IPI Academy

MANAGEMENT forum



Presented by
Management Forum

GMP Principles in Vaccine Manufacturing

15-16 June 27
+ 13-14 December 27

Vaccinology continues to advance and mature impressively, both in developing new and improved vaccines and in administering vaccines to prevent disease. On this course, explore GMP principles in vaccine manufacturing.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

In this two-day training, the history of vaccines and adverse events will be discussed, information will be presented about various vaccine types and production platforms, raw material, production, quality control, quality assurance, storage, and distribution processes in a GMP-compliant vaccine facility will be explained to the participants with examples and real-time scenarios.

With the advent of vaccine development, life expectancy has increased and the quality of life has improved visibly. Vaccinology continues to advance and mature impressively, both in developing new and improved vaccines and in administering vaccines to prevent disease. Some vaccines used today were developed in the 1940s and 1950s and have remained virtually unchanged. This situation is not surprising for experts who can read the pharmaceutical industry and the ecosystem dynamics that develop around it well. Just like small molecule chemical drugs, to maximise the life cycle of a vaccine, the most important prerequisite is that the raw materials, components, and consumables are in the same composition and consistency from the beginning.

The SARS-CoV-2 pandemic highlighted the importance of vaccines to control the consequences of COVID-19. Most of these GMP facilities are in the EU, USA, China, and European countries. To facilitate the access of these types of products to the rest of the world, the expansion of production capacities and installation of new GMP production plants is essential.

To optimise vaccine production processes and develop efficient and effective processes, it is necessary to continuously supply quality raw materials from reliable suppliers that have been audited and approved by internationally recognised, certified, competent, and experienced GMP auditors.

Compliance with cGMP requires setting up a quality system (QS), which will vary in complexity according to the size of the company. However, there are some basic principles to be followed in terms of design, manufacture, validation, quality control, packaging, labelling, and storage. As it is known, the use of living organisms in the vaccine manufacturing process brings safety requirements to the fore. This situation points to a more complex structure outside of traditional drug production.

One of the most obvious risks in vaccine production is undoubtedly cross-contamination. In such a risky environment, the importance of ensuring the cleanliness and safety of the area, equipment, and personnel and cleaning and disinfection increases. GMP compliance and safety requirements brought about by the use of negative and positive pressure rooms are some of the challenges of vaccine production. Although innovative approaches such as mRNA technology seem to minimise some risks, there is still a lot to be done.

This course will provide an excellent opportunity to become fully briefed on the GMP principles in vaccine manufacture and enable participants to discuss the techniques with an expert in this field.

Benefits of attending

On this course, participants will:

- **Gain** information about vaccine manufacturing technologies
- **Understand** the advantages and disadvantages of different production platforms
- **Learn** the differences between vaccine and traditional drug production
- **See** how to adapt risk management principles and contamination control strategy to a facility
- **Explore** detailed information about biosafety cabinets and their uses
- **Look** at insights into the principles of raw material controls, production, quality control, release, storage and distribution in a GMP-compliant vaccine production facility
- **Focus** on examples of how difficulties in vaccine production can be overcome
- **Appreciate** the chance to take a closer look at viral, subunit and mRNA GMP applications
- **Examine** concepts such as viral safety, stability and TSE in vaccines through examples
- **Assess** the information about upstream, downstream and cell banks
- **Form** an opinion on the layout plan of a vaccination facility

Who should attend

Personnel from these job departments will benefit from the course:

- Quality Control
- Quality Assurance
- Manufacturing (Upstream & Downstream)
- Engineering
- GMP Compliance
- Audit
- Suppliers to Vaccine Manufacturers

Programme

Day 1

History of vaccines

- Why and how were vaccines developed?
- What are the technological developments from the first vaccine to today?
- Making, purifying, formulating

Vaccine types and manufacturing platforms

- Live attenuated vaccine types
- Non-live vaccine types
- New types of vaccines

Viral vector vaccines & GMP

- Media & inoculum
- Cell growth
- Clarification
- UF/DF
- Purification
- UF/DF
- Formulation, sterile filtration

Subunit vaccines & GMP

- Media & inoculum
- Cell growth
- NA removal
- Clarification
- Chromatography
- UF/DF
- Virus removal
- Formulation, sterile filtration

mRNA vaccines & GMP

- Plasmid
- Chromatography
- In-vitro transcription
- Chromatography
- Capping
- Chromatography
- UF/DF
- Encapsulation
- Formulation, sterile filing

Vaccine components

- Adjuvants
- Stabilisers
- Buffers
- Solvents
- Preservatives
- Animal derived ingredients

Group exercise – health authority inspection citations about vaccine manufacturers

Traditional platforms for protein-based vaccines

- Bacteria
- Yeast
- Insect
- Mammalian
- New approaches

Day 2

Upstream processing essentials

- Example vaccine antigens
- Critical quality attributes
- Critical process parameters
- Critical material attributes
- How to maintain stable cell lines?

Downstream processing essentials

- Purification principles
- Which chromatography method to choose? How many?
- Viral clearance essentials
- Filtration methods best practices

Stability of vaccines

- Stability concerns
- Buffers and stabilisers in vaccine stability

Lyophilisation of vaccines

- Lyophilisation and validation
- New Annex 1 expectations for Lyophilises

Group exercise – how to select a final container for a vaccine?

Quality control of vaccines

- Which tests are performed?
- Technology transfer issues
- Method validation
- Analytic requirements on vaccine manufacturing

Manufacturing constraints of vaccines

- Purity vs cost
- Central vs distributed manufacturing
- Vaccine manufacturing failures
- Timing of investments
- GMP deficiencies of vaccine manufacturing

How to design a vaccine facility

- Cleanroom design rules
- Containment approaches
- Risk-based principles of design purposes
- Segregation
- Hygiene
- Airlocks & pressure differentials
- Personal gowning
- Contamination control strategy

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

15-16 June 27	**Live online** 09:30-16:30 **UK (London)** (UTC+01) *Course code 17240*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 20 Apr**
13-14 December 27	**Live online** 09:30-16:30 **UK (London)** (UTC+00) *Course code 17568*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 18 Oct**

How to book

Online:
ipi.academy/2840

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

Email:
info@ipiacademy.com

Phone:
+44 (0)20 7749 4749

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.

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

Reviews

★★★★☆

Overall, I greatly appreciated the course and I am very pleased to have had the opportunity to participate. The knowledge I gained will be very useful in my work and will help me continue to grow and improve professionally. The speaker was very kind and attentive.

María Dominguez
Técnico
BIOFABRI
Dec 10 2025

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.

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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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