aizon

SOLUTION BRIEF

Regulated Data Lakes to Break Data Silos

Introduction

Regulated industries and organizations face tremendous pressure to meet increasingly stringent regulatory requirements. This requires highly specific security measures and restrictions, and tends to lead to the creation of isolated data silos that make using and analyzing data a troublesome task.

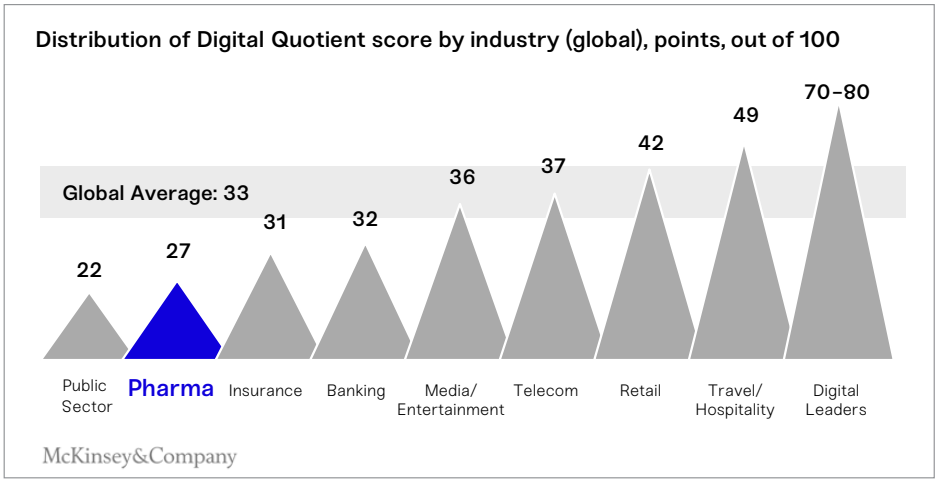
Furthermore, the growing use of biotechnology in drug development has led to more complex manufacturing processes and, as a result, an increasing need to analyze and understand the data. These highly complex processes are difficult to control and anticipate. Therefore, it is necessary to take as much data as possible from different sources and of different nature into account to gain as much knowledge on the manufacturing operation as possible and as a result, optimize the processes.

Why break down data silos?

Even the smallest details of an experiment can have a massive impact on the outcome, and for that reason it is critical to control every aspect of the process. Environmental conditions, quality of the raw materials and type of cleaning products used are examples of the many factors that can affect a process directly, and have to be closely monitored and controlled in real time.

Consequently, analyzing the data from just one data source is no longer an option. This makes the combination of different data sources into a single data lake a key requirement in modern drug manufacturing.

Nevertheless, a historic reluctance to adopt new technologies has led to the pharmaceutical industry using obsolete systems, causing much of the industry to lag behind in digital maturity. This makes removing data silos a very challenging and expensive process that not all drug manufacturers are willing to make.

