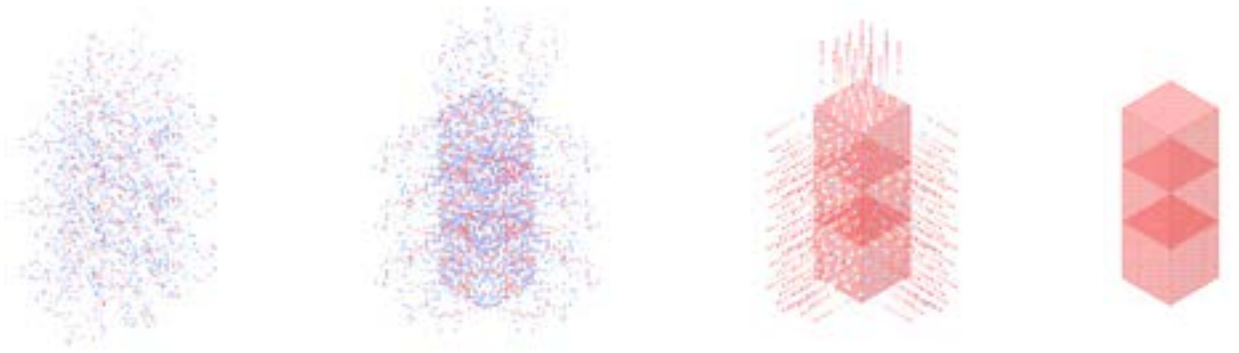
SYSTEC & SERVICES
KÖRBER SOLUTIONS

DATA INTEGRITY

Correct data at all times

Data is the cornerstone for progress in the life sciences industry. Ensuring the constant availability of complete and non-manipulated data minimizes the risks to patient safety and your business. We help you to comply with cGMP data integrity requirements to do just that.



SITUATION

For some years now, an increased focus has been placed on data integrity in government inspections. In many cases, this has led to Findings and Warning Letters.

Following the ALCOA+ principles* can ensure compliance with regulatory requirements and minimize patient risk.

Thanks to our many years of experience from projects with Top 10 international pharmaceutical companies and SMEs, we can provide you with customized advice. We will show you how to design your processes and systems for Data Integrity compliant work according to the requirements of the FDA, EMA, MHRA. We will make sure to highlight the necessary points in order to ensure all participants internalize the topics.

* Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available

BENEFITS

- Use the industry's best practices to evaluate and optimize your processes.
- In-depth and up-to-date knowledge of the relevant regulatory requirements of the FDA, MHRA and EMA.
- Execution of Data Integrity Assessments to quickly identify potential Data Integrity gaps.
- Support for audit readiness and data integrity through the definition of action and risk mitigation plans.
- A pragmatic approach for effective and sustainable results, carried out by experienced experts.

CONTACT

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