



*Presented by*  
**Management Forum**

# Understanding and Interpreting the Proposed Changes to EU GMP Annex 11

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:**  
Bespoke training



**CPD:**  
3 hours for your records  
(depending on your requirements)



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](https://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

## Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

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**  
Academy

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