IPI Academy

MANAGEMENT forum



Presented by
Management Forum

FDA Approval Process for Medical Devices

1-2 December
+ 24-25 May 27, 30 November-1 December 27

This course 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

Gain a comprehensive understanding of how medical devices achieve approval and clearance in the United States. This course provides a solid foundation in the legal and regulatory framework governing medical devices - covering essential topics such as device classification, establishment registration, and device listing.

With this foundation in place, you'll explore the approval and clearance pathways for both new and modified devices, including 510(k), IDE, PMA, HDE, and De Novo applications. Each major submission type will be examined in depth - from application contents and review timelines to key guidance documents and FDA expectations.

You'll also discover how to make the most of the FDA pre-submission process, a powerful tool the agency strongly recommends to help ensure the success of novel device submissions.

Interactive case studies will allow you to apply what you've learned, using FDA databases to research example products and deepen your practical understanding. The course content is fully up to date, reflecting the latest changes in legislation, regulations, and guidance.

Your trainer, Jonathan Hughes, brings current, hands-on experience with both medical devices and in vitro diagnostics (IVDs). Please note, however, that this course covers medical devices in general and does not include separate sessions dedicated to specific device types (such as IVDs or software).

Benefits of attending

- **Gain** a clear understanding of the overall FDA medical device regulatory process
- **Know** exactly what is required for 510(k), IDE, PMA, HDE, and De Novo applications
- **Comprehend** how the FDA reviews and processes premarket submissions
- **Identify** the key guidance documents that support a smooth and successful approval process
- **Recognise** when and how to engage in pre-submission interactions with the FDA for optimal outcomes
- **Stay** informed and aware of current and emerging areas of regulatory change

Who should attend

This course is designed for professionals who need a solid understanding of the FDA medical device approval process, including:

- Regulatory professionals
- Technical specialists
- Clinical experts
- Quality professionals

It will also be highly valuable for those in related roles who wish to deepen their knowledge of the key principles behind medical device approval, such as:

- Management
- Legal professionals
- Medical professionals
- Marketing teams
- Other industry stakeholders interested in the FDA approval landscape

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-subs)

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

1-2 December	**Live online** 09:15-17:00 **UK (London)** (UTC+00) *Course code 16591*	GBP **1,499** EUR **2,099** USD **2,399**
24-25 May 27	**Live online** 09:15-17:00 **UK (London)** (UTC+01) *Course code 17271*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 29 Mar**
30 November-1 December 27	**Live online** 09:15-17:00 **UK (London)** (UTC+00) *Course code 17534*	GBP **1,299** ~~1,499~~ EUR **1,819** ~~2,099~~ USD **2,087** ~~2,399~~ **Until 05 Oct**

How to book

Online:
ipi.academy/1022

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

★★★★☆

That was perfect, thank you! The presentation, content and presenter were very good. I hoped to get basic understanding of the FDA submission pathways and this is certainly achieved! Overall, I am very satisfied having followed the course.

Elisabet Jamez
Biocompatibility Expert
Nelson Labs
Mar 31 2025

★★★★☆

The training materials were well prepared and of high quality. These will be an excellent reference when we want to start planning device registrations for US market. Overall, very happy with the content, speaker and presented materials.

Veerle Leijnen
Senior RA Executive Manager
Nikkiso Belgium
Mar 31 2025

★★★★★

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

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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