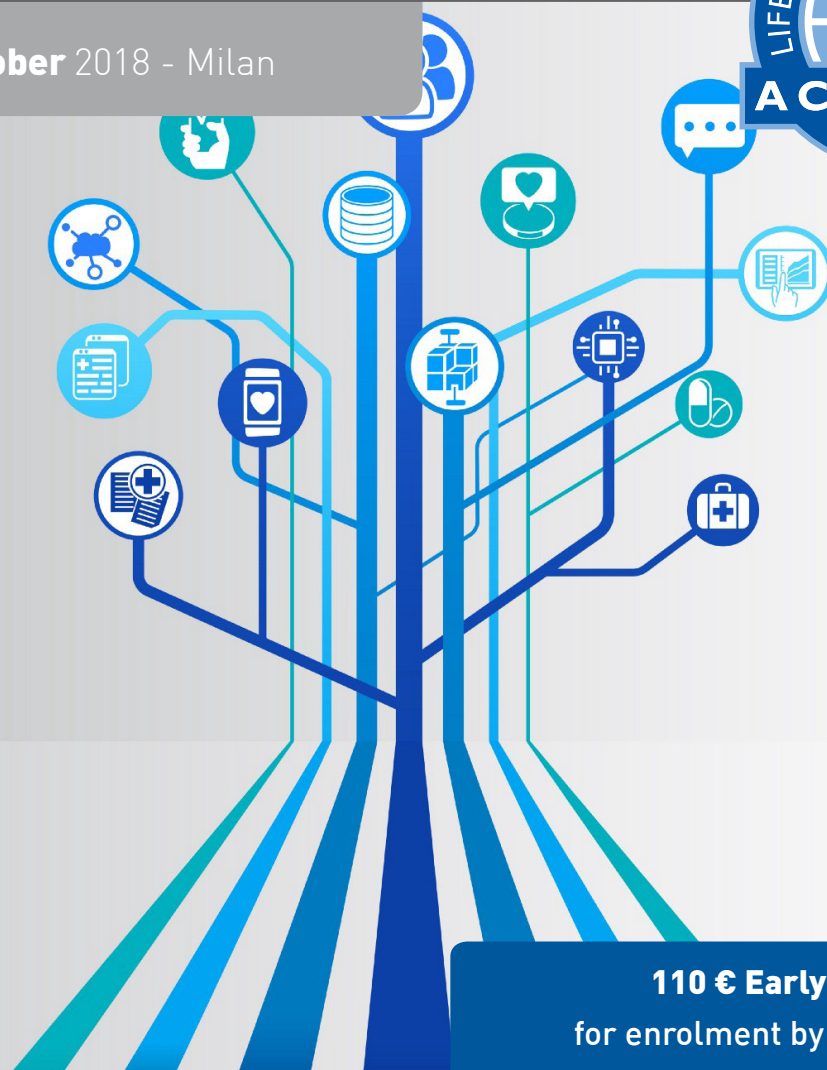


Data Integrity Assessment

An effective approach to identify data integrity gaps and to define appropriate corrective actions

Tuesday, 30 October 2018 - Milan



110 € Early Bird discount
for enrolment by **09th October 2018**

Workshop

Hotel Melià

Via Masaccio 19
20149- Milan

Tuesday, 30 October 2018

09.00 - 17.00

*Taking part in our training courses,
you support "The Vase of Flowers" project*



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Introduction

Data integrity is a fundamental element of a pharmaceutical quality system and has a direct impact on product-related decisions and traceability. Accountabilities for ensuring data integrity run throughout an organization, from product development, through manufacture and testing, to product distribution and safety monitoring.

The impact of data integrity issues can be significant on a regulated company. There has been increased regulatory focus on all aspects of data integrity, including publication of specific Regulatory Guidance on the topic, and increased number of citations in the area.

This is the time, for life science companies, to conduct Data Integrity Assessment on their processes and computerised systems to evaluate risks and identify proper mitigation actions.

Who should attend?

The workshop is suitable for people working in the Life science sector that are responsible of ensuring or assessing the compliance of processes and computerised systems to requirements and expectations relating to the control and management of GxP data.

