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LSA2019
Lübeck Summer Academy on Medical Technology

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Legal responsibility and liability of the new Responsible Person for Regulatory Compliance

LSA2019 - Lübeck Summer Academy on Medical Technology
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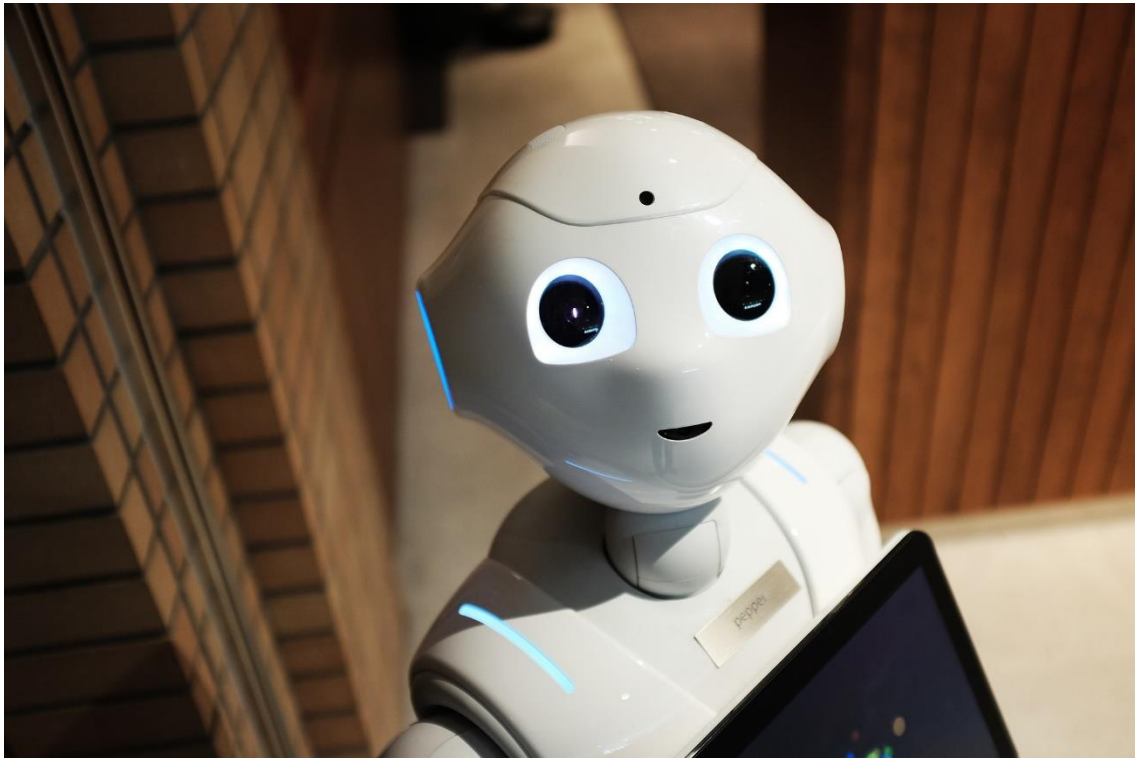
Will robots take our jobs?



Picture: StockSnap auf Pixabay

New job available

Person Responsible for Regulatory Compliance

“PRRC”

Art.15 of the Medical Device Regulation (MDR)

Is becoming PRRC a job for me?

Picture: Pixabay

Outline

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- Who is the PRRC?
- For which economic operators is the PRRC relevant?
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III. Legal responsibilities of the PRRC

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- Job description
- Several PRRCs

