IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Thinking Outside of the GMP Box

10-11 September 2024
+ 14-15 January 2025, 13-14 May 2025

In this two-day course, you will be able to gain a whole new perspective on GMP requirements, including how to implement them.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

When you look at the bigger picture, it is possible to see that Good Manufacturing Practice (GMP), which we have difficulty in implementing from time to time, can actually be evaluated from different perspectives which can provide insight that gains even more value for your GMP processes and application This training course has been specially prepared to serve exactly this purpose.

In the rush to fully meet technological developments in the pharmaceutical industry, together with the expectations of the health authorities; updated and evolving guidelines; and the needs of the end-user patient, the emphasis on complying with the GMP regulations and guidelines is becoming increasingly important. In this GMP training course, the topics will be examined with a very different perspective, enabling you to refresh your existing knowledge and gain new expertise on the subject. After the sessions, your GMP knowledge will be enhanced with scenario studies and bonus complementary documents which will be given in addition to the training programme and will aid your application of the new learnt techniques to the work place.

Benefits of attending

- **Gain** an insight into top management's approach to risks
- **Learn** the training and documentation system, including planning GMP trainings and process mapping tips
- **Understand** the personnel selection criteria in accordance with GMP
- **Explore** GMP compliant lateral-thinking techniques, behaviour change models in GMP and the mechanisms to prevent errors in sampling and validation
- **Ensure** cost reduction tactics in validations
- **Adapt** lessons learnt from other sectors to GMP

Who should attend

Personnel who are in a wide range of GMP-related jobs will benefit from this course, including those in:

- Quality Assurance
- Quality Control
- GMP Compliance
- Validation
- Engineering
- Operation
- Manufacturing
- Supply Chain
- Logistics
- IT
- Purchasing

Programme

Day 1

Introduction to GMP regulations

- What is GMP?
- International guidelines and directives for GMP

Management responsibility

- Who are 'Top Management'? Can we reach them?
- What are the main responsibilities of 'Top Management'?
- How does 'Top Management' approach and manage risks?
- Do they ask smart questions on the shop floor?

Lessons learnt from other industries

- GMP excellence by design
- Aviation and Automotive industries best practices
- The 'learning by doing' approach in a regulated environment

Learning organisation and quality culture

- What is 'knowledge management'?
- Do we learn effectively what's taught?
- Is it different than that of quality risk management?
- Quality culture in Pharma and Biotech industries
- Which one is the best? Company culture or quality culture?

Personnel and training expectations in GMP

- How to simplify trainings without compromising GMP rules
- How to select and qualify personnel
- Aligning job descriptions with cGMP
- How to deal with passengers in a QC laboratory
- New employee orientation program structure
- Proven tactics of keeping the GMP training records
- What are the ten training errors?

Documentation pitfalls

- How to simplify documentation without compromising GMP rules
- Real dangers behind data integrity applications
- How to handle data for GMP expectations
- How to reduce or eliminate documentation errors
- How do you ensure data integrity during validation?

Group exercise: let's improve our SOPs in microbiology laboratory

Deviation management and CAPAs

- How to simply handle deviations by asking lateral questions
- Who is responsible for the deviation or OOS?
- Sophisticated PAs approaches
- Where's CA gone?
- Why is it so exhaustive to find the true root cause?

GMP behaviour models

- How to change old GMP behaviours
- Why multitasking is lurking somewhere in GMP compliance
- Four magic words for GMP Compliance
- Eliminating the non-value-added activities form GMP

Day 2

A new validation approach

- How to handle deviations in cleaning and process validation
- Is it possible to reduce the costs in validation activities?
- How to prevent sampling errors in validation
- How to simplify computerised system documentation? (computer software assurance and GAMP5 – second edition)
- Successful QC integration with GMP compliance

Knowledge-based change control

- What is 'knowledge-based change control'?
- Change control vs. change management
- How to adapt QRM to changes
- How to avoid pitfalls in CC
- How frequently to monitor the effectiveness of changes
- FDA 483s for change control

Before and after shutdown

- Things to do before and after facility shutdown
- Do we have to repeat aseptic process simulation?
- What are the main responsibilities of the engineering department during the shutdown period?
- How to switch from preventive maintenance to predictive maintenance
- How robust are our critical utilities (HVAC, water, steam, gas) according to current GMP guidelines?