Course language: English

Programme

The workshop provides a general introduction of data integrity principles taken from the different guidance to provide a clear picture of the main concepts.

The workshop methodology focus is on practical case studies analysis, in particular on computerized systems.

The attendees are continuously involved in the identification of data integrity gaps, risks evaluation and definition of mitigation actions.

Type of Training

Workshop

Data Integrity Assessment

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Agenda

9:00 - 9:30	☑	Participants registration
9:30	🚩	Course commences
11:00 - 11:15	☕	Coffee Break
13:00	🍴	Lunch
15:30 - 15:45	☕	Coffee Break
17:00	🚩	Q&A and conclusion

Lecturer's Bio



Stefano Piccoli is the Founder of Qstep srl, a consultancy company, working in the Life Science industry, specialized in Data Integrity, Computer System Validation and IT Compliance services for the GxP environment. Stefano has an extensive experience spanning more than 15 years in the regulated (GxP) pharmaceutical environment within the following areas: Computer System Validation (CSV), IT QA/Compliance, IT GRC (governance, risk & compliance), Data Integrity, Data Privacy and regulatory audits.

Participant Experience

Participants should have a good knowledge of GxP regulations in particular of GDocP and strengthen basic knowledge of computer validation regulations and guidance (e.g. GAMP5).

At the end of the training, you will be able to:

- Understand the data integrity principles
- Identify data integrity impact on processes
- Increase awareness on data integrity risks
- Know how to incorporate the aspects of data integrity into the design and qualification of new computer system

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TO REGISTER FOR THE COURSE YOU CAN FILL IN AND SEND **THE REGISTRATION FORM**

OR DIRECTLY **REGISTER ONLINE:** <https://dataintegrityassessment-2018.lscademyevents.it/orders/new>

REGISTRATION FEES:

- Early bird: **€ 750,00 *** until 09/10/2018
- Ordinary: **€ 860,00***
- Freelance – Academy – Public Administration: **€ 460,00***

***For Italian companies: + 22% VAT**

The fee includes: tuition, teaching materials, lunches and coffee breaks, organizational office assistance, attendance certificate.

Methods of payment

The full amount must be paid on registration to EasyB s.r.l. by bank transfer or by credit card. If paying by bank transfer please attach proof of payment to the registration form. Bank transfer payable to:

EasyB S.r.l.

Via Roma, 20 - 24022 Alzano Lombardo (BG)

P. IVA **03633040161**

Banco BPM - Filiale di Carobbio Degli Angeli

IBAN: **IT81 F 05034 53960 000000003450**

SWIFT CODE: **BAPPIT21AY5**

For additional information:

	Secretarial office	Phone	Fax	Mail
	LS Academy	+39 (0)35.515684	+39 035.4501262	training@LSacademy.com

Please fill in and send: **(+39) 035.4501262** | **training@LSacademy.com** or register online.

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Invoicing details

Company name _____

Address _____

Mail address (If different) _____ **Post code** _____

City _____

VAT number _____

Terms & conditions

Terms of payment The registration fee must be paid at the time of registration. Confirmation of course admission will be given on receipt of payment. EasyB reserves the right to refuse late registrations or additional registrations above the maximum accepted number of participants.

Cancellation Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received at least one week before the course date. Cancellations will only be valid if made in writing. Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities. LS Academy reserves the right not to accept registrations not compatible with the event's target audience.

The course will proceed with a minimum of 8 participants. Should this number not be reached the registered participants will be notified one week prior to the commencement of the course.

In accordance with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, we inform you that EasyB S.r.l. (with headquarter in Via Roma 20, Alzano Lombardo, Bergamo, Italy, VAT number IT03633040161) will use your personal data voluntarily provided by you only with the consent and in compliance with the principles dictated by the European Regulations on the protection of personal data for sending newsletters, for marketing purposes (sending advertising material, market research and commercial communication) and for communication purposes to third parties (lecturers), also for marketing goals. You can read the complete information, including your rights and the procedures for the exercise of the same, [following this link](#).

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