IPI Academy

MANAGEMENT forum



Presented by
Management Forum

APIs in Focus: Understanding ICH, GMP and Supply Chain Excellence

28-29 April 27
+ 20-21 October 27

This course will cover key terminology, the EU and USA regulatory framework, Good Manufacturing Practice (GMP) requirements including controls and validation, and consider Good Distribution Practice (GDP) and how to manage your supply chain.

Format:
Live online

CPD:
12 hours for your records

Certificate of completion

Course overview

An active pharmaceutical ingredient (API) or drug substance is the heart of every medicinal product, delivering the pharmacological activity or therapeutic effect needed to diagnose, treat, or prevent disease. Mastering the complexities of API manufacture is essential for ensuring quality, safety, and regulatory compliance in the pharmaceutical industry.

This course is designed to equip you with a clear and practical understanding of best practices and the regulatory landscape governing APIs. You'll explore critical terminology, dive into the EU and USA regulatory frameworks, and gain insight into Good Manufacturing Practice (GMP) requirements, including controls and validation. The course also places strong emphasis on the International Council for Harmonisation (ICH) guidelines, which are increasingly central to global API regulation. You'll learn how recent and upcoming ICH updates shape expectations for API development, manufacture, and quality assurance.

This course will also cover Good Distribution Practice (GDP) and will give you the tools to manage your supply chain effectively. With interactive exercises integrated throughout, you'll cement your learning and leave ready to apply your knowledge in real-world settings. Whether you're building your expertise or refreshing your understanding, this course provides an essential understanding of expectations for success in the development, purchase and manufacture of Active Pharmaceutical Ingredients.

Benefits of attending

- **Gain** a comprehensive overview of the API regulatory framework and position yourself to navigate compliance challenges with confidence
- **Enhance** your understanding of the key terms used in API manufacture so you can communicate effectively and make informed decisions
- **Recognise** how Good Manufacturing Practices (GMP) apply to API synthesis and discover how to embed them seamlessly into your processes
- **Understand** the different approaches between small molecule and large molecule processing to stay ahead in a rapidly evolving industry
- **Learn** how to manage the risk associated with your supply chain and safeguard product quality from development to delivery

Who should attend

- New entrants to those individuals working in a GxP environment
- Quality management manufacturing specialists
- Regulatory compliance specialists
- Pharmaceutical technical professionals
- Pharmaceutical professionals looking to enhance their Continuous Professional Development (CPD)

Programme

Day 1

Introduction to APIs

- Terminology and acronyms
- Globalisation
- Introduction to the regulatory framework

Methods and equipment – Part 1

- Chemical synthesis
- Reactors
- Isolation
- Drying
- Exercise: managing particle size

Methods and equipment – Part 2

- Biological
- Fermentation
- Harvesting
- Exercise: impurities

Good Manufacturing Practice (GMP)

- Requirements
- Regulations
- EU
- FDA
- Exercise: similarities and differences

GMP requirements (continued)

- Pharmaceutical Quality System
- Validation and Qualification
- Outsourcing
- Exercise: specialist or generalist

Supply chain considerations

- Falsified Medicines Directive (FMD)
- Good Distribution Practice (GDP) for APIs
- Exercise risk mitigation

Day 2

Introduction and recap

Registration aspects of production and control

- The registration process
- The Common Technical Document (CTD)
- Active substance/drug master files
- Exercise: strategy

Laboratory controls

- Good Quality Control Laboratory Practice (GQCLP)
- Validation
- Stability
- Exercise: data Integrity

Process validation

- Purpose of validation
- General considerations
- Exercise: critical attributes

Cleaning validation

- Cleaning strategy
- Key requirements
- Residues
- Exercise: purpose

API control packaging materials

- What to consider
- Data requirements
- Extraction, interaction, migration and sorption
- Toxicology
- Exercise: environmental factors

Wrap up and Q&A

Presenters



Farah Nadeem

Farah Nadeem is an Operations Manager at Paul R. Palmer Limited/ Pharmaceutical Consultant and a Trainee Qualified Person. Farah is a Pharmacist and recognised QA expert and has over 20 years of experience in the Pharmaceutical industry in the development, manufacture and supply of medicinal products.

Throughout her career, she has held various quality assurance roles and actively pursued new opportunities to expand her knowledge and expertise. As a result, she has gained a comprehensive understanding of manufacturing, storage, and distribution processes, as well as the facilities and services that support them. Involved in documentation management: writes, reviews, and audits SOPs and QMS implementations. Assists companies in meeting regulatory requirements.

In her current role as a QA Operations Manager for a Pharmaceutical Consultant Company, Farah Nadeem provides various solutions, including assistance in obtaining the first MIA(IMP) and MIA licenses, as well as preparation and hosting for regulatory inspections. Her work involves collaborating with Paul Palmer to offer services such as QP declarations for API manufacturers, regulatory inspection hosting, commercial and clinical batch release, compliance audits, and coaching and training in GxP.



Aneta Jell

Aneta Jell is a seasoned Quality Assurance professional with over 20 years of experience across manufacturing, contract operations, and quality leadership in the pharmaceutical industry. Currently serving as Quality and training manager at PaulPalmer limited she oversees global contract manufacturing quality, ensuring GxP compliance, regulatory alignment, and supply chain integrity. Her expertise spans GMP, ISO 9001, ISO 17025, and QMS administration, with proven strength in audits, CAPA, deviations, and technical agreements. A qualified QMS lead auditor with bilingual proficiency in English and Slovak, Aneta is recognised for driving continuous improvement, fostering compliance culture, and leading high-performing quality and HSE teams.

Course dates

28-29 April 27	**Live online** 09:30-17:30 **UK (London)** (UTC+01) *Course code 17128*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 03 Mar**
20-21 October 27	**Live online** 09:30-17:30 **UK (London)** (UTC+01) *Course code 17435*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 25 Aug**

How to book

Online:
ipi.academy/2505

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

★★★★☆

I have accomplished a better understanding of API's after the two day webinar. Very good webinar which covers a good range of content, a little dense, so will need to refer back to it at some stage. Speakers were nice and accommodating. They clearly have a good understanding of the content they are presenting.

Stephany Banglayan
Research and Development Analyst
Xeolas Pharmaceuticals
Jul 16 2025

★★★★☆

I hoped to achieve a full picture of APIs for my new job and yes I accomplished it. A lot of information..

Marie Lucchini
Regulatory affairs Supervisor
Actylis
Jul 16 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.

With over 600 trainers, all practitioners and experts across a huge range of fields, we can provide the training you need, where you need it, when you need it, and at a price which suits your budget. Our approach to tailored learning and development consists of designing and delivering the appropriate solution for each client.

For your FREE consultation and to find out more about how we can work with you to solve your training needs, please contact our training advisers:



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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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