Complaints and recalls

- What is risk-based recall management?
- Who manages complaints in your company?

Group exercise: audit shortcuts

Technology transfer best practices

- How to manage aseptic product technology transfer?
- What are the main pillars of GMP compliant test method transfer?
- How to prevent drug shortages without compromising GMP expectations?

Outsourcing

- How to find the most appropriate quality agreement template
- Effective tactics to manage quality when outsourcing
- What lessons to learn from Heparin and other crises

Do you know your GMP compliance score?

- Is it possible to achieve 100% GMP compliance?
- How to implement a gap analysis to detect quality problems
- Do you know how to measure your GMP performance?
- How elegant is your GMP system?
- How to spot weakness in GMP compliance?

Presenter

Mustafa Edik

Mustafa Edik is an Independent GMP Consultant and Auditor.

After graduating as a Chemist from university, Mustafa began his 25 year plus career as a Laboratory Supervisor at Bayer, a German Pharmaceutical Company. After 15 years of working as a Quality Assurance Assistant Manager, Laboratory Supervisor, Pharmaceutical Quality Management Systems, and GMP Lead Auditor, he decided to continue his career as a Consultant. He has served the Turkish Atomic Energy Authority (TAEA) as Principal GMP Auditor and Consultant for 6 years. TAEA was audited by the Republic of Turkey Ministry of Health and granted GMP Certificate for 5 Radiopharmaceuticals. This success has won great acclaim from all health authorities and industry.

He has prepared and presented various training courses and workshops to more than 8000 individuals from 150 International and local Pharmaceutical, Medical Device, and Cosmetics companies on GMP, GDP and Pharmaceutical Quality Management Systems. He has taken part in several International Pharmaceutical Facility Establishment projects as GMP Consultant and has also set up various Quality Management Systems for Local Pharmaceutical and Medical Device Companies.

While he was the Vice President of Quality and Technical Operations at a Quality Academia Training and Consultancy firm, he acquired and converted it into a 100 % Turkish Company. As the only IRCA Certificated Pharmaceutical Quality Management Systems and GMP Lead Auditor in Turkey, he currently conducts API, Excipient, Packaging Materials Suppliers and Manufacturers, Third Party Logistics Service Providers, Sterile and Non-Sterile Manufacturing Facilities Audits according to FDA, EMA, PIC /S, TMMDA, MHRA, TGA Health Canada, and WHO regulations and guidelines.

He finished his second university degree in Biopharmaceutical Sciences BSc (Hons) at Atlantic Technological University - Ireland. He is the author of chapter 6 of the book published by PDA named “Good Distribution Practices” and his new book on ‘GMP Audits in Pharmaceutical and Biotechnology Industires’ will be published by Taylor & Francis in June 28, 2024.

Course dates

10-11 September 2024	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 15198*	GBP **1,099** ~~1,299~~ EUR **1,569** ~~1,849~~ USD **1,786** ~~2,098~~ **Until 06 Aug**
14-15 January 2025	**Live online** 09:30-17:00 **UK (London)** (UTC+00) *Course code 15199*	GBP **1,099** ~~1,299~~ EUR **1,569** ~~1,849~~ USD **1,786** ~~2,098~~ **Until 10 Dec**
13-14 May 2025	**Live online** 09:30-17:00 **UK (London)** (UTC+01) *Course code 15200*	GBP **1,099** ~~1,299~~ EUR **1,569** ~~1,849~~ USD **1,786** ~~2,098~~ **Until 08 Apr**

How to book

Online:
ipi.academy/2839

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

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info@ipi.academy

Phone:
+44 (0)20 7749 4749

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 the 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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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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