IPI Academy

MANAGEMENT forum



Presented by
Management Forum

Integrating AI into the GMP Environment

7 May 27
+ 5 November 27

A practical masterclass on integrating AI and Machine Learning into GMP environments, covering regulatory expectations, AI governance, validation, auditing, and compliant implementation within pharmaceutical quality systems.

Format:
Live online

CPD:
6 hours for your records

Certificate of completion

Course overview

The integration of Artificial Intelligence (AI) and Machine Learning (ML) into the Good Manufacturing Practice (GMP) environment represents a profound shift in pharmaceutical quality management. No longer confined to theoretical or discovery applications, AI technologies are actively restructuring manufacturing, automated quality control, and predictive quality assurance. However, moving from traditional rule-based computerized systems to dynamic, data-driven AI systems introduces complex challenges to established GxP pillars: reproducibility, traceability, and absolute control.

This intensive, masterclass-level training program is specifically engineered for senior quality assurance professionals, lead auditors, and regulatory compliance managers. It bridges the gap between advanced data science and practical GMP compliance, heavily grounded in the latest regulatory expectations, including the 2026 FDA-EMA Joint Guiding Principles of Good AI Practice in Drug Development, the evolving EU GMP Annex 11 revision concepts, and the EU AI Act.

Rather than treating AI as a 'black box,' this course provides a systematic framework to validate, audit, and govern AI technologies safely within a Risk-Based Quality Management System (QMS), shifting an organisation's capability from retroactive error finding to proactive error prevention.

By the end of this course, participants will be able to:

- Decode Regulatory Expectations: Interpret and apply the latest 2026 FDA/EMA joint principles and GxP expectations regarding AI system lifecycles
- Establish Robust Governance: Implement internal AI governance frameworks that define clear 'Human-in-the-Loop' (HITL) and 'Human-on-the-Loop' (HOTL) boundary controls
- Validate Non-Linear Systems: Adapt traditional Computerized System Validation (CSV) workflows into modern Software Validation / Learning Assurance frameworks suited for AI algorithms
- Audit with Confidence: Conduct targeted internal and vendor audits on data lineage, Retrieval-Augmented Generation (RAG) security, and algorithm drift
- Optimise Quality Workflows: Securely leverage Generative AI (GPT platforms) to accelerate deviation handling, Root Cause Analysis (RCA), and Supplier Notifications of Change (SNC)

Benefits of attending

- **Understand** the latest FDA/EMA AI principles, EU AI Act requirements, and evolving GMP expectations
- **Gain** practical strategies for integrating AI into regulated GMP environments with confidence
- **Learn** how to establish effective AI governance with HITL and HOTL oversight controls
- **Adapt** traditional CSV approaches to modern AI/ML validation and lifecycle management
- **Enhance** auditing capabilities for AI systems, vendors, data integrity, and model governance
- **Discover** secure applications of Generative AI for deviation handling, CAPA, and quality workflows
- **Reduce** compliance and quality risks through predictive, AI-driven risk management approaches
- **Strengthen** collaboration between QA, Validation, IT, and Regulatory Affairs teams
- **Discuss** real-world case studies, implementation challenges, and regulatory expectations
- **Network** with industry peers and senior professionals navigating AI adoption in GxP environments

Who should attend

This course is specifically designed for high-level technical professionals, decision-makers, and lead personnel who are responsible for designing, auditing, validating, or approving computerised systems within GxP-regulated environments. It is highly recommended for:

- Quality Assurance Directors, Managers & QMS Specialists: Professionals seeking to transition their QMS from reactive tracking to AI-driven predictive CAPA, automated deviation triaging, and proactive error prevention
- GMP & GDP Lead Auditors / Consultants: Independent or internal auditors who need to establish rigorous audit checklists for vetting AI software vendors, evaluating data science pipelines, and assessing data lineage integrity
- Computerised System Validation (CSV) & Computer Systems Quality (CSQ) Engineers: Specialists tasked with evolving traditional CSV methodologies into modern Software Validation and Learning Assurance frameworks capable of handling non-linear, adaptive algorithms
- Qualified Persons (QPs) and Quality Directors: Senior executives who ultimately carry the regulatory and legal responsibility for product release and must understand the boundaries of 'Meaningful Human Oversight' (HITL/HOTL)
- IT Lead Architects and Data Integrity Officers: Professionals responsible for the deployment of secure local LLMs, Retrieval-Augmented Generation (RAG) guardrails, and data infrastructure within manufacturing networks
- Regulatory Affairs Professionals: Experts responsible for documenting and defending AI-driven processes, automated visual inspections, or predictive modeling systems during health authority inspections (FDA, EMA)

Programme

Context-setting and the paradigm shift

- Moving from traditional deterministic software to probabilistic AI frameworks
- The strategic shift: Transitioning from error finding to error prevention

The regulatory landscape for AI in GxP (2025-2026)

- Deep Dive: The 2026 FDA-EMA Joint Guiding Principles for AI along the medicines lifecycle
- Impact of the EU AI Act on high-risk GxP classification
- Aligning AI with current EU GMP Annex 11 and upcoming revision concepts
- Defining the mandatory 'Context of Use' (CoU) boundary statement

