DIA LEARNING

Pharmacovigilance IT Systems: Practical Approaches to Validation and Compliance

Virtual Live Training Course
17-18 June 2026 | 14:00-18:00 CEST

Overview

Employing robust, fit-for-purpose pharmacovigilance computerised systems and procedures not only safeguards data integrity but also enables companies to leverage their data effectively. A deeper understanding of validation requirements and regulatory expectations can substantially shorten the time needed to implement and maintain these applications.

This virtual live training course covers essential principles that guide computerised systems in pharmacovigilance and provides guidance on how to implement and use these systems in a compliant manner and maintain these systems always audit ready.

This course is designed based on industry acceptable standards from US FDA, GAMP, EMA and MHRA guidelines, but will also cover other regulations as reasonably possible.

Participants benefit from the hands-on experience of trainers who have worked for many years in implementing and maintaining various computerised systems and are ready to not only explain the legislation but also provide personal experience and most commonly followed practices that are often considered as industry standards.

Learning Objectives

At the conclusion of this virtual live training course, participants will be able to:

- Gain better understanding of various regulations from US FDA, EMA and Health Canada pertaining to computerised systems
- Identify various computerised systems which could be subject to audits and inspections
- Identify and mitigate risks associated with routinely used applications like Outlook, MS Office, SharePoint, Shared Drives, Google Drives, PDFs, etc.

Who Will Attend

This virtual live training course is designed for professionals working in:

- Pharmacovigilance (including EU QPPVs)
- Drug Safety and Risk Management
- Signal Management and Safety Science
- Pharmacovigilance Consultancies and Service Providers
- Quality and Compliance

Course Level: Intermediate, for professionals with 3-5 years (or more) of experience in PV and related functions who are directly or indirectly involved in implementing and managing computerised systems.

Faculty

Stefan Brüning
Co-Founder & Consulting Practice Lead
Viginext Advisors, Germany

Ravishankar Gunturu
Director, Global Pharmacovigilance
Canada

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

Schedule-At-A-Glance

DAY 1

14:00 WELCOME AND INTRODUCTION

14:30 SESSION 1

COMPUTERISED SYSTEMS - OVERVIEW, REGULATIONS AND LIST OF SYSTEMS

- Overview
  - Definitions (what constitutes computerized systems)
  - Principles (Based on regulatory expectations i.r.t. patient safety and data integrity)
  - GxP vs non-GxP documents in PV
  - Trivia Quiz
- Classification and categorisation of computerised systems based on commonly acceptable guidance documents and regulatory documents (GAMP 5, Annex 11 of EudraLex, 21 CFR part 11 of FDA, etc.)
- Compare and contrast some major regulations (EMA, US FDA, MHRA, Health Canada, etc.)
  - High-level overview
  - Similarities and differences i.r.t. validation expectations
  - Trivia Quiz

16:00 BREAK

16:30 SESSION 1 CONTINUED

COMPUTERISED SYSTEMS - OVERVIEW, REGULATIONS AND LIST OF SYSTEMS

- List of common computerised systems and their applicability
  - How to use
  - When to use and when not to use - i.r.t. regulatory expectations and maintaining data integrity
  - Pitfalls to avoid
  - Email clients - Outlook, Google mail, etc.
  - MS Office tools-- Word, PowerPoint, Excel, SharePoint, Note, Visio, Project, etc.
  - Storage tools - Laptop local drives, Network drives, Electronic Documents
  - Management Systems
  - Safety Applications-- Argus, ArisG, Veeva Vault, etc.
  - Regulatory databases - to maintain regulatory approval information
  - Quality Management Systems – Track-wise or similar
  - Inbuilt dashboards or other Business Intelligence (BI) applications
  - Adobe PDF
  - E-signature applications - Adobe sign, Docusign, etc.
  - Training portals and tracking systems
  - SOP Management applications - LiveLink, Opentext, etc.
  - Trivia Quiz

