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Speaker

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As a member of the Quality Assurance Department at Baxter Vienna, Roland Miksche was responsible for developing a Quality System for Computerized Systems Validation CSV and Data Integrity DI. For many globally deployed IT-Projects (LIMS, ERP, Serialization, EDMS, Change Management, etc.) he acted as Quality Representative for the area Central Europe (Baxter > Baxalta > Shire) before he accounted as global Validation Lead for the Electronic Batch Management EBM Solution at Shire. Currently he is working as consultant for different pharmaceutical companies (Berlin Chemie, BioNtech, CSL Behring, Jungbunzlauer, Roche, Takeda, Nordmark, Juno Therapeutics, ...).

Excel in the GxP-regulated Environment

Live Online Training on Tuesday, 29 April 2025, 13.30 – 18.00 h CEST

Highlights

- Regulatory, technical and data integrity requirements
- Lifecycle approach according to GAMP 5
- Classification (criticality and complexity)
- Developer qualification
- Procedure for use and operation
- Protection and access management
- Maintenance and changes
- Backup, disaster recovery, business continuity

With Q&A sessions, practical examples and exercises

Objectives

This Live Online Training aims to give participants a comprehensive overview of regulatory, technical and data integrity requirements for using Excel spreadsheets in a regulated GxP-environment. The translation of regulatory requirements into a lean and compliant approach will be demonstrated. Practical examples, exercises (including polling questions) and Q&A sessions ensure interaction and that all questions are answered.

Background

Excel is widely used in laboratories, in production as well as in quality departments in both larger and smaller companies for GxP-relevant applications. The easy to use of spreadsheets allow making calculations, selections and colourful presentations in a very convenient way.
Quite often, numerous risks with regard to data integrity result from the diverse, flexible and sometimes very complex application possibilities. If Excel is used in a GxP-regulated environment for quality-relevant tasks, regulatory and data integrity requirements must be met. Files and calculations should be secured in such a way that formulas are not accidentally overwritten, templates are not changed or deleted and traceability of input, processing and output is trustworthy. Furthermore, accidental input of an inappropriate data type should be prevented.
However, controls are quite often inadequate and this may result in a compliance risk. Such Excel applications may easily come into focus in authority inspections.

Target Audience

This Live Online Training course is aimed at all those responsible for Excel applications in the various departments (e.g. quality control, quality management, production, IT).
It will be of interest in particular for personnel from the following industries:

- Pharmaceutical companies
- API manufacturer
- GLP Laboratories
- other companies working according to GxP

Also addressed are employees of medical device manufacturers as well as of universities and research institutions who, for regulatory reasons, have to use Excel in a GxP compliant way.

Moderator

Dr Markus Funk

Programme

Regulatory and Data Integrity Requirements

- Overview of regulatory and data integrity requirements
- ALCOA+
- Industry standard (GAMP 5)
- Findings for spreadsheets

Application of Requirements (including Exercises)

- Lifecycle approach according to GAMP 5
- Intended use (user requirements)
- Inventory
- Classification (criticality and complexity)
- Areas of usage (e.g. quality control, manufacturing)
- Developer qualification
- Design (operations, data flows, functional and design specification)
- Installation and qualification (build, test plan and report)
- Formal release
- Procedure for use and operation (SOP)
- Procedure for system administration
- Decommissioning
- Practical examples

Technical Solutions

- Central services (terminal server, data server)
- Protection, access management
- Data validation, user guidance
- Name manager
- Coding standards
- Maintenance, changes (template cycle)
- Backup, disaster recovery, business continuity
- IT support

Questions and Answers Sessions

Date of the Live Online Training

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Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members EUR 590
APIC Members EUR 640
Non-ECA Members EUR 690
EU GMP Inspectorates EUR 590
The conference fee is payable in advance after receipt of invoice.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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Registration

By e-mail or you register online at
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