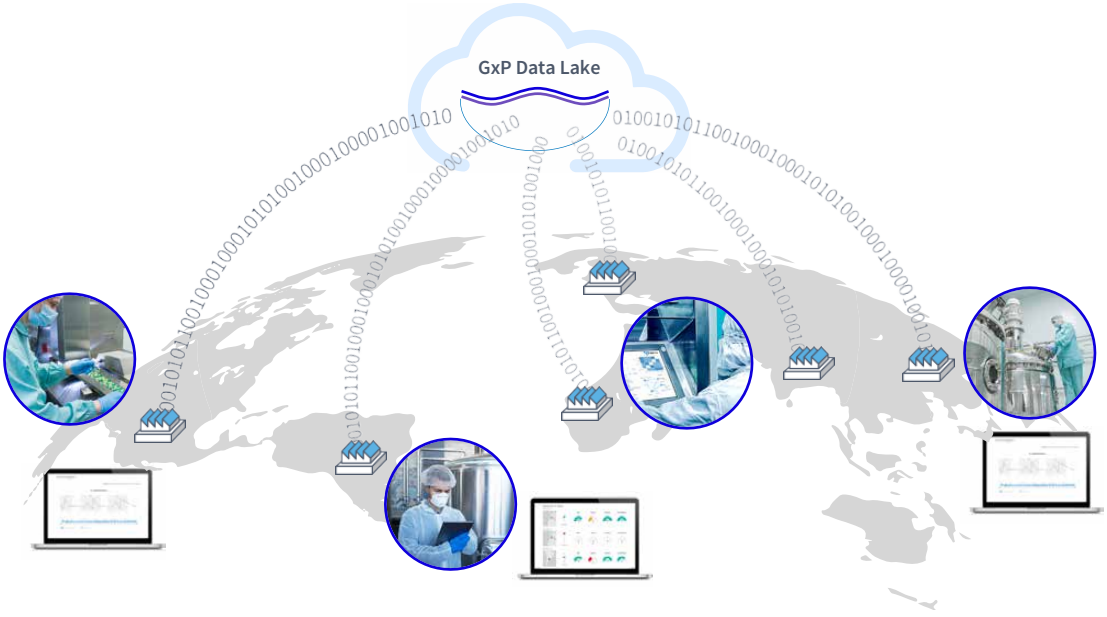


Moreover, after having to deal with the legacy systems and offline equipment, it is not uncommon for pharmaceutical companies to find themselves still hosting data silos. While they are bigger and more advanced, they remain unconnected systems, burdening users with low accessibility and compatibility.

As a result, establishing a good data architecture in a compliant cloud data lake can be a huge step forward for any organisation in the drug manufacturing industry.

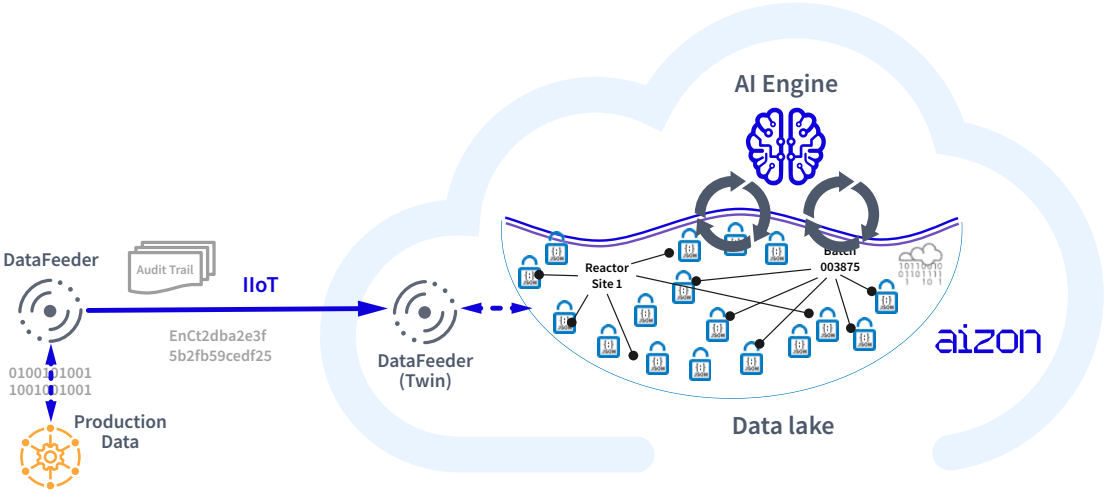
Aizon data lake for GxP environments

This is not an easy task to achieve: as soon as each datapoint moves away from its source system, traceability and integrity starts becoming a critical concern. These are factors that every organization in this industry is required to fulfill.



For these reasons, Aizon provides a cloud-based, regulated, secure and encrypted data lake for GxP environments. Built upon a serverless architecture where data from different sources can be easily ingested, visualized and analyzed, Aizon breaks data silos while maintaining compliance. This enables data integration and helps guarantee product quality.

In addition, the Aizon platform is developed under a quality system specially designed to be aligned with the GAMP 5 guideline, adding the innovative perspective for cloud and serverless systems. It satisfies standards for critical records based on data integrity (ALCOA principles) as well as being 21 CFR Part 11 Compliant for electronic records (U.S. Food and Drug Administration, 2018a). Aizon is certified for ISO 9001: 2015 and for information security, ISO / IEC 27001: 2013 management systems, and the ISO / IEC 27017: 2015 extended control module for cloud services.



Conclusion

Breaking the concept of data silos is a key requirement in modern drug manufacturing. The ability to analyze and learn from the data across multiple different data sources will soon no longer be a competitive advantage, and instead will become a necessity for all pharmaceutical companies to succeed.

The complexity of the drug manufacturing processes is at its all time highest, as is the control of the regulatory institutions, under enormous pressure to ensure the health and safety of every person taking medication in the world.

The need for a regulated cloud data lake in the near future of pharmaceutical manufacturing is evident. The sooner companies adopt these emerging technologies in their drug manufacturing processes, the more drastic the benefits will be in the short-term.

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.