



Data Integrity: A Key Topic for CARBOGEN AMCIS as a leading API Supplier

•• **An Insight by Dirk Badura, Ph.D.**
Senior Head of Quality & ESH

Data Integrity is an aspect which concerns all areas involved in a GMP regulated manufacturing of pharmaceutical products. It is an integral part of all GMP guidelines since the beginning but has become a more and more important over the last decades.

This is mainly due to the increased complexity of our current compliant management as sophisticated electronic data management processes are standard today.

In the last few years data Integrity became a more prominent topic in the several guidance documents like:

- *US FDA "Guidance for Industry Q&A "Data Integrity and Compliance With Drug CGMP", December 2018*
- *MHRA 'GxP' Data Integrity Definitions and Guidance for Industry, March 2018*

In this context a overall recognised basic framework to assure the integrity of any kind of data is represented by the so called ALCOA+ - principles:

A L C O A	Attributable	Complete	P L U S
	Legible	Consistent	
	Contemporaneous	Enduring	
	Original	Available	
	Accurate		

CARBOGEN AMCIS has adopted these principles in its Data Governance Policy and this article will present how CARBOGEN AMCIS has accepted the challenge of a companywide implementation of these principles. Specifically the approach which has been chosen to further develop our quality level regarding integrity of all GMP critical data will be outlined.

Historically Data Integrity has always been an integral element in all processes performed under GMP by CARBOGEN AMCIS. „Classical“ Data Integrity measures applied to paper documentation like:

- Controlled printing of batch records
- Signing with date / time for the performed significant production steps
- Traceable correction of written entries
- Thorough and safe archiving of documents for storage over decades
- ...

Nevertheless the extremely rapid progress in the field of computer technology and its widespread use in manufacturing generated new challenges regarding data integrity which lead to certain gaps in the daily work. To tackle these challenges CARBOGEN AMCIS has established a Data Governance Plan for the entire company, which has already been acknowledged in several customer audits.

This „Data Governance Strategy for Computerized Systems“ outlined a three-phase approach:

Phase I:

To focus on the most critical systems first a priority ranking of all computerized systems was performed based on a predefined set of „risk questions“ with predefined possible answers which have certain risk numbers assigned to. Depending on the specific answers given for each system a final risk number was calculated.



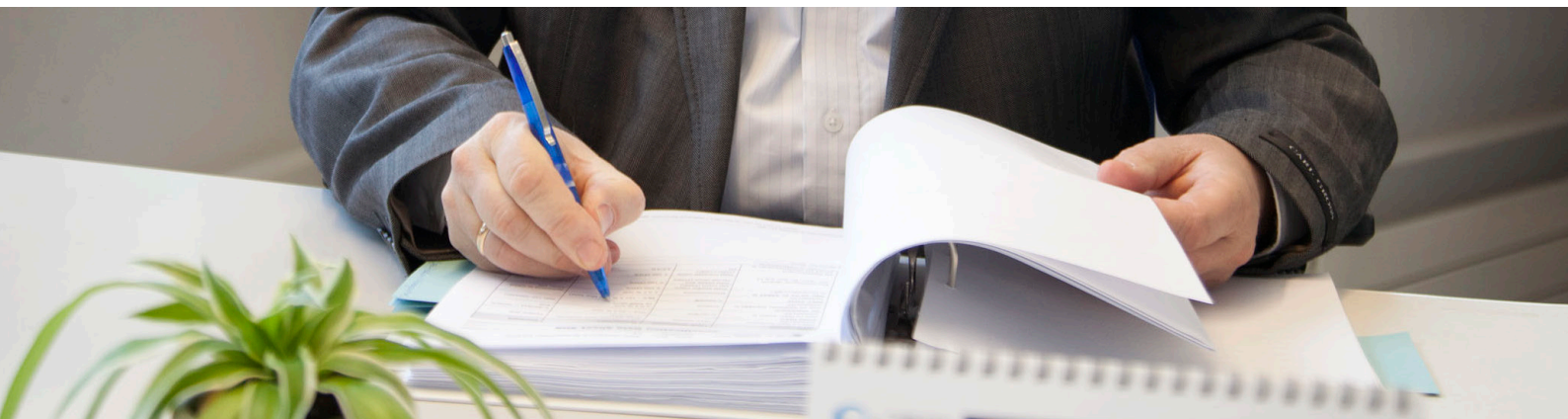
Phase II:

Detailed Data Integrity Assessment were then performed starting with the most critical systems. More than 32 questions based on the part 11 / Annex 11 requirements had to be answered for each computerized system. By this „target/actual comparison“ the specific gaps of each system were identified and mitigation measures were proposed.

In a final summary report for all systems, the final mitigation measures and timelines were defined and committed in agreement with senior management.

Phase III:

The result of the whole exercise are more than 300 mitigation measures which will raise our Data Governance Compliance to a new level. All these activities are now closely followed-up to monitor their progress. Therefore CARBOGEN AMCIS is convinced that this project has further strengthened our compliance and trustworthiness which are major assets for our customers in the regulated environment.



For more information about CARBOGEN AMCIS, visit www.carbogen-amcis.com

BRINGING
YOUR
SCIENCE
TO LIFE