



Rescop Academy presents

# GXP DATA INTEGRITY

Handling of GxP relevant Data should follow the data lifecycle and GxP Data should be captured, maintained, and destroyed compliant conform regulations. How this should be done is described in diverse Data Integrity Guidelines, amongst which ISPE GAMP® 5 Good Practice Guide: Records & Data Integrity, MHRA 'GXP' Data Integrity Guidance and Definitions, and FDA Data Integrity and Compliance with CGMP Guidance for Industry.

To help you follow these guides and comply with regulations, Rescop has developed GxP Data Integrity training on different levels; Foundation and Practitioner. Both training levels combine the theory from the diverse guides with exercises to simulate the practical implementation.

The Foundation level training is suitable for people who need to know about Data Integrity and its application throughout the lifecycle. This training will take 1 day.

The Practitioner level training is suitable for people who are responsible for Data Integrity and its application throughout the lifecycle of the regulated data. This training will take 2 days.

Both GxP Data Integrity training levels can be booked in our Open Classroom Schedule at one of our training locations, or as an In-Company training at your location.

## GxP Data Integrity Foundation

The GxP Data Integrity Foundation training will include the theory from the diverse Data Integrity Guidelines, amongst which ISPE GAMP® 5 Good Practice Guide: Records & Data Integrity, MHRA 'GXP' Data Integrity Guidance and Definitions, and FDA Data Integrity and Compliance With CGMP Guidance for Industry, combined with the practical experience of our trainers. The foundation training is setup to teach trainees the basics of Data Integrity.

Topics regarding Data Integrity will be discussed, like:

- Where do we typically find Data Integrity Risks?
- How can we mitigate those Risks?
- What are Audit Trails used for?
- Why do we perform User Reviews?
- What to do with old data?

## Information?

For additional information or questions, kindly contact:

Rescop Academy

E: [academy@rescop.com](mailto:academy@rescop.com)

M: +31 (0) 85 201 72 77

[academy.rescop.com](http://academy.rescop.com)

## GxP Data Integrity Practitioner

The GxP Data Integrity Practitioner training extends the GxP Data Integrity Foundation training with an even more process focused approach and more in-depth content on the activities to build, assess and maintain systems in an integer way.

The practitioner training is setup to teach trainees a process focused and risk based approach to GxP Data Integrity.

In addition to the Foundation training, topics regarding Process Modeling and System Overviews will be discussed, like:

How can we identify Data Integrity Risks?

- Why do we need Audit Trails?
- How can we setup accounts to be secure for Data Integrity?
- What maintenance activities are required to maintain integer data?

*Find our upcoming classroom training via*

[www.rescop.com](http://www.rescop.com)

GXP Compliance, Services & Solutions