SEMINAR

FORUM
40 YEARS

The Person Responsible for Regulatory Compliance

The MDR and new responsibilities and challenges for medical device companies

TOPICS

- Legal and regulatory requirements for the PRRC in Europe
- Interfaces within the company
- Effective preparation and practical challenges
- Audit and compliance readiness
- Liability risk for the PRRC and manufacturer

YOUR SPEAKERS

Dr Dr Adem Koyuncu
Law firm Covington & Burling LLP,
Brussels & Frankfurt

Dr Arkan Zwick
CROMA PHARMA GmbH,
Leobendorf, Austria

14 MAY 2020 IN AMSTERDAM/LEIDEN

Aims and objectives

Since the publication of the new EU regulatory framework for medical devices, many innovations need to be implemented. One of them is the person responsible for regulatory compliance (PRRC).

This 'responsible person' has important tasks and responsibilities, which, together with liability risk, will be discussed in detail in this seminar.

How must the responsibilities be defined? What are the internal interfaces? What preparation is required for this new role?

Our seminar will address precisely these questions and show you how to make the necessary preparations. Our team of experts will give you practical tips on how to meet the upcoming challenges and explain the most important issues in practice.

Who should attend?

This seminar is aimed at managers as well as qualified and responsible people in medical device and pharmaceutical companies, as well as participants aspiring to this role, particularly those in the following departments:

- Vigilance and Regulatory Affairs;
- Quality Assurance and Management; and
- Management and Law.

YOUR SPEAKERS

Dr Dr Adem Koyuncu
Law firm Covington & Burling LLP, Brussels & Frankfurt

Lawyer and Medical Doctor,
Partner in the Brussels and Frankfurt offices

Dr Arkan Zwick
CROMA PHARMA GmbH, Leobendorf, Austria

Regulatory Affairs Director

Learning success control

At the end of the course you have the opportunity to take a multiple-choice test online. Upon successful completion, you will receive an extra certificate. We will send you the access data after the training course via email.

The PRRC: tasks and duties

Your programme from 09:00 - 17:00

09:00

The MDR 2017/745 and its impact

- Regulation overview - major impacts
- Transition period excursus: Art. 120 (3) on significant changes
- Implementation plan

09:30

Legal and regulatory requirements for the PRRC in Europe

- Who needs a PRRC and when?
- Organisational integration, hierarchy and governance issues
- Expertise and qualification
- Task and responsibilities
- Conformity assessment of products
- Technical documentation
- Declaration for investigational products

10:45 Coffee break

11:00

Workshop: PRRC interfaces within the company

- Marketing & sales: Art. 7: Claims
- Production and quality
- Clinical - limitations on equivalency and special procedures
- Regulatory survey process and certification
- R&D process: ensure compliance
- National responsible persons - how to organise collaboration
- Delegation (to external parties) and deputising opportunities
- PRRC - overview and practical challenges

12:30 Lunch

13:30

Effective preparation and practical challenges

- Are you prepared? What comes first? What follows?
- Impact on labelling requirements
- Handling off-label use
- MDR implementation steps and instruments
- PRRC implementation options
- Required SOPs; adjusting internal processes
- Audit and compliance readiness
- Industry examples
- Q&A

15:00 Coffee break

15:15

Liability risk for the PRRC and manufacturer

- Legal framework under civil, criminal, labour and device law
- MDR impact on liability risk
- Manufacturer liability vs PRRC liability
- Specific requirements for personal PRRC liability
- Liability risk for manufacturers and legal representatives
- Outsourcing, delegation and the impact on liability risk
- Special practical cases on liability issues
- Discussion of liability risk mitigation measures

The Person Responsible for Regulatory Compliance

REGISTRATION UNDER

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REGISTRATION FORM

Yes, I will attend

☐ The Person Responsible for Regulatory Compliance
14 May 2020 in Amsterdam/Leiden

☐ Yes, I agree that FORUM Institut may inform me about events by:
☐ email; and/or ☐ telephone.
I may withdraw my consent at any time.

Name

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Company

Street

Post code, city, country

Tel. no./Fax no.

E-mail

Contact person at office

Date, signature

Date and venue
Thursday, 14 May 2020 in Amsterdam/Leiden
08:30 registration; 09:00-17:00 seminar

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Fee
€ 1090.00 (+ 21% VAT)
The fee includes course documentation (including free download), the online test as well as refreshments, lunch and a certificate. You will receive an invoice as well as confirmation.

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CANCELLATION POLICY

Our general terms and conditions (as of1 January 2016) apply and are available upon request.We can send them to you at any time. Alternatively, you can access them online at www.forum-institut.com/t&c

YOUR CONTACT

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