

Benefits of Early Introduction of Data Historian Software in Today's Digital GMP Landscape



In this paper, we provide valuable insights into data management best practices for life science systems. Additionally, we will outline the expectations laid out by regulatory bodies in this field.

By incorporating these best practices and meeting regulatory requirements, your organization will be wellequipped to ensure the integrity, accessibility, safety, security, traceability, and reliability of your data.

In today's GMP regulated Life Science environment it is our duty to ensure that our organizations harness the power of data effectively. A data historian software is a powerful tool that allows organizations to manage, capture, store, and analyze vast amounts of data in real-time. It not only provides a historical record of data but also enables companies to gain valuable insights into their operations, detect patterns, and make more informed decisions.

Here are a few reasons why investing in a data historian software should be a top priority for your company. We want to start with regulatory compliance and data integrity as these are the main risks in our industry to getting issued warning letters or non-compliance statements by the authorities.

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Regulatory Compliance

- Data-Driven Decision-Making
- Collaboration and knowledge sharing
- Predictive analytics
- Operational efficiency
- Root cause analysis

Regulatory compliance

Compliance with GMP requirements on data integrity is a must from the beginning of GMP-regulations / and or / or only the beginning of Process Development. Working with paper-based historic manufacturing data is very labor intensive, so the trend to paper-less solutions is unstoppable, restricted only by the capabilities (and the price tag?) of the various systems available on the market.

The consequences of non-compliance with data integrity regulations can be severe and include supply withdrawal, product recalls, warning letters, and significant reputational damage.Regulations from FDA, EMEA and WHO point out requirements to be fulfilled to ensure data integrity by following keyattributes: *attributable, legible, contemporaneous, original and accurate (ALCOA)*. For electronic systems additional emphasis is laid on the data of being complete, consistent, enduring and available from their entry until the end of their retention period.

Especially the requirement "enduring" might give some challenges to electronic systems. Retention periods for some data can easily be more than 20 years, and data must keep their integrity until the end of this period. Given the rapid development of soft- and hardware the way data is stored needs to be considered carefully.



Using one GMP-compliant data historian for all data gained during the process development, analytical testing and maybe even from contract organizations enables companies to use their data through the whole life cycle of manufacturing.



Organizations must invest in tools, training and education to emphasize the importance of data integrity to their employees even in development departments. This is not only crucial for regulatory compliance but also for





ensuring the overall quality and safety of products being brought to market.

The Source of Truth -Collaboration and knowledge sharing

Collaboration and knowledge sharing are crucial components of a successful and innovative workplace. In today's datadriven world, having a centralized repository for data is essential to facilitate effective collaboration and knowledge sharing across teams and departments. This is where a data historian software comes into play.



A data historian software serves as a centralized repository for storing and organizing data. This powerful tool enables employees to access, analyze, and share *original* data easily, regardless of their location or department. By providing a single source of truth, it eliminates the need for individuals or teams to manage and maintain their separate data silos *and prevents errors by duplication of data*. Moreover, the accessibility and ease of use of a data historian software leads to a democratization of data within the organization. Employees at all levels can access relevant data and contribute to datadriven decision-making processes. This empowers them to make informed decisions based on accurate, *complete* and up-to-date information, resulting in better outcomes and more efficient operations.

In addition to facilitating collaboration and knowledge sharing, a data historian software plays a vital role in promoting a culture of innovation. By providing a vast repository of historical data, it allows employees to identify patterns, trends, and insights that can drive innovation and give an organization a competitive edge.

It serves as a valuable resource for research, development and *manufacturing improvements*, enabling organizations to learn from their past experiences and make data-driven improvements.



With a data historian software in place, employees can collaborate more efficiently by working on the same datasets, reducing duplications and inconsistencies. By breaking down the barriers between teams and departments, data historian software promotes crossfunctional collaboration, enabling a holistic and comprehensive approach to innovation and process improvements.

Data-driven decision-making

With the use of a data historian software, organizations are able to access an extensive repository of historical data instantaneously. This powerful tool empowers decision-makers to make informed choices based on accurate, comprehensive, and up-to-date information. The availability of such comprehensive data allows for more precise and successful decision-making processes for e. g. process improvements.

By employing a data historian software, organizations have the ability to retrieve and analyze historical data points for a multitude of purposes. This includes identifying patterns, trends, and correlations that may not be immediately evident and useful information for setting limits in process validation.

These insights allow decision-makers to gain a deeper understanding of the factors that have influenced past outcomes, enabling them to make more informed and strategic decisions for the future.



Additionally, by having a reliable and accessible data historian software, organizations can ensure that their decision-making processes are objective, unbiased and GMP-compliant.

The software provides a platform for storing and accessing data in a centralized manner, eliminating the risk of relying on outdated or inconsistent information. This promotes transparency and accountability, as decision-makers can confidently base their choices on accurate, reliable and traceable data.