18:00 END OF DAY 1

DAY 2

14:00 SESSION 2

VALIDATION, TRAINING AND AUTOMATION

- Validation
  - Basic validation principles
  - Risk-Based validation approach- CSV vs CSA
  - IQ, OQ and PQ
  - Levels of validation
  - Configuration vs Customisation
- Audit trail and e-signatures
- Procedures and Training
  - Version control i.r.t system updates
  - Training documentation

16:00 BREAK

16:30 SESSION 2 CONTINUED

VALIDATION, TRAINING AND AUTOMATION

- Automation
- Procedures or tasks that are worth automating
  - ICSR reporting rules
  - PSUR scheduling rules
  - Signal detection and validation
  - Intake
- Some available commercial AI tools, their applications and limitations

18:00 END OF THE TRAINING COURSE

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

Group Discounts

Register 3 individuals from the same company for the same course and receive complimentary registration for a 4th!*

To take advantage of this offer, please print the registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together via email to basel@diaglobal.org.

**Terms and Conditions apply. Please contact DIA EMEA office for more information.*

Customized Professional Development for Your Team

Get a customized training for your department (or even across different departments!) and benefit from increased:

- Knowledge of a topic of your choice
- Flexibility & Convenience
- Cost Effectiveness

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For more information please contact basel@diaglobal.org

About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

Technical Requirements

To test your system compatibility, please click on the link: https://diaglobal.zoom.us/test

For further information on system requirements, please visit the website:
https://www.diaglobal.org/General/System-Requirements

Continuing Education

All DIA training courses have been awarded a PharmaTrain Centre Recognition.

PharmaTrain Federation is a not for profit organisation that started its activities as an IMI (Innovative Medicines Initiative) European Project. Its mission is to drive implementation of globally recognized high-level standards for postgraduate education and training in Medicines Development. To that aim, the Federation is assessing Continuous Professional Development (CPD) Courses and Course Providers around the world that deserve recognition.

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REGISTRATION FORM

Pharmacovigilance IT Systems | Virtual Live Training Course | # 26558
17-18 June 2026 | 14:00-18:00 CEST

DIA LEARNING

REGISTRATION FEES

Registration fee includes full admission to virtual course, electronic access to training course materials. **Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material.** Please check:

FEES	MEMBER EARLY-BIRD valid until 20 May 2026	MEMBER valid from 21 May 2026	NON-MEMBER
INDUSTRY/ REPRESENTATIVE	€ 720.00 ❑	€ 800.00 ❑	€ 1'060.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	NA	€ 400.00 ❑	€ 660.00 ❑
A special discount is available for organisations which are listed in the EMA SME register. Number of discounted seats is limited.			

All registration fees are subject to VAT if applicable.

Please enter your company's VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

DIA MEMBERSHIP

All nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at DIAglobal.org/Membership.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at DIAglobal.org. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership.**

The DIA Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 09:00 and 17:00 CE(S)T. **Tel.** :+41 61 225 51 51

Email: **Basel@DIAglobal.org** **Mail:** DIA, Küchengasse 16, 4051 Basel, Switzerland
Web: **www.DIAglobal.org**

TERMS AND CONDITIONS

Cancellation Policy
All cancellations must be made in writing and be received at the DIA office four weeks prior to the event start date. Cancellations are subject to an administrative fee:
- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy
You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

Event Stream and Recording
If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click https://www.diaglobal.org/general/photography-policy.

Privacy Policy
DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/about-us/privacy-policy.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Attendee email required for course material access

PAYMENT METHOD

DIA accepts only Credit Card as a payment method.

Payments by VISA, Mastercard or AMEX are accepted. Other types of credit card are not accepted.

You will receive a payment link in the coming days to complete the payment.

Please complete payment within 7 days of receipt of the payment link.

If you have not received your confirmation within five working days, please contact basel@diaglobal.org.

By signing below, I confirm that I read and agree with DIA's Terms and Conditions of booking.

These are available from the office or online by clicking:

http://www.diaglobal.org/EUterms

Date	Signature