IPI Academy

MANAGEMENT forum



Presented by
Management Forum

GMP Advanced Masterclass for Pharmaceutical and Biotechnology Industries

7-9 June 27
+ 8-10 December 27

An advanced GMP masterclass designed for pharmaceutical and biotechnology professionals, focusing on modern quality systems, regulatory expectations, risk management, data integrity, and inspection readiness in highly regulated environments.

Format:
Live online

CPD:
18 hours for your records

Certificate of completion

Course overview

In the rapidly evolving pharmaceutical and biotechnology sectors, maintaining a robust, compliant, and forward-looking Good Manufacturing Practice (GMP) framework is not just a regulatory necessity, it is a core business driver.

This GMP Advanced Master Class is designed for experienced industry professionals who want to move beyond basic compliance and master the complexities of modern quality systems. The programme bridges the gap between traditional GMP principles and cutting-edge advancements, including ATMPs (Advanced Therapy Medicinal Products), automated systems, data integrity, and proactive risk management.

Participants will explore the 'why' behind global regulatory expectations (FDA, EMA, WHO, and PIC/S), learning how to design and execute robust quality strategies that withstand rigorous inspections, optimise operational efficiency, and, above all, guarantee patient safety.

Benefits of attending

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

- **Navigate** and implement advanced regulatory requirements for both small molecule pharmaceuticals and complex biopharmaceuticals/ATMPs
- **Design** a resilient Data Integrity Governance Framework that mitigates ALCOA+ risks across automated and manual systems
- **Apply** advanced Quality Risk Management (QRM) methodologies to complex manufacturing deviations and tech transfers
- **Build** an inspection-ready culture by mastering modern regulatory audit techniques and strategic CAPA implementation
- **Optimise** contamination control strategies (CCS) in alignment with evolving global standards (such as EU GMP Annex 1)

Who should attend

This master class is designed specifically for professionals with a minimum of 3-5 years of experience in the pharmaceutical, biomanufacturing, or medical device industries, including:

- Quality Assurance (QA) Directors, Managers, and Specialists
- Quality Control (QC) Managers and Lead Analysts
- Regulatory Affairs Professionals
- Production/Manufacturing Managers and Engineers
- Validation Engineers and Specialists
- Qualified Persons (QPs) and Responsible Persons (RPs)
- GXP Auditors and Regulatory Inspectors

Programme

Day 1

The evolving global GMP landscape

- Harmonization updates: ICH Q8, Q9, Q10, Q11, and Q12
- Divergence and convergence: FDA, EMA, PIC/S, and WHO expectations
- Transitioning from compliance-driven to performance-driven quality systems

Next-generation quality risk management (QRM)

- Deep dive into ICH Q9(R1) revisions
- Advanced risk tools: Beyond basic FMEA to FTA (Fault Tree Analysis) and HACCP in pharma
- Formal vs. informal risk approaches: Knowing when to scale

Advanced deviation management & root cause analysis (RCA)

- Investigating complex, multi-variable deviations
- Human error reduction: Moving past 'retraining' to systemic human factors engineering
- Determining true root cause using Is/Is-Not and Fishbone integration

Workshop: risk-based deviation case studies

- Interactive group exercise: delegates analyse a real-world systemic cross-contamination deviation, perform an RCA, and present a risk-justified CAPA plan

Day 2

Modern data integrity governance

- Enforcing ALCOA+ principles in a digitalised facility
- Hybrid systems and the risks of paper-to-electronic transitions
- Defining and auditing 'Audit Trails' for analytical and manufacturing equipment

Computer systems validation (CSV) to software quality assurance (CSA)

- The paradigm shift from CSV to FDA's Computer Software Assurance (CSA)
- Risk-based testing of automated manufacturing systems (GAMP 5 2nd Edition)
- Cloud computing and SaaS validation in a regulated environment

Sterile manufacturing and annex 1 dynamics

- Implementing a holistic Contamination Control Strategy (CCS)
- Barrier technologies: RABS (Restricted Access Barrier Systems) vs. Isolators
- Environmental Monitoring (EM) trending and rapid microbiological methods

Biotechnology and ATMP Specific GMP Challenges

- GMP for Cell, Gene, and Tissue therapies: Scale-out vs. scale-up challenges
- Managing open vs. closed processing systems
- Cold chain logistics, chain of identity (COI), and chain of custody (COC)

Day 3

Product lifecycle and tech transfer (ICH Q12)

- Technical transfer of analytical methods and manufacturing processes
- Implementing Post-Approval Change Management Protocols (PACMPs)
- Continuous Process Verification (CPV): Establishing a Stage 3 validation strategy

Supply chain GMP and vendor qualification

- Managing global supply chain complexities and API traceability
- Advanced auditing of Contract Development and Manufacturing Organisations (CDMOs)
- Quality agreements: common pitfalls and legal/regulatory boundaries

Inspection readiness and handling hostile audit scenarios

- Modern regulatory inspection trends (FDA Remote Interactive Evaluations vs. On-site)
- The psychology of an audit: Managing the war room and front room dynamics
- How to respond to 483s, Warning Letters, and EMA Non-Compliance Reports

Panel discussion and future pharma (pharma 4.0)

- AI and machine learning in GMP decision-making
- Continuous manufacturing quality controls

Wrap-up and evaluation test

- Course wrap-up, final Q&A and test

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

7-9 June 27	**Live online** 08:30-17:00 **UK (London)** (UTC+01) *Course code 17606*	GBP **1,599** ~~1,899~~ EUR **2,239** ~~2,659~~ USD **2,571** ~~3,039~~ **Until 12 Apr**
8-10 December 27	**Live online** 08:30-17:00 **UK (London)** (UTC+00) *Course code 17664*	GBP **1,599** ~~1,899~~ EUR **2,239** ~~2,659~~ USD **2,571** ~~3,039~~ **Until 13 Oct**

How to book

Online:
ipi.academy/3404

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

Email:
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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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