IV. Liability

- Criminal liability
- Civil liability
- Actual risk of liability

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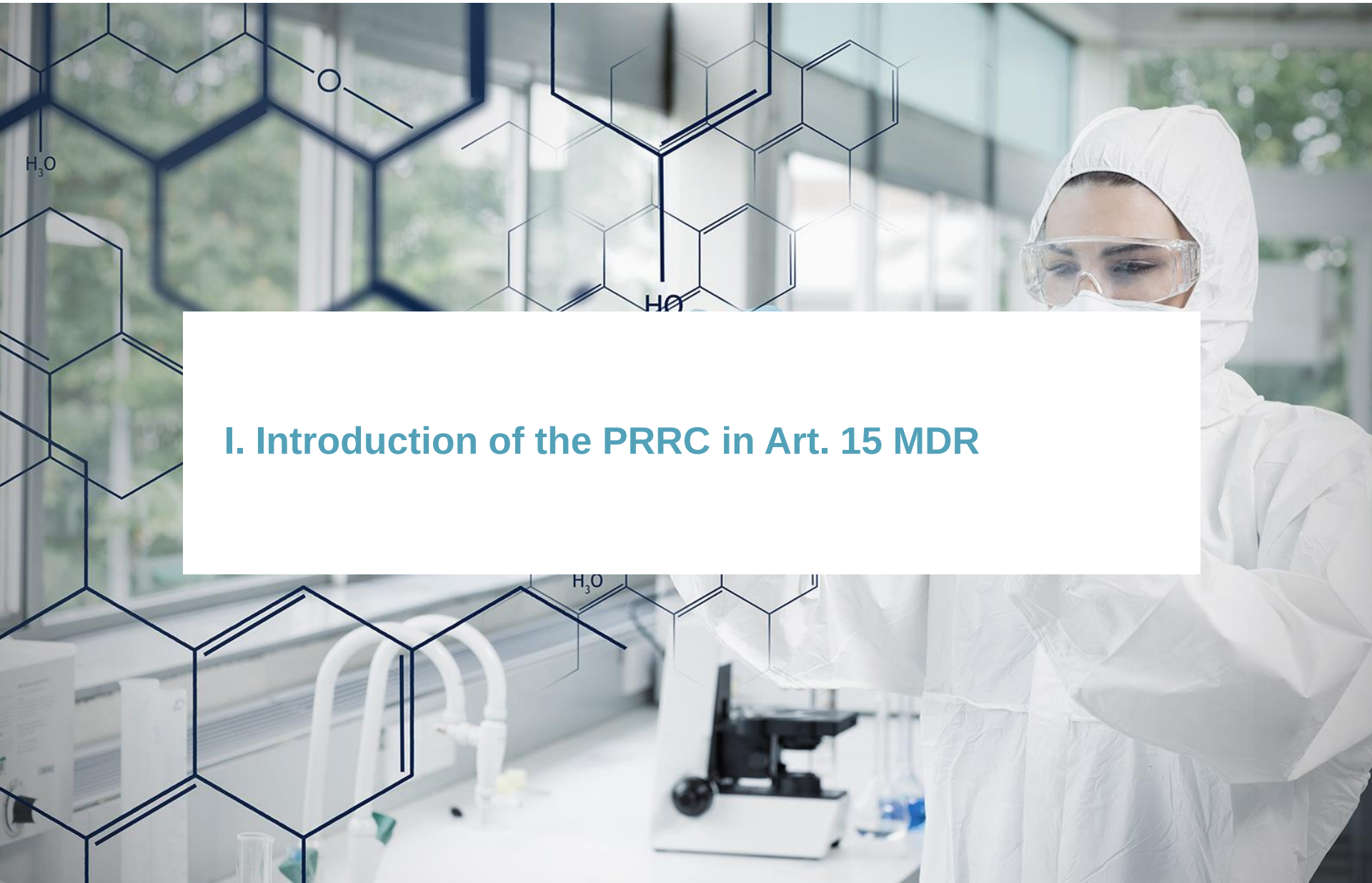

I. Introduction of the PRRC in Art. 15 MDR

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Who is the PRRC?

- Recital 34 MDR

It should be ensured that supervision and control of the manufacture of devices, and the post-market surveillance and vigilance activities concerning them, are carried out **within the manufacturer's organization** by a **person responsible for regulatory compliance** who fulfils minimum conditions of qualification.

Orientation to the German „Sicherheitsbeauftragter“ pursuant to Sec. 30 Medical Device Act („MPG“) - but more comprehensive tasks

I. Introduction of the PRRC in Art. 15 MDR

Who is the PRRC?

- Art. 15 (1) 1 MDR

  Manufacturers shall have available within their organisation **at least one person responsible for regulatory compliance** who possesses the requisite expertise in the field of medical devices.

- Principle: **Integration within the organisation**

- Designation of **several PRRCs** is possible

  - If a number of persons are jointly responsible (…) respective areas of responsibilities shall be stipulated in writing, Art. 15 Abs. 4 MDR
  - Economic operators have to provide the contact details of the person or persons responsible for regulatory compliance (Annex VI, No. 1.4; Art. 31 MDR)

I. Introduction of the PRRC in Art. 15 MDR

For which economic operators is the PRRC relevant?

