PEC PHARMA EDUCATION CENTER

April 4, 2023 - ONLINE

DATA INTEGRITY IN THE DIGITAL TRANSFORMATION STAGE

Iscriviti su www.pharmaeducationcenter.it

Pagina: Pharma Education Center

Abstract

Starting from the presentation of the most significant failures in the data integrity area, it will be shown the expectations of the regulatory agencies on a compliant data life cycle. The new release of GAMP5 will be analysed, focusing the attention on the new sections, and changing. Moreover, the Self-assessment techniques will be presented to properly identify the compliance level of GxP processes and data handled by systems, providing examples of gaps and related mitigation and corrective actions.
Finally, best practices of validation will be explained by presenting best cases of systems implementation exploring the opportunities that digital technologies can offer to ensure a fully compliance of data management.

Main topics

Getting the opportunities of digital transformation solutions for improving the manufacturing operations in Life Science area and ensuring a full Data Integrity compliance. Realizing opportunities from a digital transformation requires an overall strategy which requires a strong awareness on Data Integrity requirements.

Learning Objectives

The object of the course is to make a clear understanding on the current best practices in the interpretation of rules regarding the handling of GxP data (FDA, EU cGMP, MHRA, PIC/S). The course will go through the new revised version of GAMP5 on Validation of computerized systems. It will be shown processes and procedures for understanding the data life cycle in different business environments.
Finally, it will be shown the link between data integrity controls of a GxP process and the validation of computerized systems in the same business process. The course will provide key elements to enable the implementation of the data integrity requirements within your organization, supporting the internal digitalization programs.

Speaker

Mirko Mori

Degree in chemistry at the University of Florence, PhD in chemistry at the C.E.R.M. institute, Florence. He spent three years in the academic world as researcher, applying the NMR techniques to biomolecules study. Since 2010, He has been working as Senior Validation Consultant and Validation Project Manager in consultant companies with expertise on Computer System Validation and compliance to 21 CFR Part 11 and EU cGMP Annex 11.
In over 15 years of experience, He has managed the validation process for the Computerised Systems used in the Life Science environment (e.g., ERP, MES, LIMS, LAS, PCS) and He has supported the implementation of Quality Systems for the IT governance. He got expertise on the management of GxP Data, focusing on the Data Governance Life Cycle in regulated environments. In this frame, He has managed hundreds validation projects worldwide for the biggest pharmaceutical companies. Currently, He operates at C&P Engineering s.r.l. as the head of CSV business unit.

Who Should Attend

QP/QA – Manager and Specialist, QC – Manager and Specialist, Validation Manager and Specialist, Production Manager, IT Manager, Digital Innovation Manager.

PROGRAM

Times are UTC +1 (Rome time)
9:30 am - 12:30 am MORNING SESSION
2:00 pm - 5:00 pm AFTERNOON SESSION

- **Recent Warning Letters: overview of inspector finding on data management**
- **Regulatory Expectations: analysis of PIC/S, FDA, MHRA guidelines**
- **Inspection Trends: latest trends on Data Integrity**
- **Compliance Assessment: Systems, Procedures and Awareness**
- **SW Validation: focus on GAMP5 revised version**
- **Data Integrity Solutions and Digital transformation**

PEC PHARMA EDUCATION CENTER

ENTRY FEE
800 €

Book 2 months before: 10 % discount!
Book 1 month before: 5% discount!

Discounts are not cumulative
VAT not included

For discounts on multiple enrollments, please contact info@pharmaeducationcenter.it

TERMS OF PAYMENT
Advance payment is required with respect to the event date by bank transfer to BANCO BPM Spa – Firenze, IBAN IT81P0503402801000000007431, Bic/SWIFT BAPPIT21N25 made payable to Pharma Education Center S.r.l., Via dei Pratoni 16, 50018 Scandicci (FI), VAT number 02173670486, specifying event title along with name and surname of the participant enrolling. Attendance to the event will be allowed upon payment received. Invoice of payment will be issued after the second half of the month after the course.

For further information and/or further assistance please contact (+39) 0550465181 or email: amministrazione@pharmaeducationcenter.it

COURSE/EVENT CANCELLATION
If the minimum number of participants is not reached, Pharma Education Center reserves the right to cancel or schedule the event for another date. Formal communication will be given within 5 days before the event date. In this case Pharma Education Center will refound the registration fee in full and without additional charges. Alternatively, the participant can request a spendable coupon for participating in another PEC event scheduled in the current year.

CANCELLATION TERMS
In order to cancel enrolment to a event, please email info@pharmaeducationcenter.it within 2 weeks before the starting date of the event. Once this term will be expired, the entire fee will be charged.

PARTICIPANT REPLACEMENT
It is possible to replace a without additional cost, simply by contacting info@pharmaeducationcenter.it. It is asked to notify the participant replacement within 5 days before the starting of the course/event, specifying the full name and surname of the enrolled participant as well as the full name and surname of the substitute.

HOW TO REGISTER
Please, fill the form on the web site https://www.pharmaeducationcenter.it/

To stay updated on our courses Follow us on