

## **Understanding the requirements of the MDR 2017/745 regarding person responsible for regulatory compliance**

Ajra Sinanova\*, Lora Atanasovska, Marija Davceva Jovanoska, Elizabetha Karadzinska, Nada Popstefanova, Olivera Paneva

*Pharmaceutical Chemical Cosmetic Industry ALKALOID AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje, Republic of North Macedonia*

### **Introduction**

Compliance of the medical devices has become progressively more complex with the introduction of the EU Medical Device Regulation 2017/745. One of the newly introduced requirements of the European Union's Medical Device Regulation (MDR) is appointment of a person responsible for regulatory compliance (PRRC). The focus of this regulatory requirement is mainly to improve control over manufacturing processes, post-marketing surveillance, clinical evaluation and medical device vigilance. The ultimate goal of the manufacturer is to ensure conformity and safety of the medical device.

### **Availability, liability and qualification requirements of the PRRC**

The MDR requires every manufacturer of medical devices to appoint a PRRC within their organization. The authorized representative of a manufacturer located outside the EU should also appoint a PRRC. The PRRC for the manufacturer and its authorized representative cannot be the same. According to the MDR, the authorized representative is supposed to add additional level of scrutiny. If the same person acts as PRRC for both, the additional level of scrutiny would be compromised. The appointed PRRC for the manufacturer and for the authorized representative should be part of the organization. Exception to this is possible only for micro and small organizations. Micro and small manufacturers can subcontract the responsibilities of a person responsible for regulatory compliance to a third party.

Medical devices manufacturers and their authorized representatives must observe a multitude of legal requirements which must be fulfilled. According to the MDR, the person responsible for regulatory compliance is not personally liable. The liability requirements of the MDR refer to the manufacturer and its authorized representative as an entity. Different national legislation may enforce liability on PRRC who infringe Article 15 of the MDR, so these laws should certainly be taken into consideration.

There are two ways to fulfill the qualification requirements for PRRC. According to the MDR and the MDCG 2019-7 guidance document, the PRRC must have: expertise in the field of medical devices, university degree, diploma, or some other formal qualifications and at least one year of experience in European regulatory affairs or quality management system related to medical devices. If no university degree, diploma, or other qualification, the PRRC must have four years of professional experience in European regulatory affairs or quality management system related to medical devices. It is important to emphasize here that any qualification acquired outside the EU should be recognized by an EU Member State as equivalent to the EU corresponding qualification.

More than one PRRC can be appointed by the companies and the responsibilities can be divided, as long as the qualification requirements are met and the division of responsibilities is documented.

## Roles and responsibilities of a person responsible for regulatory compliance

The roles and responsibilities of a person responsible for regulatory compliance is mandated in Article 15, clause 3 of the EU MDR 2017/745. The regulation requires all manufactures and authorized representatives to have a designated employee in their company who is responsible for regulatory compliance with the applicable EU MDR. What are the responsibilities of a PRRC?

EU MDR outlines five major responsibilities for a PRRC, each described with detailed activities for ensuring conformity and safety of the medical devices. The PRRC is responsible for ensuring that (Jury & Pinsi, 2021):

1. the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;
2. the technical documentation and the EU declaration of conformity are drawn up and continuously updated;
3. the post market surveillance obligations are compiled. The PRRC is responsible for ensuring that post-market surveillance system is planned, established, documented, maintained and kept up-to-date;
4. the reporting obligations referred to vigilance are fulfilled. The PRRC is responsible for ensuring that vigilance system (reporting of serious incidents and field safety corrective actions) and implementing acts is established;
5. in the case of investigational devices, that the signed statement by the natural or legal person responsible for the manufacture of the investigational device that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical investigation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subject.

Alkaloid AD Skopje, as a manufacturer of medical devices has allocated the PRRC responsibilities to five different persons. Each person is individually responsible for:

- ensuring compliance with QMS (batch release not included) and ensuring that EU declaration is drawn up and updated continuously;
- ensuring compliance of the medical device with batch release included;
- ensuring that the technical documentation is drawn up and ensuring that in the case of investigational devices, the statement referred to

in Section 4.1 of Chapter II of Annex XV of the MDR 2017/745 is issued for clinical investigations performed with devices which do not bear the CE marking of conformity;

- ensuring that the technical documentation is kept up to date, ensuring that the post-market surveillance obligations are complied with in accordance with Article 10 of the MDR 2017/745 and ensuring that in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV of the MDR 2017/745 is issued for clinical investigations performed with devices which bear the CE marking of conformity;
- ensuring that the reporting obligations referred to in Articles 87 to 91 of the MDR 2017/745 regarding vigilance are fulfilled.

The responsibilities of the PRRC for the EU authorized representative ALKALOID – INT d.o.o. are allocated to two persons.

## Conclusion

The requirements of the MDR regarding PRRC are not completely new. Under the MDR, the tasks now outlined as responsibilities of this new role of PRRC, would already have existed as part of the Quality Management System. What is new under MDR is the requirement to designate a specific person or persons as PRRCs. It is critical that the role of PRRC is not recognized only formally, but also as a crucial role to foster a culture of compliance awareness within the organization and to ensure safety of the medical device.

## References

- Jury A., Pinsi, M., 2021. Person responsible for regulatory compliance (PRRC) - MDR/IVDR Article 15, British Standards Institution (BSI) StandardsLtd Available at >  
<https://www.bsigroup.com/globalassets/meddev/localfiles/fr-fr/whitepapers/wp---person-responsible.pdf>
- MDCG 2019-7 Guidance on Article 15 of the Medical Device Regulation (MDR) and in vitro Diagnostic Device Regulation (IVDR) regarding a ‘person responsible for regulatory compliance’ (PRRC). Available at:  
<https://ec.europa.eu/docsroom/documents/36166>
- Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, 2017. Official Journal of the European Union. Available at: <https://eur-lex.europa.eu/>