IPI Academy

MANAGEMENT forum



*Presented by*
**Management Forum**

# Navigating Regulatory Compliance Whilst Developing and Distributing Polymerase Chain Reaction (PCR)-Based IVD Tests

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:**
Bespoke training

**CPD:**
3 hours for your records (depending on your requirements)

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), Pre Market Approval, Emergency Use Authorisation)
- 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 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

## 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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