Furthermore, the ability to access up-todate information provides decision-makers with the agility needed to respond to market trends, shifts in customer preferences, and other external factors that may impact the organization's success.



With this data-driven approach, organizations can stay one step ahead of the competition while minimizing the risk of costly mistakes of process improvements. If GMP-compliant data historians are used already in process development it minimizes the effort for setting limits of critical process parameters and enables Quality by Design principles for process validation.

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Effective troubleshooting and root cause analysis

In times of crisis, the ability to rely on a comprehensive and complete historical data record is indispensable. A data historian software provides organizations with an invaluable tool to identify trends, track changes, and analyze data over time. It facilitates effective troubleshooting and helps to uncover the root cause of issues.



When issues arise within an organization, it is crucial to have a system in place that can capture and retrieve data associated with those problems in short time. By implementing a data historian software, organizations can ensure that all relevant data is collected and preserved for future analysis. This historical data record serves as a valuable resource in identifying recurring patterns or unusual values for a deep understanding of the history of a specific issue.

By collecting and analyzing data from various sources, organizations can detect patterns and fluctuations that may be contributing to the occurrence of certain issues. This insight can be paramount in identifying potential root causes and taking proactive measures to prevent future problems.

Furthermore, the ability to track changes in data over a long time and even different processes is essential for effective troubleshooting. With a GMP-compliant data historian software starting in development, organizations can compare all historical data to current data, allowing them to quickly pinpoint and compare the current issue with findings already discovered long before the process was used for routine operation.



Root cause analysis is another critical aspect of effective troubleshooting. By analyzing historical data, organizations can delve deeper into the underlying causes of problems. This process involves examining various factors such as system configurations, environmental conditions, and operational limits to determine the root cause of an issue.

Predictive analytics

Having a robust data historian software in place enables companies to harness advanced analytics techniques like predictive modeling and machine learning. By analyzing patterns in historical data, organizations can predict future trends, anticipate customer needs, and gain a competitive edge.

Predictive analytics is a powerful tool that allows businesses to make informed decisions based on data-driven insights.



With the help of a reliable data historian software, companies can efficiently collect, store, and analyze vast amounts of historical data. This data serves as a foundation for understanding patterns and trends that can occur in the future.

One key benefit of predictive analytics is the ability to forecast future trends. By examining historical data, organizations can identify patterns and relationships that exist within the data. These patterns can then be used to create predictive models, which help anticipate future outcomes.

In today's fast-paced and highly competitive business environment, staying one step ahead of the competition is crucial.



Predictive analytics plays a vital role in achieving this by providing organizations with key insights and foresight into market trends and customer preferences. By leveraging predictive analytics, companies can proactively adapt their strategies and offerings, ensuring they are ahead of their competitors and maximizing their chances of success.

Operational efficiency

By capturing and storing large volumes of data from various sources, a data historian software helps identify inefficiencies, bottlenecks, and areas for improvement. It enables organizations to optimize processes, reduce costs, and enhance productivity by making data-driven adjustments. The power of data cannot be underestimated when it comes to optimizing processes and making informed decisions. A data historian software allows organizations to analyze vast amounts of data and extract valuable insights. These insights are critical in spotting patterns, identifying trends, and understanding the factors contributing to inefficiencies within the operational processes.

By leveraging the capabilities of a data historian software, organizations can make data-driven adjustments, leading to enhanced productivity. It allows them to identify and eliminate redundant and nonvalue-added tasks, streamline workflows, and allocate resources more effectively.

In addition to process optimization, a data historian software helps in reducing costs. By identifying areas where resources are being utilized inefficiently, organizations can take corrective actions. For example, if the data analysis reveals a machine that is frequently breaking down, it may be a sign for maintenance or replacement, thereby preventing costly downtimes and repairs.



Moreover, a data historian software provides organizations with the ability to monitor and track key performance indicators (KPIs) in real-time. This enables timely decision-making and interventions when deviations from desired targets occur. Being proactive rather than reactive allows organizations to address potential bottlenecks before they escalate into larger issues, ensuring smooth operations and customer satisfaction.



Executive Summary

Data integrity requirements are essential for GMP driven organizations, and regulatory bodies actively target data integrity failures. Organizations must prioritize data management and provide adequate training to ensure compliance, protect their reputation, and safeguard product quality and safety.

Implementing a data historian software enhances decision-making by utilizing accurate and comprehensive historical data. This data-driven approach reduces reliance on incomplete information and gut feelings, resulting in more successful and strategic decision-making. It also promotes objectivity, transparency, and adaptability, enabling organizations to thrive in a dynamic business environment.

A data historian software serves as a centralized repository for data, fostering collaboration, knowledge sharing, and a culture of data-driven decision-making and innovation. It empowers employees by enabling easy access, analysis, and sharing of data across teams and departments, driving organizational success.



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