



Presented by
Management Forum

FDA Approval Process for Medical Devices

2-3 December 2024

+ 31 March-1 April 2025, 22-23 July 2025, 2-3 December 2025

This seminar will provide a solid foundation in the approval and clearance processes for medical devices in the United States including the underlying legal and regulatory requirements and the 'general controls' applicable to all devices.



Format:
Live online



CPD:
12 hours for your records



Certificate of completion

Course overview

This seminar will provide a solid foundation in the approval and clearance processes for medical devices in the United States. Participants will gain an understanding of the underlying legal and regulatory requirements and the general controls applicable to all devices, including device classification, establishment registration and device listing. With the underlying framework in mind, the approval and clearance processes for new and modified devices will be presented, including 510(k), IDE, PMA, HDE and De Novo applications. Application contents, review processes, timelines, and key guidance documents will be discussed for each major type of submission. Participants will also learn about the pre-submission process, which FDA strongly recommends to help ensure the successful submission of novel devices.

Case studies will help participants to put some of the learnings into practice and to use FDA databases to research example products. The course includes up to date information which covers recent changes in legislation, regulations and guidance. Please note that the trainer has recent experience with both medical devices and in vitro diagnostics. However, please note that the course covers medical devices in general and does not provide separate sessions for specific types of medical devices (such as IVDs, software, etc).

New

Benefits of attending

Upon completion of this seminar, participants will:

- **Understand** the overall FDA medical device regulatory process
- **Know** what is required for 510(k), IDE, PMA, HDE and De Novo applications
- **Understand** how FDA processes premarket submissions
- **Identify** key guidance documents to help ensure a successful process
- **Determine** when pre-submission interaction with FDA is recommended
- **Be aware** of areas of change

Who should attend

This seminar is intended for regulatory, technical, clinical and quality professionals who require an understanding of the FDA medical device approval process. Management, legal, medical, marketing and other professionals who are interested in understanding the key principles of the medical device approval process will also benefit in attending.

Programme

Day 1

MODULE 1 – Overview of US Medical Device Regulatory Principles

Part 1 - Introduction to US FDA

History, Structure and Mission of FDA

Part 2 - Overview of US Regulatory Process and Pathway

Including how to work with FDA and pre-submissions (Q-sub)

MODULE 2 – Medical Device Definition, Classification, Device Listing & Establishment Registration

Part 1 - Medical Device Definition, Classification, Device Listing & Establishment Registration

Part 2 – Classification Case Study

Day 2

MODULE 3 – Submissions

Part 1 - Pre-Market Notification 510(k)

Part 2 – De-Novo / Automatic Class III Reclassification

Part 3 - Pre-Market Approval (PMA)

Part 4 – HDE & IDE (& IUO)

Part 5 – Submission Case Study

MODULE 4 – Borderline & Combination Products

Product Designation & Combination Products

Presenter



Jonathan Hughes

Jonathan Hughes, Ph.D., FTOPRA, has over 35 years of worldwide regulatory and clinical affairs experience across medical devices, drug / biologic – device combination products and in-vitro diagnostics. He has worked with medical device and pharmaceutical companies, both large and small, across multiple locations to help develop and execute regulatory strategies for market clearance, approval and access.

Jonathan has hands-on experience in a variety of therapeutic areas and has worked across different technologies and types of medical products including medicated devices (devices containing ancillary drug and biologic constituents), drug delivery systems and componentry, sterile and non-sterile disposables and durable equipment, in-vitro diagnostics, software controlled devices and standalone software (including mobile apps). He has experience of regulating medical devices and combination products across most international markets including the European Union, US, Japan, China, Canada and Australia.

Jonathan specialises in regulatory strategy, regulatory and clinical development pathways, worldwide regulatory submissions and training. He has a strong knowledge of quality management systems and has direct hands-on experience of US FDA, MDSAP, EU NB, Brazilian ANVISA and Chinese NMPA inspections. He has worked with all the major international regulatory agencies, in particular (multiple) Notified Bodies and US FDA, EU Competent Authorities, Japanese PMDA, Chinese NMPA.

Jonathan has served on two European Commission Expert Working Groups on the Drug / Device Borderline and Device Classification. He is a Fellow of the regulatory professional organisation, TOPRA, and is a regular contributor on numerous educational and training programmes. Jonathan has registered teacher status at Cranfield University, is a Visiting Industrial Fellow at the University of Hertfordshire and also a visiting lecturer at University of Newcastle upon Tyne.

Course dates

2-3 December 2024

Live online

09:15-17:00 **UK (London)** (UTC+00)

Course code 14068

GBP **1,299**

EUR **1,869**

USD **2,129**

31 March-1 April 2025

Live online

Course code 14542

GBP **1,099** ~~1,299~~

EUR **1,589** ~~1,869~~

USD **1,817** ~~2,129~~

Until 24 Feb

22-23 July 2025

Live online

09:15-17:00 **UK (London)** (UTC+01)

Course code 14760

GBP **1,099** ~~1,299~~

EUR **1,589** ~~1,869~~

USD **1,817** ~~2,129~~

Until 17 Jun

2-3 December 2025

Live online

09:15-17:00 **UK (London)** (UTC+00)

Course code 15113

GBP **1,099** ~~1,299~~

EUR **1,589** ~~1,869~~

USD **1,817** ~~2,129~~

Until 28 Oct

How to book



Online:

ipi.academy/1022

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



Email:

info@ipi.academy



Phone:

[+44 \(0\)20 7749 4749](tel:+442077494749)

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 our terms, the event cancellation policy and the terms and conditions are on our website, please visit ipi.academy/content/terms-and-conditions

Reviews



Excellent conference, speaker, material etc were perfectly balanced and understandable.



Andrew Pearce
Corporate Quality & Regulatory Director
GVS
Sep 10 2024



This course is very informative and interactive and touched all aspects off Medical device approval process by FDA. Overall excellent, webinar logistics are surprisingly easy, Jonathan's presentation of FDA content is exemplary. Jonathan is a great educator and shared all his experiences.



Sai Prasad
Global Clinical & Medical Advisor, Surgical Structural Heart
Edwards Lifesciences Corp
Jun 18 2024



Jonathan was really very excellent. Clearly has a thorough understanding of the FDA and is able to impart that knowledge incredibly well. The slides were extensive (Jonathan clearly put a lot of time and effort into these) and will be a great resource for me in the future.



Vikki Young
Head of Quality and Regulatory
Prothea Technologies
Jun 18 2024



Jonathan was a really good speaker and took his time to answer any of our questions. He was very knowledgeable.



Henry Bland
QARA Specialist
Adtec Healthcare
Jun 18 2024

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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