



Aizon Contextualization Functionalities

Introduction

Variables, attributes, events measurements, amongst any other outputs derived from different and dispersed sources from manufacturing companies, are commonly stored for the sake of conducting audits compliant within the 21CFR P11 code, or for business/operational analysis.

In this way, valuable data is stored in multiple systems creating an ever-increasing amount of silos. This results in uncontextualized, disconnected large-scale data sets which are commonly accessible by only a small group of people, departments, or business units with the proper access permissions and tools to consume it.

Modern manufacturers are increasingly realizing that the lack of contextualized data, leads to low visibility, collaboration, and in some cases to inaccuracy, having a non-positive impact on efficiency.

Aizon provides a regulated, secure, and encrypted data lake for GxP environments to acquire data and transform it into knowledge, dismantling data silos, and enabling data contextualization.

Data contextualization is considered one of the main remedies for simplifying data interpretation, aggregation, or modeling, providing useful insights about how your end-to-end process is operating and allowing you to greatly trivialize the decision-making process.

Data Contextualization

Data contextualization is described as the organization of related data collected from several types of equipment, machines, actions, amongst others, that enable a particular analysis and interpretation.

One way to do this is through a new concept called metadata, which is typically described as “data about data” and refers to the fact that data is often meaningless without additional understanding about the context in which the data were generated.

Contextualization plays a key role in Process and Quality data analysis. From comparing batch information, analyzing process data and finding correlations between upstream and downstream, all the way towards controlling and comparing site conditions, monitoring environmental sensors, etc., contextualized data is what allows us to understand and gain knowledge from a sea of data.

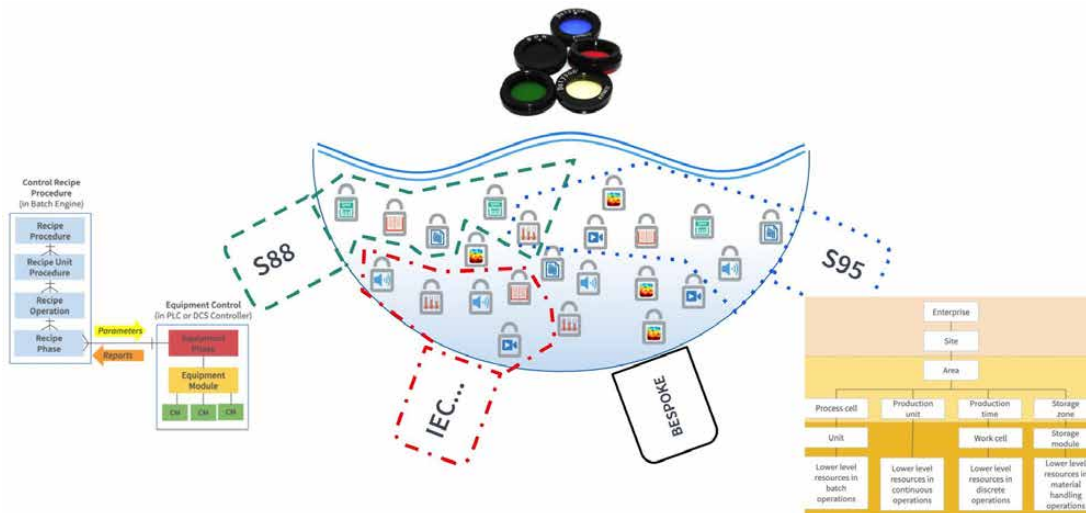


Fig 1:The landscape of entities and structures in the Aizon platform.

Benefits

Contextualized data helps obtaining a deep process understanding and unlock key insights by:

- Transforming data into knowledge for different objectives, and for different stakeholders, e.g. Quality, Process and System Engineering, etc.
- Associating relevant data points from a process to gain a proper understanding of that process
- Assigning a hierarchy to groups of data, enabling different points of views for interactions between processes

The Aizon platform empowers data users through data contextualization

The Aizon platform allows the combination of data from multiple sources to provide a unified view in just a few steps, automatically providing a holistic view of the operational realities.

Moreover, the Aizon platform brings powerful and user-friendly features to contextualize data, such as associations, processes and scenarios.

- Associations: Create hierarchical associations between your structured and unstructured variables to contextualize each data point.
- Processes: Allow the proper definition of a process' lifecycle and its most relevant parameters without the restraints of time. In addition, Aizon's Process Instances allow the automatic identification of batches according to these process structures.
- Scenarios: Create and save particular relations between entities with a time range to display it as information for specific users in a collaborative framework.

