Die Unternehmen der
Medizintechnologie :
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Online Seminar
25th and 26th November 2025

Medical Devices in the USA

From Approval to Reimbursement

BVMed AKADEMIE

Medical Devices in the USA

25th and 26th November 2025 | Webinar

Topic

The Food and Drug Administration (FDA) is the regulatory body responsible for a wide range of products, including food, drugs, and medical devices. Its task is to protect and promote public health in the USA. The FDA oversees the safety and effectiveness of human drugs and medical devices. This applies to products manufactured in the USA as well as imported products.

Manufacturers of most Class II medical devices (according to US classification) must submit an FDA 510(k) application. To obtain marketing clearance for a product from the FDA, a com-parable product that has already been cleared by the FDA must first be identified. This product must be similar to the one being applied for and intended to be cleared by the FDA. Extensive evidence must then be provided.

Objective

The seminar provides an insight into the American healthcare system and medical device regulations and offers practical guidance on preparing and formally submitting applications. For participants who are interested, the meeting will involve a discussion of up to six case studies of actual products in development along with some key advice on how to proceed.

Target Audience

The seminar is aimed at manufacturers of medical devices who want to gain an overview of the major hurdles and opportunities when entering the US market.

Speaker

> **Stephen Hull**
Sr. Vice President, Market Access & Reimbursement
Avania | Boston

> **Liz Munro**
Vice President, Regulatory and Advisory Services
Avania | Toronto

Seminar Management & Moderation

> **Tina Wilke**
Consultant BVMed-Akademie
Bundesverband Medizintechnologie e. V. (BVMed) | Berlin

Program

Day 1 | 25th November 2025

1:45 PM *Participant Registration*

2:00 PM BVMed-Academy
Welcome

2:05 PM Liz Munro
FDA Regulatory Pathways for Medical Devices
- Overview of U.S. medical device landscape
- FDA classification and the 510(k) process
- Key activities and timelines
- Digital health regulatory considerations
- Communication with the FDA

Discussion
Evidence demands of US payers and how it differs from the FDA

Participant Questions

3:30 PM *End of Day 1*

Day 2 | 26th November 2025

1:45 PM *Participant Registration*

2:00 PM BVMed-Academy
Welcome und reflection Day 1

2:05 PM Stephen Hull
Market Access and Reimbursement in the U.S.
- Overview of the U.S. Medicare program
- Evidence demands of U.S. payers vs. FDA
- Digital health reimbursement strategies
- Practical advice for engaging U.S. partners and payers

Practical advice
Optimal approach to US partners, payers and customers

Participant Questions

3:30 PM *End of Day 2*

Registration until 24.11.2025
online | **www.bvmed.de/mp-usa-2025**

Participation is only possible after prior registration.

Access Data
Participants will receive the login details by email no later than 2 days before the seminar.

Cancellation
A free cancellation is possible up to 5 working days before the start of the seminar. After that, the fee is due even in the case of non-participation. Please note our »**participation and cancellation conditions**«.

Participation fee
Includes seminar materials.

BVMed Members
325,00 € | plus VAT | per person
386,75 € | including VAT | per person

Non-Members
355,00 € | plus VAT | per person
422,45 € | including VAT | per person

The participation fee is due upon receipt of the invoice without any deductions. Invoicing will take place after the event.

Organizer
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