

4. Medical Devices II: Market Access

This pack of lectures provides knowledge about the main elements to consider and work with when introducing a medtech product into the market, including the development of health technology assessment, the definition of market access strategies and knowledge of the regulatory pathways, from both a European and a US perspective. What should I demonstrate about my product? Who should I contact to introduce my product into the hospital? Should I patent it in the US or in the EU first?

Number of sessions: 5

Starting date: 18th June 2018

Whole Package Price: 432 euros (with a 10% of discount added)

Buy one or more sessions: price varies depending on the session

Venue: PCB - Barcelona Science Park, C/ Baldiri Reixac 4-8, 08028 Barcelona

4.1 Medical Devices Regulation (double session)

Lecturer: Luis Soensken

Date: June 19, 2018

Time: 11:00 – 13:00h and 14:00 – 16:00 h

Price: 150 euros

Course outline: This course consists of two parts and will provide information about the regulation of medical devices, specifically in comparison to the pharmaceutical process, and with regard to the United States market, under Multiple Technology Appraisal (MTA) guidance. Luis Soensken will increase our knowledge about the regulatory approval required from the Food and Drug Administration (FDA) in the USA. You will also take an in-depth look at the European regulatory process under the CE Marking process, and the key differences between both approvals. International regulation on medical devices for other regions such as South America, Asia and the Middle East is also presented. Numerous products and case studies will be covered.



4.2 Reimbursement Basics

Lecturer: Belen Martí

Date: 24th September 2018 TBC

Time: 15:00 – 17:00 h

Price: 100 euros

Course outline: The objective of this session is to teach attendees the fundamental principles of European reimbursement and health economics, so that they understand the importance of it in health innovations from the very first day.

4.3 Health Technology Assessment

Lecturer: Laura Sampietro

Date: 5th September 2018 TBC

Time: 10:00 – 12:00 h

Price: 100 euros

Course outline: This session is a very useful introduction to the healthcare value chain. and will teach you how to bring an idea into the market. Some of the topics that will be covered are: economic context, healthcare paradigm, healthcare technology life cycle, the basis of market approval and quality analysis, etc. You will learn the basic steps of HTA (Health Technology Assessment) and what is considered value in this specific market.

4.4 Market Access, Reimbursement Strategy and Implementation

Lecturer: Meike Bomhof

Date: 4th September 2018 TBC

Time: 11:00 – 14:00 h

Price: 130 euros

Course outline: This lesson covers reimbursement, which is a key process in the medtech sector. The lecturer explains what reimbursement is, the difference between countries in terms of reimbursement strategies, and the implementation strategies available to medtech start-ups.

Promotions

We offer a 50% discount (for any category, but not accumulative) to students who are in their final academic year at university, or who are studying a Masters degree related to the following fields: business, engineering, life sciences or design. If interested, please send an e-mail to lrogel@biocat.cat, with the subject "Short Programs Discount", providing your details and attaching a copy of your university registration. Promotions are limited and will be assigned on a first-come, first-served basis.

SMEs:

Companies participants in Boost4Health Project coordinated by Biocat at the Bioregion of Catalonia will have **free of charge registration** to training from [Moebio Short Programs](#). The eligible SMEs will need to register to Boost4Health.eu and select their interest in receiving coaching. Then Biocat will provide the procedure to access the training and a registration code that will be valid until 3 business days prior to the starting of the activity. Those registrations made with the code without participating into B4H program will not be able to access the room.

Cancellation Policy

To withdraw from a session you must send an e-mail to: lrogel@biocat.cat. If cancellation is received more than one week (7 working days) before the date of the Short Program session, you will be reimbursed for 100% of the registration fee. If cancellation is received during the week prior to the date of the lesson, you will be reimbursed for 50% of the registration fee. If no notice is given, participants will not be reimbursed even if they do not attend the session.