AI Validation, data integrity and algorithm lifecycle management

- Adapting GAMP 5 principles to Machine Learning: From CSV to Continuous Validation
- Managing the AI Lifecycle: Data provenance, preprocessing, training, and testing datasets
- Technical Focus: Mitigating "Model Drift" and ensuring model interpretability/explainability
- Data Integrity: Securing data lineages and establishing unalterable audit trails for algorithmic decisions

Practical implementation - GenAI & Machine Learning in QA/QC

- **Quality Assurance Applications:** Using secured GPT platforms and Retrieval-Augmented Generation (RAG) with local guardrails for parsing FDA 483s, guidelines, and generating audit reports
- **Operational Workflows:** Automating Supplier Notifications of Change (SNC) classification and driving predictive CAPA/Deviation triage
- **Quality Control Applications:** Computer vision pipelines for visual inspection (tablets, blisters, parenterals) and predictive environmental monitoring

Risk management and auditing AI vendors/systems

- Implementing ICH Q9 (R1) principles for AI risk classification
- Defining and documenting 'Meaningful Human Oversight' (Human-in-the-Loop vs. Human-on-the-Loop boundaries)
- **Audit Strategies:** Key checklists for auditing AI/ML software vendors and data science providers
- **Addressing AI cybersecurity threats:** Model manipulation, data breaches, and unauthorised parameter changes.

Interactive practicum & case studies

- **Group exercise:** reviewing a mock validation protocol for an AI-driven deviation triaging system
- Highlighting critical gaps in data lineage, human override logs, and drift monitoring plans

Panel discussion, Q&A, and closing remarks

- Open floor for complex scenario analysis
- Summary of key takeaways and actionable next steps for your QMS

Presenter



Mustafa Edik

Mustafa Edik is a leading pharmaceutical, biotechnoloy, medical device quality and GXP expert with over 28 years of hands-on leadership in GMP, GDP, GCP, GLP, and broader GxP compliance across the pharmaceutical, biotechnology, and medical device industries.

As Turkey's first IRCA-certificated Lead Auditor for GMP and Pharmaceutical Quality Management Systems (PQMS), he brings unmatched credibility and depth to audits, compliance strategies, and regulatory readiness. Holding a BSc in Chemistry, and a BSc (Hons) in Biopharmaceutical Sciences & Engineering from Atlantic Technological University (Ireland), and an Executive MBA, Mustafa combines strong scientific foundations with strategic business acumen.

His career highlights include senior roles at Bayer Türkiye, where he progressed from Quality Control Lab Supervisor to Deputy QA Manager, and GMP Lead Auditor to Global GMP Lead Auditor, managing complex quality operations and audits in a multinational environment. He has personally led more than 4,200 hours of GxP audits across over 200 facilities worldwide.

Today, as Founder and Lead Consultant at Quality Academia Eğitim & Danışmanlık, Mustafa delivers high-impact consulting, training, and project management services to local and global clients. His expertise spans across:

- GMP/GDP audits and supplier qualification
- Validation, qualification, and quality risk management (ICH Q9)
- Root cause analysis, CAPA, OOS/OOT, change control, and data integrity
- Sterile/non-sterile manufacturing, process improvement, and cost-of-quality optimisation
- Clinical trials (GCP & ICH E6), pharmacovigilance, and third-party manufacturing
- Regulatory alignment with FDA, EMA, PIC/S, MHRA, TGA, TMMDA, WHO, and ICH standards

Mustafa has trained over 9,000 professionals in GxP topics and designed certified auditor programs for Turkish authorities including Turkish MOH and Ministry of Agriculture and Foresty. He served as Principal GMP Consultant & Auditor at the Turkish Atomic Energy Authority, supporting successful TMMDA GMP approvals for 5 radiopharmaceutical products. As the first Turkish consultant selected by the Developing Countries Vaccine Manufacturers Network (DCVMN), he has led teams of 100+ engineers, auditors, and quality specialists while managing dozens of international projects.

A prolific author, Mustafa's works include:

- “Sorularla GMP Dokümantasyonu” – a practical guide to GMP documentation
- “GMP Audits in Pharmaceutical and Biotechnology Industries” (Taylor & Francis / CRC Press, June 2024) – a comprehensive reference on effective GMP auditing practices

Recognised internationally for his practical, risk-based approach and knowledge transfer focus, Mustafa Edik is dedicated to elevating pharmaceutical quality standards, helping companies achieve compliance excellence, reduce risks, and drive operational efficiency.

Course dates

7 May 27	**Live online** 08:30-17:00 **UK (London)** (UTC+01) *Course code 17602*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 12 Mar**
5 November 27	**Live online** 08:30-17:00 **UK (London)** (UTC+00) *Course code 17665*	GBP **649** ~~749~~ EUR **909** ~~1,049~~ USD **1,043** ~~1,199~~ **Until 10 Sep**

How to book

Online:
ipi.academy/3347

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

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Discounts

- Booking more than one delegate on any one date qualifies for a **30% 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.

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IPI Academy

IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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