- Art. 15 (1) MDR

  Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance (…).

- Art. 15 (6) MDR

  Authorised representatives shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance (…).

- Art. 16 (1) MDR

  A **distributor, importer or other natural or legal person** shall assume the obligations incumbent on manufacturers if it does (…).

I. Introduction of the PRRC in Art. 15 MDR

Special situations

- **Micro and small enterprises – Art. 15 (2) MDR**
  - criteria: less than 50 employees and less than 10 million Euro annual turnover
  - not required to have the PRRC within their organization
  - but shall have **such person permanently and continuously at their disposal**

- **Authorised representative – Art. 15 (6) MDR**
  - shall have **permanently and continuously** at their disposal at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union.
  - Recital 35 MDR
    (…) requirement [of the authorized representative] of having available a person who fulfils minimum conditions of qualification **which should be similar to those** for a manufacturer's person responsible for regulatory compliance.

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II. Qualification requirements for the PRRC

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Art. 15 (1) MDR

- **Manufacturers** shall have available within their organisation at least one person responsible for regulatory compliance **who possesses the requisite expertise in the field of medical devices**.

- Demonstration of requisite expertise by:
  - a diploma, certificate or other **evidence of formal qualification**, **awarded on completion of a university degree** or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and **at least one year of professional experience** in regulatory affairs or in quality management systems relating to medical devices; **or**
  - **4 years of professional experience** in regulatory affairs or in quality management systems relating to medical devices.

II. Qualification requirements for the PRRC

Art. 15 (6) MDR

- **Authorised representatives** shall have permanently and continuously at their disposal at least one person responsible for regulatory compliance **who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union**.

- Same wording as regards the expertise of authorised representative´s PRRC in Art. 15 (6) 2 MDR.

- Special feature: **Manufacturers of custom-made products** can demonstrate the required expertise through **two years of professional experience** in a corresponding production area (see Article 15 (1) 3 MDR)

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III. Legal responsibilities of the PRRC

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Minimum responsibilities of the PRRC, Art. 15 (3) MDR

The PRRC shall at least be responsible for ensuring that:

- the **conformity of the products** is appropriately **checked** in accordance with the **quality management system** under which the devices are manufactured, before a device is released

- the **technical documentation** and the **EU declaration of conformity** are drawn up and kept up-to-date

- the **reporting obligations** referred to in Article 87 to 91 are fulfilled

- the **post-market surveillance obligations** are complied with in accordance with Art. 10 (10)

- in the case of **investigational devices**, the **statement** referred to in Section 4.1 of Annex XV is issued

III. Legal responsibilities of the PRRC

Areas of responsibility of the PRRC

- The minimum responsibilities pertain to the areas
  - Quality management
  - Regulatory affairs
  - Vigilance

- Prohibition of discrimination Art. 15 (5) MDR

  The person responsible for regulatory compliance **shall suffer no disadvantage** within the manufacturer's organisation in relation to the proper fulfilment of his or her duties, regardless of whether or not they are employees of the organization.

Possible delegation of tasks?
Supervision?

III. Legal responsibilities of the PRRC

Job description

- Job description is key for the responsibility of the PRRC → liability (!)
- Clear and unambiguous wording
- Determination of the PRRC´s respective rights and competencies to ensure PRRC´s ability to conduct all relevant tasks independent from any instructions
- Determination of clear rules for cases of diverging opinions within the company, e.g. as regards release of products, notification of incidents
- Documentation of all resources that are available to PRRC

III. Legal responsibilities of the PRRC

Several PRRCs

- Art. 15 (4) MDR → Possibility that several persons together responsible for the regulatory compliance of the products.
- **Important**: In cases of work sharing the clear determination of the respective working areas in writing is key

Organisation chart + SOPs + Job description

III. Legal responsibilities of the PRRC

Several PRRCs

- Useful allocation of responsibilities on the basis of individual skills and competencies
- Practical implementation of allocation of tasks?
  - Allocation based on the tasks outlined in Article 15 (3) MDR, e.g.
    - A PRRC → quality management
    - A PRRC → regulatory affairs
    - A PRRC → vigilance
  - Allocation based on products or product groups
- Indicating all PRRCs at registration in Eudamed
- **Each** PRRC must have and proof the required expertise pursuant to Art. 15 (1) MDR.
- Liability of each PRRC only conceivable within the individually allocated field of tasks

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IV. Liability

IV. Liability

Criminal law liability?

