



Speakers



Roland Miksche
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Excel in the GxP-regulated Environment



Live Online Training on Thursday, 06 May 2021,
09:00 – 13:00 h CEST



Highlights

- Regulatory requirements
- Technical requirements
- Areas of usage
- Developer qualification
- IT support
- Protection and access
- Maintenance and changes
- Lifecycle



With two Q&A sessions, practical examples and exercises

Objectives

This Live Online Training aims to give participants a comprehensive yet compact overview of regulatory and technical requirements of using Excel in a GxP-regulated environment. Practical examples and exercises (including polling questions) and two Q&A sessions ensure interaction and that all questions are answered.

Background

Excel is widely used in laboratories as well as in production in both larger and smaller companies for GxP-relevant applications. The easy to use calculations allow making calculations in a very convenient way.

Quite often, numerous risks with regard to data security result from the diverse and flexible application possibilities. If Excel is used in a GxP-regulated environment for quality-relevant tasks, special requirements must be met. The files and the calculations should be secured in such a way that formulations are not accidentally overwritten. 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 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 Requirements and Areas of Usage

- Regulatory Requirements
- Findings
- Areas of usage in the GxP environment (e.g. Quality Control, Manufacturing)

Technical Requirements and Security

- Technical solutions
- Security
 - Developer Qualification
 - Protection, Access
 - Maintenance, Changes
 - Lifecycle: Intended use – Decommissioning
- IT support



Questions and Answers Sessions

- Participants are invited to ask questions.

Exercises

- Practical examples
- Poll questionnaires

Agenda

09:00 – 09:15 h Welcome and Introduction

09:15 – 10:15 h **Presentation 1**

10:15 – 10:30 h **Q&A Session 1**

10:30 – 10:45 h Break

10:45 – 11:45 h **Presentation 2**

11:45 – 12:00 h **Q&A Session 2**

12:00 – 12:15 h Break

12:15 – 12:45 h **Exercises**

12:45 – 13:00 h **Final Discussion**

Speaker



Roland Miksche
MiRo Consulting, Vienna, Austria

As a member of the Quality Assurance Department at Baxter Vienna, Roland Miksche was responsible for developing a Quality System for Computerized Systems Validation and Data Integrity. For many globally deployed IT-Projects (LIMS, ERP, ePedigree, EDMS, 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 Solution at Shire. Currently he is working as consultant for different pharmaceutical companies (Berlin Chemie, BioNtech, CSL Behring, Jungbunzlauer, Roche, Takeda, ...).

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Company

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Date of the Live Online Training

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All times mentioned are CEST.

Technical Requirements

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Fees (per delegate, plus VAT)

ECA Members € 490

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Registration

Via the attached reservation form, by e-mail or by fax message. Or you register online at www.gmp-compliance.org.

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.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can order the recording of the Live Online Training at the earliest 10 days after the live performance at <https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars>.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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