LIFE SCIENCE ACADEMY

New MDR/IVDR Requirement: the ‘Person Responsible for Regulatory Compliance’ (PRRC)

Responsibilities & challenges for medical device companies within MDR & IVDR

Type	Date	Language	Location
Online Training - Limited number	27 and 28 May 2021	English	Online

ABOUT

Since the publication of the revised EU regulatory framework for medical devices (MDR 2017/745 and IVDR 2017/746), many innovations need to be implemented to insure compliance to the new environment. One of them is the Person Responsible for Regulatory Compliance (PRRC). This "responsible person" has important tasks and duties in the manufacturer organization.

In this course, the background of the revised regulations as well the tasks and responsibilities of the PRRC are explained in detail. It could be difficult for a single person to fulfil all of them. The legislation therefore provides for the tasks to be distributed among more than one person. But how do responsibilities have to be defined and how can the PRRC insure to have oversight on the most critical processes? What are the internal interfaces and what should be prepared for this new role?

The course is dedicated exactly to these questions. It shows ways and possibilities how to make the necessary preparation and will give you practical tips to meet the challenges and find out more about the most important aspects for the daily practice.

PROGRAMME

MODULE 1
The new Regulation on Medical Devices

- Introduction, regulation overview and impact on industry
- Transition period
- Latest updates and MDCG Guidance
- Industry experience on MDR preparation

Legal requirements for the PRRC

- Legal framework for the PRRC
- Who needs a PRRC and when?
- Organizational integration and hierarchy
- Qualifications, tasks and responsibilities
- Options how to implement

Liability risks for the PRRC

- Fundamentals of civil, criminal, labor and medical device law
- Liability of the company for damage claim
- Individual liability
- Risk mitigation measures

MODULE 2
Tasks of the responsible person, what is new in the MDR

- Conformity check of products and release
- Technical documentation and EU declaration of conformity
- Technical documentation on post market
- Reporting obligations
- Declaration for investigational products
- PRRC oversight and practical challenges – the release matrix

PRRC interfaces – Examples for processes / SOPs

- Marketing/Sales. Impact of Art 7. Release of advertisement materials
- R&D process: is the PRRC in the core team, how to insure compliance at early stage?
- Production/Quality – OOS, CAPA processes
- Clinical Evaluation: Limitations to equivalency, special procedures for thigh risk devices, SSCP and the role of the PRRC.
- Regulatory survey process and Conformity Assessment processes and the involvement of the PRRC
- Chang control and life cycle, Reportable changes and significant changes (Art 120), PSUR processes
- Vigilance and trend reporting Art 88 Challenge.

WHO SHOULD ATTEND

The seminar is first aimed at qualified and responsible persons in medical devices and pharmaceutical companies and participants, who have ben aspiring to these tasks. The seminar is also valuable for all staff having interference with the PRRC to improve understanding of its role and responsibilities. Employees of the following departments profit from our seminar:

- Vigilance & Regulatory Affairs
- Quality Assurance & Quality Control
- Management and Legal

Participant experience
Experience with medical devices regulatory processes in Europe may be helpful.

TEACHING METHODS

The training will consist in lectures, case studies discussion and Q&A sessions.

LECTURERS

Arkan Zwick

Corporate Regulatory Affairs Director at CROMA Pharmaceutical, Austria

Mr. Arkan Zwick is the Corporate Regulatory Affairs Director of CROMA Pharmaceutical, Austria. CROMA is a private global pharmaceutical and surgical company with products in ophthalmology, orthopedic and aesthetic dermatology. With more than eleven years of regulatory professional experience Arkan´s role includes regulatory advocacy for drug, medical device, combi products and cosmetic compliance projects as well as in house legal advice for contract management, merger and acquisition, and intellectual property projects. He is responsible for the company's regulatory compliance in the EU working with several notified bodies and for global market authorizations in the Americas and Asia-Pacific. Arkan has a master's degree in Law from the University of Vienna and a PhD in European Law. His expertise includes in house legal and regulatory consulting as well as lecturing at the University of Applied Sciences in Vienna and scientific board member and speaker on life cycle conferences and trainings. He is fluent in English, German and French.

AT THE END OF THE TRAINING, YOU WILL BE ABLE TO

- Appropriately understand and define the PRRC responsibilities
- Know what the internal interfaces are and what should be prepared for this new role

USEFUL INFORMATION

Online Training – 2 modules

May 27th, 2021 9:30 am – 12:30 pm CET
May 28th, 2021 9:30 am – 12:30 pm CET

After the registration, you will receive all details about the connection.

The course will proceed with a minimum number of participants. Should this number not be reached the registered participants will be notified one week prior to the commencement of the course.

REGISTRATION FEE

Early Bird: € 660,00* (until 28 April 2021)

Ordinary: € 850,00*

Freelance – Academy – Public Administration:** € 430,00*

* *for Italian companies: +22% VAT*

**Early Bird discount not applicable to Freelance – Academy – Public Administration fee

The fee includes: tuitions, organizational office assistance, teaching materials and attendance certificate that will be sent after the training via e-mail.

SEDE DEL CORSO

Online interactive training on Zoom platform.
LS Academy will provide the access link to the virtual platform a few days before the training.