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FDA Approval Process for Medical Devices

22-23 Mar 2021, London • 24-25 Mar 2021, London
+ 2 more dates - see back page for full schedule

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.

Programme at a glance:

- Overview of US medical device regulatory principles
- Pre-submissions
- 510(k) process (pre-market notification)
- De Novo applications for low-moderate risk devices
- Investigational device exemption (IDE) for clinical investigations
- Pre-market approval (PMA) for Class III devices
- Humanitarian device exemptions

Full programme inside

★★★★ *"The course gives a very nice overview; especially valuable when you are just starting to considering to apply for FDA market clearance. (The speaker was) very knowledgeable about the FDA approval procedure for MDs in general. Mark is a good speaker, approachable, and he leaves plenty of room for discussion."*

Ivo van Bostelen, Project Leader, MRC-Holland BV

★★★★ *"The course was good and a thorough run through of the FDA approval process, with an easy to understand Mark Kramer."*

Jens Johansen, QA/RA Director, RSP Systems

★★★★★ *"I'm very pleased with the overall learning objectives, presentations and the quality of the handout given at the course. Good presentation and good focus on driving the presentations forward. A bit difficult to coordinate presentation with time table given in handouts."*

Jarle Mikalsen, CSO, Lyfstone

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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.

Demonstrations of how to find key information in FDA databases will be presented using participants' products and interests as examples. There will also be updates on recent legislation changes, new regulations and guidance documents.

Please note that while the law, regulations, principles and processes covered in the course apply to both medical devices and in-vitro-diagnostics (IVDs), the trainer's primary experience is with medical devices.

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.

★★★★★ *"[The course] was all very good and very informative. Very informative content given by a very knowledgeable speaker on a complex area, but I now have a much better understanding of the overall submission processes."*

Simon Collings, Director, IDC

★★★★ *"Mark was a very good speaker and it was clear from the start that he was very knowledgeable. The course was well structured, pitched at the right level for the attendees, in a clear and concise manner, with plenty of opportunity to ask questions."*

Adam Williams, Senior Quality Engineer, Sharp Life Science (EU) Ltd

★★★★★ *"I met Mark Kramer in a previous course of Combination Products. His explanations are very clear, I can perceive that he knows how FDA works, what FDA expects to get for every situation. I have enjoyed a lot and think it's been very profitable. Mark answered all our questions being pretty interactive. The course is about a general and consistent view of the FDA approval processes for medical devices, clear and comprenhensive presentation. I can sense that Mark knows very well how FDA works and what FDA expects. Very profitable and highly recommended to catch a general knowledge."*

Maria Jose Hijarrubia Ibrahim, Medical Devices Registers, Grifols S.A

Expert trainer

Jonathan Hughes

Jonathan Hughes, Ph.D., FTOPRA, has over 32 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 EU NB, MDSAP, US FDA, Brazilian ANVISA and Chinese NMPA inspections. He has worked with all the major international regulatory agencies, in particular (multiple) Notified Bodies and EU Competent Authorities, Japanese PMDA, US FDA, 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.

Overview of US medical device regulatory principles

- FDA mission and organisation
- FDA's Center for Devices and Radiological Health (CDRH)
- History and law
- Device classification
- General controls
- Special controls
- Product codes
- Registration and listing
- 513(g) process
- e-Copy program
- MDUFA (Medical Device User Fee Act)
- Review performance goals
- Finding information in FDA databases
- 21st Century Cures legislation, FDARA and MDUFA IV

Pre-submissions

- Types of pre-submissions
- Contents of a pre-submission
- Review timelines
- Preparing for an FDA meeting
- Dos and don'ts

510(k) process (pre-market notification)

- History and purpose of 510(k) process
- Traditional, special and abbreviated 510(k) submissions
- Contents of 510(k) applications
- Substantial equivalence decision making process
- 510(k) review processes
- Acceptance screening of 510(k)s ('Refuse to Accept' policy)
- Review timelines
- Interactive review processes
- 510(k) decisions
- When a new 510(k) is needed for a device modification

De Novo applications for low-moderate risk devices

- De Novo reclassification process
- Potential pros and cons of seeking De Novo Reclassification
- Contents of De Novo applications
- De Novo decision-making process
- Review timelines

Investigational device exemption (IDE) for clinical investigations

- Significant risk, non-significant risk and exempt investigations
- Contents of IDE applications
- IDE review timelines
- IDE decision-making process
- FDA actions on IDE applications
- 5-day notices
- IDE supplements
- Annual reports
- Sponsor responsibilities

Pre-market approval (PMA) for Class III devices

- Contents of PMA applications
- PMA review standard
- Acceptance screening and filing of PMAs
- Phases of PMA review
- Review timelines
- Advisory panel review
- Interactive review processes
- PMA decisions
- PMA supplements
- PMA reports
- Post-approval requirements

Humanitarian device exemptions

- Humanitarian Use Designation (HUD)
- HDE review standard
- Contents of HDE applications
- HDE review timelines
- HDE supplements
- HDE reports

FDA Approval Process for Medical Devices

Schedule and prices

Three ways to book:

Online
management-forum.co.uk/1022

Email
bookings@management-forum.co.uk

Telephone
+44 (0)20 7749 4730

Ref	Date	Location	Price	Early booking price	Until*
11293	**22-23 Mar 2021**	Venue TBC	GBP **1,499** + VAT = 1,798.80 EUR **2,099** + VAT = 2,518.80 USD **2,338** + VAT = 2,805.60	GBP **1,299** + VAT = 1,558.80 EUR **1,819** + VAT = 2,182.80 USD **2,026** + VAT = 2,431.20	**8 Feb 21**
11093	**24-25 Mar 2021**	Live webinar	GBP **1,299** + VAT = 1,558.80 EUR **1,859** + VAT = 2,230.80 USD **2,098** + VAT = 2,517.60	GBP **1,099** + VAT = 1,318.80 EUR **1,579** + VAT = 1,894.80 USD **1,786** + VAT = 2,143.20	**10 Feb 21**
11367	**13-14 Sep 2021**	Venue TBC	GBP **1,499** + VAT = 1,798.80 EUR **2,099** + VAT = 2,518.80 USD **2,338** + VAT = 2,805.60	GBP **1,299** + VAT = 1,558.80 EUR **1,819** + VAT = 2,182.80 USD **2,026** + VAT = 2,431.20	**2 Aug 21**
11096	**15-16 Sep 2021**	Live webinar	GBP **1,299** + VAT = 1,558.80 EUR **1,859** + VAT = 2,230.80 USD **2,098** + VAT = 2,517.60	GBP **1,099** + VAT = 1,318.80 EUR **1,579** + VAT = 1,894.80 USD **1,786** + VAT = 2,143.20	**4 Aug 21**

Your choice of date & location

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Multiple booking discounts

Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.

* Note the early booking discount cannot be combined with any other offers or promotional code

The 'Small Print'

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

Falconbury Ltd 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, Falconbury will refund the registration fee and disclaim any further liability.

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