. For example, if a model is built with data from a good and a bad batch, the user will visualize two different patterns, each representing the combination of values from either the successful or failed batch. As a result and in order to detect anomalies, the real-time data can be compared to the prints of reference batches, ensuring that either the trace of the current process follows the desired behavior or that it does not deviate towards a negative path. The combined variable analysis allows users to detect potential deviations even when all the critical parameters seem to be under control. In the image below, range 2 and range 3 are displaying the pattern of the good batches while range 1 represents the pattern of a bad batch. Range 4 (red dots) is the real-time behavior of the current batch.







Conclusion

Aizon's multivariate monitoring tools and especially the PCA, allow manufacturers to, on one hand obtain a better understanding of the manufacturing process and, on the other hand, see in real time when their process is deviating from the expected behavior even before variables are out of control. This is because these functionalities analyze the combination of parameters, and not the individual values.

This provides drug manufacturers with time to react and correct the process before any major issues occur and thus preventing both batch rejections, which could cost millions, or delays in getting the drug to market.

This can enable pharmaceutical companies to significantly improve yield output and drastically reduce manufacturing costs for any given process. Being able to control the state of a process and minimize variability can have a huge positive impact for any manufacturing operation and not only from an economic standpoint but also from a Quality Assurance situation.

About Aizon: Aizon is a software provider that transforms manufacturing operations with the use of IoT, cloud, advanced analytics, artificial intelligence, and pharma 4.0 technologies focused on optimizing pharmaceutical and biotech companies. The Aizon analytics platform seamlessly integrates unlimited sources of structured and unstructured data to deliver actionable insights across all manufacturing sites. Aizon offers an intuitive way to gain meaningful operational intelligence with data by enabling real-time visibility and predictive insights in a GxP compliant manner with end-to-end data integrity. Founded in 2014, the company is based in San Francisco, California and also has a European office in Barcelona, Spain.

sales@aizon.ai
+1 628-243-2513