IPI Academy

MANAGEMENT forum

Presented by
Management Forum

Navigating Regulatory Compliance Whilst Developing and Distributing PCR-Based IVD Tests

14 November 2024
+ 6 March 2025, 26 June 2025, 6 November 2025

In this three-hour course, learn from an expert about developing and distributing PCR-based IVD tests, as well as exploring the latest regulatory requirements.

Format:
Live online

CPD:
3 hours for your records

Certificate of completion

Course overview

In the rapidly evolving field of molecular diagnostics, understanding the regulatory and quality requirements is crucial for successful product development and market entry. This course is designed to equip participants with comprehensive knowledge and practical insights into navigating the regulatory and quality landscapes in the United States (US) and the European Union (EU), specifically tailored for PCR-based diagnostic tests.

Participants will delve into the intricacies of regulatory frameworks governing PCR-based diagnostic tests in both regions, including but not limited to:

- Overview of FDA (Food and Drug Administration) regulations applicable to PCR-based diagnostics
- Understanding the different pathways for regulatory approval or clearance (e.g., 510(k), PMA, EUA)
- Requirements for clinical trials, and performance evaluation studies
- Recent updates and trends impacting regulatory pathways in the US
- Overview of CE marking requirements under the MDR (Medical Device Regulation) and IVDR (In Vitro Diagnostic Regulation)
- Conformity assessment procedures and notified bodies in EU
- Post-market surveillance and vigilance requirements

The course will also address quality management systems essential for compliance with regulatory standards, such as ISO 13485 and Good Manufacturing Practice (GMP) guidelines. Regulatory expectations for quality control, risk management, cybersecurity and documentation will be covered to ensure participants gain a holistic understanding of designing, verifying and validating PCR-based tests for quality and regulatory compliance throughout the product lifecycle.

A review of two case studies will give participants the opportunity to see how the knowledge current regulatory environment applies to real-world scenarios, enhancing their ability to navigate challenges and optimise strategies for successful market entry of PCR-based diagnostic tests in the US and EU.

Benefits of attending

- **Gain** the confidence and knowledge necessary to effectively navigate the complex regulatory and quality landscape of the US
- **Learn** the EU regulatory and quality landscape
- **Accelerate** the development and commercialisation of PCR-based diagnostic tests
- **Ensure** compliance with evolving regulatory requirements
- **Participate** in case studies and group discussions

Who should attend?

- Professionals involved in the development, regulatory affairs, quality assurance, or manufacturing of PCR-based diagnostic tests
- Researchers, scientists, and entrepreneurs aiming to bring innovative diagnostic technologies to market
- Consultants and advisors seeking to expand their expertise in regulatory affairs and quality management within the diagnostic industry

Programme

Navigating the US regulatory and quality landscape

- FDA submission preparation (pre-sub/ Q-sub)
- FDA regulatory paths/premarket submission types

US case study and key takeaways

Navigating the EU regulatory and quality landscape

- General Safety and Performance Requirements (GSPR)
- Economic operators and conformity assessment organisations
- EUDAMED
- Declaration of Conformity
- Certificate
- Conformity assessments pathways

Presenter

Dmitriy Kosarikov

After more than a 30-year career in R&D for the pharmaceutical and medical diagnostics industry, Dmitriy started the D&L Consulting, Education and Services LLC in 2023. Prior to that, he spent 23 years developing PCR tests and platforms at Roche Group – a company that had acquired the original PCR patent from Cetus in 1992 and soon after launched the first commercial PCR assay. During those years he had the privilege of learning from the giants like R. Saiki, D. Gelfand and H. Erlich, leading the teams developing three automated PCR platforms and being part of paradigm shift in cervical cancer screening. He also had the honour of serving as an R&D lead for a record breaking 37 days product development of the first high throughput PCR-based SARS-CoV-2 test in 2020.

Course dates

14 November 2024	**Live online** 14:00-17:00 **UK (London)** (UTC+00) *Course code 15344*	GBP **299** ~~349~~ EUR **439** ~~509~~ USD **501** ~~579~~ **Until 10 Oct**
6 March 2025	**Live online** 14:00-17:00 **UK (London)** (UTC+00) *Course code 15345*	GBP **299** ~~349~~ EUR **439** ~~509~~ USD **501** ~~579~~ **Until 30 Jan**
26 June 2025	**Live online** 14:00-17:00 **UK (London)** (UTC+01) *Course code 15346*	GBP **299** ~~349~~ EUR **439** ~~509~~ USD **501** ~~579~~ **Until 22 May**
6 November 2025	**Live online** 14:00-17:00 **UK (London)** (UTC+00) *Course code 15347*	GBP **299** ~~349~~ EUR **439** ~~509~~ USD **501** ~~579~~ **Until 02 Oct**

How to book

Online:
ipi.academy/2754

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

Email:
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

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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