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The 5 Vs of Pharmaceutical Data Integrity



The volume of data created, captured, copied, and consumed is rising rapidly, and at an ever growing pace. **In the next 5 years, global data creation is expected to increase by more than 50% year-over-year.** With this growth and complexity, it's essential to categorize, contextualize, and visualize data so that it can be properly used by both humans and machines.

Keep reading to find out the Five Vs of Pharmaceutical Manufacturing Data.



Volume

Variety

Validation

Veracity

Velocity

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Volume

Each piece of equipment and each step in the manufacturing process can generate a significant **volume** of data. Tens of thousands of data points for every batch add up, and GMP relevant documentation needs to be stored for many years. Manufacturers are investing millions each year in warehousing and archiving facilities and resources to manage the billions of pages they own.





Variety

All data is not created equal. Sensors, log files, Certificates of Analysis, batch records, ERP data, MES data. The **variety** of data that comes out of manufacturing processes isn't standardized either in type or in format. This problem is magnified when organizations leverage on-premise solutions, as individuals or departments are managing their own data and procedures without standardized controls.

No standardized control means no consistency or contextualization. The result? Loss of time and negative impact to revenue, product yield, and patient safety.

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Validation

In the biopharma industry, **validation** is crucial to ensuring drug (and ultimately patient) safety. Biopharma data is used to validate manufacturing processes and confirm that any process in a pharmaceutical facility will operate within the specified parameters whenever required. This, in turn, ensures that manufacturers are producing consistent, quality products, even when processes and data are not directly being validated. Without good data, it's nearly impossible to meet the regulatory requirements showing that manufacturing processes are validated.

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Veracity

Factual and accurate. It's not just ensuring that the data is right, it's that the data collection process is right, and that organizations can answer questions like: what was the source, who collected it, how was it collected, when? Ultimately, with data **veracity**, pharma manufacturers are looking for three things: precision, trustworthiness, and quality.

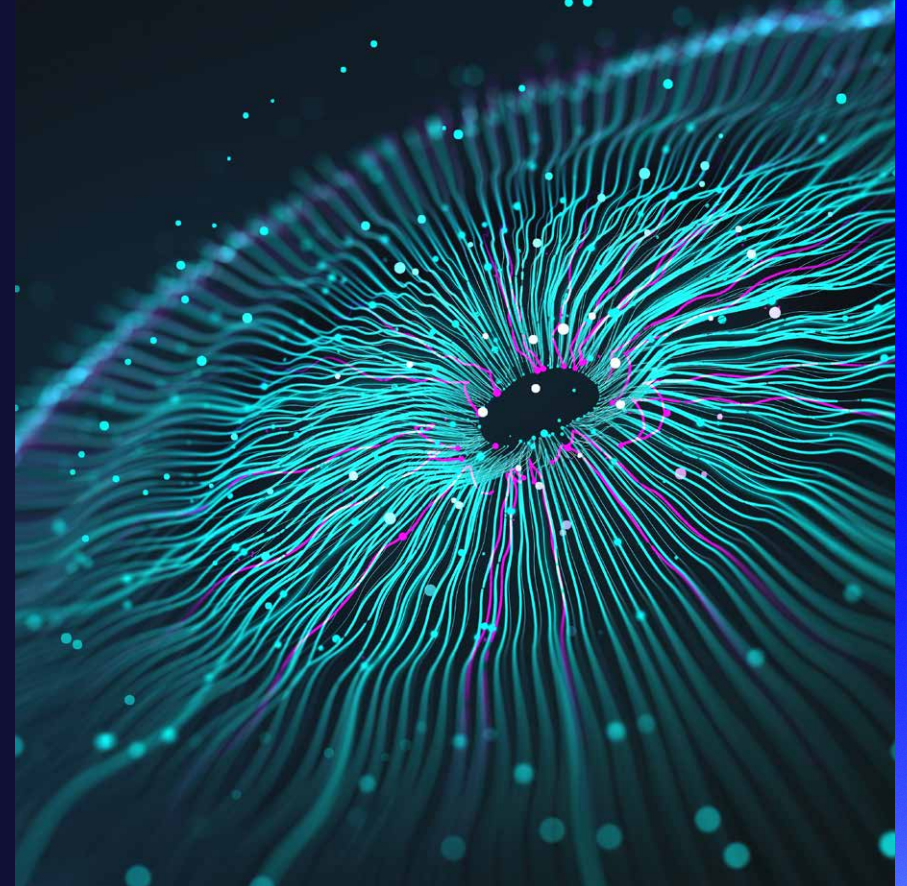
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Velocity

All this data and nothing to do with it? Not exactly. To make informed decisions and accurate predictions, organizations need to access their data. The **velocity** at which organizations can and should access their data provides an additional layer of challenge. On 'paper' or on-premise solutions make it next to impossible to access data with any speed, making decisions slower and more complicated.

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Making it Happen with Aizon

Ensuring compliance, integrity, and performance starts with changing your manual and paper-driven processes towards digitization. Aizon's GxP compliant, cloud-based software platform leverages AI and Machine Learning (ML) to enable the production of drugs at higher quality while reducing time to market.

The journey to Pharma 4.0 starts with Aizon's platform. For manufacturers just starting on digital transformation (or who are still operating in a hybrid model), Aizon Digitize takes organizations' manual and spreadsheet-driven processes and allows for digital storage and validation of the data through OCR ingestion (with AI interpretation) and customized forms based data entry. It also enables fully compliant processes with the use of electronic signatures.

Aizon also makes it possible to break data-silos and begin contextualizing data so it can be analyzed and used for better decision making. With Aizon Unify, manufacturers gain the ability to seamlessly and efficiently capture and monitor disparate data from across the organization and turn it into actionable information.

Digitizing data is the beginning of a journey towards a digital, predictive plant, where operators have visibility to comprehensive data sets and the ability to leverage data to make decisions to increase productivity and decrease costs.

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