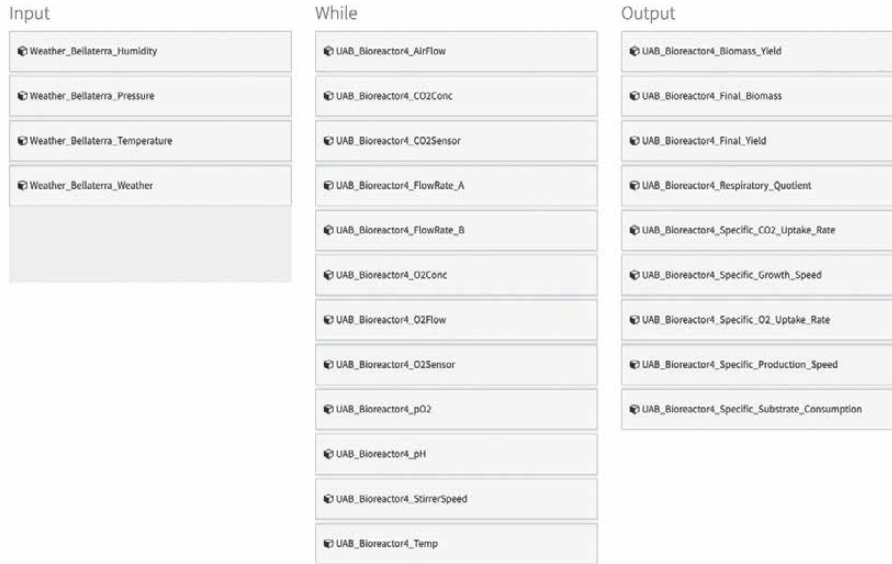


Fig 2: Processes

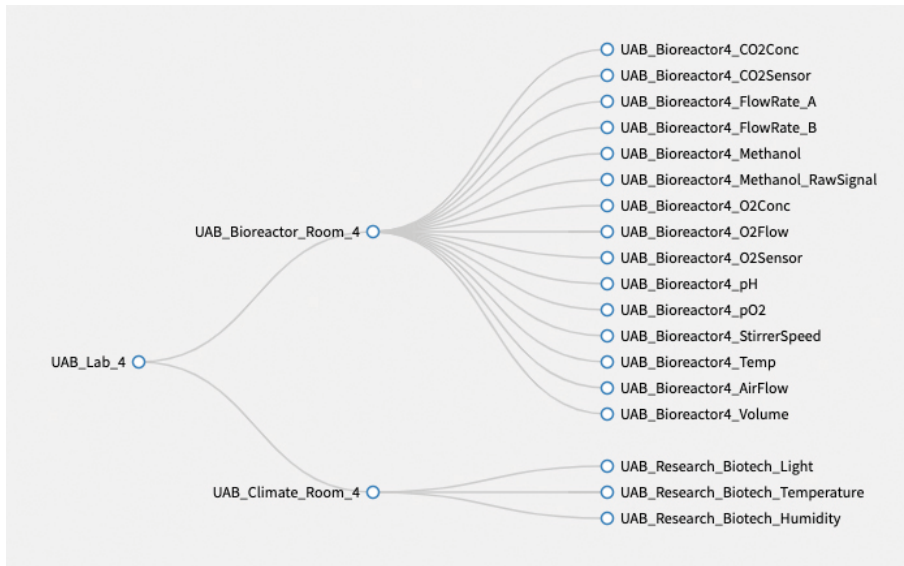


Fig 3: Associations

Conclusion

The complexity of the drug manufacturing processes is at its all time highest, as is the control of the regulatory institutions. The cost of not being able to interpret, transform or group data in drug development often tends to be highly underestimated and leads to unknowledgeable decision-making. Modern manufacturers are increasingly realizing that the lack of contextualized data leads to low visibility, collaboration, and in some cases inaccuracy, having a non-positive impact on efficiency.

Data contextualization 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.

Nevertheless, data must be stored in accordance with regulations, always ensuring data integrity and GxP Compliance. For these reasons, Bigfinte 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, analyzed and contextualized.

No matter the circumstances, the contextualization of data is becoming the bottom line of success for any organization that looks to understand their operations, make more sustainable decisions, develop smarter data users, and decrease high-cost mistakes.

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.