IPI Academy

MANAGEMENT forum

Presented by
Management Forum

GMP Principles in Vaccine Manufacturing

10-11 September 2025
+ 10-11 December 2025

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 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 2025 **Live online**
09:30-16:30 **UK (London)** (UTC+01)
Course code 15227

GBP **1,299** ~~1,499~~
EUR **1,819** ~~2,099~~
USD **2,087** ~~2,399~~
Until 06 Aug

10-11 December 2025 **Live online**
09:30-16:30 **UK (London)** (UTC+00)
Course code 15308

GBP **1,299** ~~1,499~~
EUR **1,819** ~~2,099~~
USD **2,087** ~~2,399~~
Until 05 Nov

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.

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ALEKSANDRA BEER
Tel: +44 (0)20 7749 4749
Email: inhouse@ipiacademy.com

YESIM NURKO
Tel: +44 (0)20 7749 4749
Email: inhouse@ipiacademy.com

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.

10-12 Rivington Street
London EC2A 3DU

ipi.academy
Tel: +44 (0)20 7749 4749
Email: info@ipiacademy.com