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)

「規制遵守に関する責任者(PRRC)に関するガイダンス

原文の日本語訳は参考です。

PRRC (MDR および IVDR の第 15 条) 製造業者は少なくとも 1 人の規制遵守に関する責任者を設置する事	
資格要件	以下の①又は②いずれかの要件を満たす事 ① 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. (関係する加盟国により同等と認められる法学、医学、薬学、工学、又はその他の関連する科学分野に関する大学の学位又は学問の修了時に授与される卒業証書、証明書、又はその他の正式な資格の証明、及び少なくとも 1 年間の規制関連又は医療機器の品質管理システムにおける専門的経験) 又は ② four years of professional experience in regulatory affairs or in quality management systems relating to medical devices. (規制関連業務又は医療機器の品質管理システムにおける 4 年間の専門的経験)
義務	◆ 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. (自社の組織内に少なくとも一人の PRRC を置く事) ◆ Organisations with more than one legal manufacturer under the parent company would need to ensure that each legal manufacturer has its own PRRC. (親会社の下に複数の legal manufacturer を持つ組織は、その legal manufacturer 毎に PRRC を置く事) ◆ As to the location of the PRRC, it is important that a close linkage, of a permanent and continuous nature, is established between the PRRC and the manufacturing activities. For this reason, for manufacturers located outside the EU, it must be assumed that the PRRC should also be located outside the EU. On the other hand, for manufacturers located in the EU, it must be assumed that the PRRC should also be located in the EU. (EU 域外の manufacturer は、EU 域外に PRRC を置く必要がある。また、EU 域内の manufacturer の場合には EU 域内に PRRC を置く事)

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製造業者の区分	***Manufacturers*** Enterprises which employ at least 50 persons and whose annual turnover and/or annual balance sheet total exceeds EUR 10 million. (従業員 50 人以上、及び年間売上、又は総資産が 1,000 万ユーロを超える製造業者)	***Micro and small manufacturers*** Enterprises which employ fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million. (従業員 50 人未満及び年間売上、又は総資産が 1,000 万ユーロを超えない製造業者)
		Micro and small manufacturers ◆ Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal. (Micro and small manufacturers は自社の組織内に PRRC を置く必要はない。ただし、そのような人物を恒久的および継続的に使用できる状態を確実にしなければならない。) ◆ The micro or small enterprise may subcontract the responsibilities of a person responsible for regulatory compliance to a third party, so long as the qualification criteria is met and the manufacturer can demonstrate and document how they can meet their legal obligations. For example, the PRRC may be part of an external organisation, with which the manufacturer has established a contract laying down provisions so as to ensure the permanent and continuous availability of that party. The contract should mention the relevant person's qualifications allowing compliance with points a and b of Article 15 (1). (Micro and small manufacturers は規則遵守の責任を第三者に委託することができる。ただし、資格要件の基準が満たされ、製造業者がその資格要件を満たすことを証明し文書化が必要。例として、PRRC が外部組織である場合、製造業者は恒久的および継続的に使用できる規定等を定めた契約を結んでいることが必要。契約書は MDR、IVDR の第 15 条（1）の a および b を満たす関係者の資格を記載) ◆ For micro or small enterprises located in the EU, it must be assumed that any person to be permanently and continuously at their disposal should be also located in the EU. (EU 域内の Micro and small manufacturers の場合には、恒久的および継続的に使用できる人物は EU 域内に持つ必要がある)

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役割と責任	"The person responsible for regulatory compliance shall at least be responsible for ensuring that: (PRRC の責任) ◆ 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;" Manufacturers "of devices, other than investigational [performance study] devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device" (Article 10(9) of the MDR and Article 10(8) of the IVDR). (機器が品質管理システムに従って製造され、その適合性が適切に確認されること) ◆ the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;" Manufacturers "[of devices other than custom-made devices] shall draw up and keep up to date technical documentation for those devices" (Article 10(4) of the MDR and IVDR) and "shall draw up an EU declaration of conformity" (Article 10(6) of the MDR and Article 10(5) of the IVDR). (技術文書と適合宣言書が最新の状態に維持されていること) ◆ the post-market surveillance obligations are complied with in accordance with Article 10(10) [Article 10(9) of the IVDR];" Manufacturers "of devices shall implement and keep up to date the post-market surveillance system" (Article 10(10) of the MDR and Article 10(9) of the IVDR). (市販後監視義務を遵守すること) ◆ the reporting obligations referred to in Articles 87 to 91 [Article 82 and 86 of the IVDR] are fulfilled;" Manufacturers "shall have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 87 and 88" (Article 10(13) of the MDR and Article 10(12) of the IVDR). (インシデントの記録、報告義務を履行すること)

製造業者と Authorised representatives で同一の人物を PRRC として任命可能か。

The person responsible for regulatory compliance for an authorised representative and for an 'outside EU' manufacturer cannot be the same person. There is a clear desire within the Regulations for the authorised representative to be adding an additional level of scrutiny and ensure that the supervision and control of the manufacture of devices, and the relevant post-market surveillance and vigilance activities are adequately effected. If the two roles were conducted by the same person, the additional level of scrutiny would be undermined. For the same reason, the PRRC of a micro or small enterprise and the PRRC of the authorised representative of that same enterprise shall not belong to the same external organisation.

(欧州代理人と EU 域外外製造業者の PRRC は同一にできない)