Seminar

FORUM

Step by step through Medical Device Law

Requirements for Germany and Europe

Topics

- European and German framework in Medical Device Law
- Clinical investigation and clinical trial
- Marketing and distribution of medical devices
- Rights and duties of the competent authorities
- Liability and compliance

The framework essentials compactly in one day - also for non-legal professionals!

Your speakers

Dr. Ekkehard Stößlein
Federal Institute for Drugs and Medical Devices (BfArM),
Bonn, Germany

Michael Wimmer
Sträter law firm,
Bonn, Germany

11 July 2011 in Bonn

Step by step through Medical Device Law

Aims and objectives

This intensive course explains in an understandable way the legal framework of the development and marketing of medical devices for non legal practitioners.

You will be familiar with the determining factors for the entire product lifecycle of a medical device:

- Which laws apply to a clinical trial?
- Which forms of advertising are permitted?
- Under which circumstances is the manufacturer liable? And when is the user?

Moreover, two experts will give you advice on the legal innovations of the 4th German Medical Device Act (MPG) and the associated new requirements for manufacturers in Europe.

Furthermore you will be provided with information on the broader significance of the German Federal Institute for Drugs and Medical Devices (BfArM) as the authority for medical devices in Germany.

Seminar language

The seminar language will be English. It is also possible to pose questions in German.

Your speakers

Dr. Ekkehard Stößlein
Federal Institute for Drugs and Medical Devices (BfArM), Bonn, Germany

Departement Medical Devices,
Specialism Active Medical Devices

Michael Wimmer
**Sträter law firm,
Bonn, Germany**

Lawyer, Specialism in Medical Device topics

Limited number of attendees

Please take note that this seminar is restricted to 20 participants. This limitation, a feature of all FORUM seminars, will give participants the opportunity for a thorough discussion of the complex issues to be covered by the programme.

Who should attend

This seminar will be of benefit to all co-workers of the pharmaceutical and medical device industry, especially from the following departments:

- Legal
- Regulatory Affairs
- Clinical Research
- Quality Management
- Marketing

This seminar will be addressed to new staff members in these fields of work but it is also a very good refresher course for co-operators with first experiences.

Programme 9.00 a.m. - 5.00 p.m.

> 9.00
European framework in medical device law
Dr. Ekkehard Stößlein

- New approach review
- European framework: significance of the CE mark, MEDDEV, Notified Bodies recommendations, etc.

> 10.00
German medical device law
Michael Wimmer

- Amendment of the German Medical Device Act
- Definition of medical device and demarcation between medical devices and pharmaceuticals or cosmetics
- Classification and conformity assessment

> 10.45 Coffee break

> 11.00
Clinical investigation and clinical trial - the legal framework
Michael Wimmer

- Notification requirements
- Voting of the ethics committee
- Requirements before and duties during the clinical trial
- Exemptions to clinical trials

> 12.15 Lunch

> 13.45
Marketing and distribution of medical devices
Michael Wimmer

- Distribution channels, distribution agreements and sales representative agreements
- Advertising for medical devices
- Operation of medical devices
- Legal framework for reimbursement

> 14.45
Market surveillance: rights and duties of the competent authorities
Dr. Ekkehard Stößlein

- Competent authorities in Europe and their duties
- Quality assurance of the medical device market surveillance

> 15.30 Coffee break

> 15.45
Vigilance (monitoring and reporting system)
Dr. Ekkehard Stößlein

- Basics of the vigilance system
- Risk assessment by the higher federal authorities
- Risk management by the competent authorities

> 16.30
Liability and compliance
Michael Wimmer

- Liability of manufacturers and users
- Compliance (cooperation industry and medical facilities)

> 17.00 End of seminar

Registration under registration@forum-institut.com or Fax +49 6221 500-555

Registration Form

Yes, I will attend the Seminar

☐ Step by step through Medical Device Law

☐ I am interested in more information about FORUM-Events and I agree that this information is sent to me by e-mail.

Name

Position/Department

Company

Street

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at office

Date, Signature

How to register

Registration: +49 6221 500-501

Conference-No. 11 07 280 I

Internet:
www.forum-institut.com

Date/Venue:
Monday, 11 July 2011 in Bonn
8.30 a.m. Registration; 9.00 a.m. - 5.00 p.m.
Seminar
Hilton Hotel
Berliner Freiheit 2 · 53111 Bonn
Tel. +49 228 7269-0 · Fax +49 228 7269-700

Fee:
€ 860,00 (+ 19% VAT)
The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

Hotel accommodation:
A limited number of rooms has been reserved at the hotel and are subject to availability. Please book at least six weeks prior to the seminar to obtain a hotel room at the discounted rate.
All bookings should be made directly with the hotel quoting FORUM-Institute and the seminar no.

Any Further Questions?

I am gladly at your disposal should you have any further questions about the seminar.

Dr. Diana Feidt
Conference Manager
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Cancellation Policy

Our general terms and conditions apply (as of 19 December 2008) and are available upon request. We can send them to you anytime or you can find them on the internet at www.forum-institut.de/agb_en

We recommend taking out a seminar cancellation insurance. More details at www.erv.de