- Art. 113 MDR - Sanctions

  *„The Member States shall lay down the rules on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive. The Member States shall notify the Commission of those rules and of those measures by **25 February 2020** and shall notify it, without delay, of any subsequent amendment affecting them.“*

- On national level fine and penal provision are to be expected

- Revision of the German Medical Devices Act (*Medizinproduktegesetz*, “MPG“), particularly the national provisions (sec. 40 *et sequ*. MPG) for the adaption of the MPG to the MDR are to be expected.

IV. Liability

Criminal law liability?

- Applying general criminal law (Criminal Law Act, *Strafgesetzbuch, "*StGB*"*) Criminal liability is generally conceivable, e.g. any body injury offences (sec. 223 *et sequ*. StGB)
- Ground of liability: Omission of a duty allocated to the PRRC
- **BUT**: Under German law, additional requirements have to be fulfilled for criminal liability through an omission → guarantor status, causality und fault (purpose or negligence)

IV. Liability

Civil law liability?

- Most important liability basis for the damaged party → **Manufacturer´s liability** for product flaws according to the product liability act.
  - Advantage: Liability is independent from any fault, liability covers all damage, material and non-material damage
  - Manufacturer is “closer“ for damaged party

- Civil law liability of the PRRC is conceivable on the basis of general civil law criteria (sec. 823 (1), (2) Civil Law Act, *Bürgerliches Gesetzbuch*, “BGB”)
  - Important requirement: (i) Breach of duty, causal and (ii) attributable relationship between breach of duty and occurred damage (iii) as well as willful or negligent fault
  - Civil liability is limited to the breach of duty within the allocated responsibilities.

IV. Liability

De facto risk of liability

- to be considered rather low as:
  - Requirements for a criminal law liability are high
  - In the course of a civil law liability case, normally the individual PRRC is not known to the damaged party, i.e. the damaged party is only aware of the manufacturer and/or distributor
  - The damaged party will normally address any compensation claim to the solvent manufacturer and/or distributor but not to an individual person
  - No applicable/comparable judgments available, e.g. as regards the German safety officer under the MPG (Sicherheitsbeauftragter im Medizinprodukterecht) or the graduated plan officer in the AMG (Stufenplanbeauftragter im Arzneimittelrecht);
  - As regards the liability in the inner relationship between the PRRC as employee and the manufacturer as employer, under German law, the liability privilege of the inner-company damage compensation (Haftungsprivilegierung des innerbetrieblichen Schadensausgleichs).

PRRC wanted - what about you? Interested?

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End

Questions + answers + discussion

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- Susanna Dienemann ist seit 2012 für die Kanzlei Wachenhausen Rechtsanwälte tätig und seit 2015 Partnerin der Kanzlei. Frau Dienemann berät schwerpunktmäßig zu Fragen aus dem Bereich der klinischen Forschung und hierbei insbesondere zur Vertragsgestaltung. Außerdem unterstützt Frau Dienemann Mandanten bei Fragestellungen aus dem Bereich des regulatorischen Rechts bezogen auf Arzneimittel und Medizinprodukte, sowie zu Fragestellungen aus dem Heilmittelwerberecht und zur Korruptions-Vorbeugung im Heilmittelwesen.
- Im Rahmen zweier Secondments in der Rechtsabteilung der Pharmaceuticals Division der Bayer AG (ehemals: Bayer Pharma AG) sammelte Frau Dienemann wertvolle Erfahrung als In-house Counsel. Vor dem Beginn ihrer Tätigkeit in der Kanzlei Wachenhausen Rechtsanwälte war Frau Dienemann für Arnold & Porter Kaye Scholer LLP (ehemals: Arnold & Porter (UK) LLP) in London als Mitglied der Praxisgruppe Arzneimittel, Medizinprodukte und Lebensmittel tätig.
- Frau Dienemann studierte an der Ludwig-Maximilians-Universität München und am Trinity College Dublin.
- Frau Dienemann gibt Seminare und veröffentlicht regelmäßig zu Fragestellungen aus dem Arzneimittel- und Medizinprodukterecht. Sie berät auf Deutsch und Englisch.