



Presented by
Management Forum

Understanding and Interpreting the Proposed Changes to EU GMP Annex 11

17 September 2024
+ 21 January 2025

This half-day course will provide an essential update on the proposed changes to EU GMP Annex 11 and will enhance delegate's understanding of the implications on working practices, as well as including a control framework for AI and ML.



Format:
Live online



CPD:
3 hours for your records



Certificate of
completion

Overview

Annex 11 for Computerised Systems is the regulation for both the European Union and countries working under PIC/S GMP (Pharmaceutical Inspection Cooperation Scheme), it was originally issued in 1992 and upgraded in 2011. A concept paper on the revision of Annex 11 contains a proposal published by EU and PIC/S to revise Annex 11 containing 33 areas for update and extension to include a control framework for Artificial Intelligence and Machine Learning (AI/ML).

This course will prepare you for the implications of the changes on working practices and will provide an opportunity to discuss the complexities with an expert in this field.

The programme will include facilitated discussions and polls using www.menti.com to explore some of the more interesting changes proposed for Annex 11.

Benefits of Attending

- **Understand** the potential impact of changes in Annex 11 on the operation and support of computerised systems
- **Know** the additional requirements for agreements with suppliers
- **Be aware** of the impact of the update on SaaS providers of regulated solutions
- **Secure** early engagement with suppliers to ensure technical controls can meet the changes in regulations

Who Should Attend

- Process Owners (in regulated areas) and System Owners (in IT departments) responsible for the operation of GMP computerised systems
- Computer System Validation (CSV) personnel and consultants involved with validation of regulated computerised systems
- Quality Assurance personnel involved with oversight of computerised systems
- Suppliers who sell into regulated laboratories to check if any changes are required to the technical controls in their software
- Software as a Service (SaaS) suppliers to understand the potential changes to their role that the proposed updates will bring

Programme

Introduction to the course and the trainer

Overview of the proposed Annex 11 changes

Audit trail changes: do your systems meet these requirements? If not, what are you going to do about it?

Changes impacting software and SaaS suppliers from agreements to validation support

Understanding the impact of changes on validation of computerised systems

Changes for IT support of computerised systems

Summary of the course

Presenter



Bob McDowall

Bob McDowall is an analytical chemist with over 50 years' experience including 15 years working in the pharmaceutical industry and over 30 years' working for the industry as a consultant. Bob has been involved with the validation of computerised systems for over 35 years and is the author of two editions of a book on the validation of chromatography data systems and one on data integrity and data governance for regulated laboratories. He was presented with the 1997 LIMS Award for advances in the subject including editing the first book on the subject. He writes the Questions of Quality column for LCGC International and Focus on Quality column for Spectroscopy. Bob was a subject matter expert input and review contributor to the GAMP Records and Data Integrity Guide and two of the data integrity Good Practice Guides.

Course dates

17 September 2024

Live online

14:00-17:00 **UK (London)** (UTC+01)

Course code 14377

GBP ~~299 349~~

EUR ~~429 499~~

USD ~~501 579~~

Until 13 Aug

21 January 2025

Live online

14:00-17:00 **UK (London)** (UTC+00)

Course code 14378

GBP ~~299 349~~

EUR ~~429 499~~

USD ~~501 579~~

Until 17 Dec

How to book



Online:

ipi.academy/2737

Alternatively contact us to book, or if you have any queries:



Email:

info@ipi.academy



Phone:

[+44 \(0\)20 7749 4749](tel:+442077494749)

Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an **early booking discount** prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

Further information

Fee

The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

Please note

IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

Terms and conditions

The rest of our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

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For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



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IPI
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