ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Computer Validation Manager

Speakers

Frank Behnisch
formerly CSL Behring

Dr Bob McDowall
R.D.McDowall Limited

Yves Samson
Kereon, Switzerland

Dr Wolfgang Schumacher
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Dr Arno Terhechte
GMP inspectorate / Bezirksregierung Münster

Michael Wegmann
F. Hoffmann-La Roche

Annex 11: the new Draft and its Consequences

Live Online Training on 4/5 September 2025

Highlights

- Presentation of the objectives and contents of the new Annex 11 draft 'Computerised systems'
- Presentation of the cross-reference to the new draft of the EU GMP Guideline Chapter 4 'Documentation'
- How does the new draft differ from the current Annex 11?
- Evaluation of the draft with regard to pharmaceutical practice
- What possibilities are there to influence the final version?

Published by the EU Commission on 7 July 2025: the drafts of the

- New Annex 11 'Computerised Systems'
- New Annex 22 'Artificial Intelligence'
- New Chapter 4 'Documentation'

Background

In an initial concept paper on the planned revision of the EU GMP guideline Annex 11 'Computerised Systems' in November 2022, the planned changes and content of the new document became clear. Originally planned for the end of 2024 and expected for months, the draft revision of the EU GMP Guidance Annex 11 'Computerised Systems', the draft of the completely new Annex 22 'Artificial Intelligence' and the draft revision of Chapter 4 'Documentation' were presented at the same time on 7 July 2025. All 3 documents can be commented on until 7 October 2025, preferably by 'Stakeholder Organisations' but also by anyone else.

The event will mainly focus on the draft of Annex 11 and its links to Chapter 4 'Documentation'. Although only a draft, the contents of the final document are clearly recognisable in the document. Therefore, in addition to a critical presentation of the document, missing topics as well as possible consequences for pharmaceutical practice will be discussed.

Target Audience

The event is aimed at employees from the pharmaceutical and medical devices industry and their suppliers. It is aimed at employees who deal with current regulatory developments on IT in the European environment.

Programme

The Live Online Training will deal in detail with all contents of the draft Annex 11. All chapters will be dealt with according to a standardised scheme.

- What are the contents of each chapter?
- Which points are good, which points need to be changed / improved?
- Which points are missing in the chapter?
- Comparison of the requirements in the currently valid Annex 11 with the draft of the new version
- What problems could arise from the new requirements for operational practice?

Chapters in the new draft of Annex 11

1./2. Introduction (Scope / Principles)

Cross-relation to Chapter 4 ‚Documentation '

3. Pharmaceutical Quality System

4. Risk Management

5. Personnel and Training

6. System Requirements

7. Supplier and Service Management

8. Alarms

9. Qualification and Validation

10. Handling of Data

11. Identity and Access Management

12. Audit Trails

13. Electronic Signatures

14. Periodic Review

15. Security

16. Backup

17. Archiving

Speakers

Frank Behnisch
formerly CSL-Behring, Marburg, Germany
Frank Behnisch was CSV Lead Execution Systems EMEA/Marburg at CSL Behring. He was a founding member of GAMP D-A-CH and a member of the GAMP Europe and D-A-CH Steering Committees.

Dr Bob McDowall
R.D.McDowall, Bromley, Kent, UK
Analytical chemist with over 50 years experience including 15 years working in the pharmaceutical industry.

Yves Samson
Kereon, Basel, Switzerland
Yves Samson is the founder of Kereon AG, member of the GAMP Europe Steering Committees and Chairman and co-founder of Francophone.

Dr Wolfgang Schumacher
formerly F. Hoffmann-La Roche, Basel
In 2001 he joined F. Hoffmann-La Roche, Basle, where he was Head of the Quality Computer Systems department. Wolfgang is member of the ECA Advisory Board.

Dr Arno Terhechte
GMP Inspectorate / Bezirksregierung Münster, Germany
Since 2003 he is inspector in the 'Bezirksregierung Münster'. Arno Terhechte is chairman of the German expert group 11 "computerised systems".

Michael Wegmann
F. Hoffmann-La Roche, Basel, Switzerland
Michael has headed the 'IT Security & Privacy Governance' department at Roche since the beginning of 2014.

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Reservation Form (Please complete in full)

Annex 11: the new Draft and its Consequences
Live Online Training on 4/5 September 2025

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
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- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %,
- Cancellation within 2 weeks prior to the conference 100 %.

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German law shall apply. Court of jurisdiction is Heidelberg.
Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training
Tuesday, 04 September 2025, 09.00 - 18.00 h
Friday, 05. September 2025, 09.00 - 17.00 h

All times mentioned are CEST.

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 € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045
The conference fee is payable in advance after receipt of invoice.

Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 22528.

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

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