

Medical Device White Paper Series

Person responsible for regulatory compliance (PRRC) - MDR/IVDR Article 15

An overview of the requirements
and practical considerations

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1. Overview

With the Medical Device Regulation – MDR (EU 2017/745) and In Vitro Diagnostic Regulation – IVDR (EU 2017/746), European regulators aim to ensure companies have a regulatory expert – a Person Responsible for Regulatory Compliance (PRRC) – at their disposal, to ensure that the company is meeting certain specific EU requirements.

The regulators felt it was important to have an identified individual as PRRC to ensure the compliance of released devices, as well as the post-market surveillance (PMS) and vigilance activities concerning those devices (MDR recital 34, IVDR recital 33). Moreover, where a manufacturer is located outside the EU and an Authorised Representative (AR) is required, a secondary control is expected to be conducted by the PRRC of the AR in order to verify regulatory compliance of the devices produced by those manufacturers.

This paper provides an overview of the requirements of MDR/IVDR Article 15 and as interpreted by the 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)».

Note: The UK Medical Device Regulations 2002, which remain in place in Great Britain from 1st January 2021, do not require a PRRC to be appointed but a “Responsible Person” is required whose responsibilities are more akin to those of the Authorised Representative in the EU. It is worth underlining that the UK Medical Device Regulations 2002 (as amended by the EU Exit Regulations of 2019 (SI 791) and 2020 (SI 1478)) enshrine the EU Directives (Directive 90/385/EEC on active implantable medical devices, Directive 93/42/EEC on medical devices and Directive 98/79/EC on in vitro diagnostic medical devices) into UK law until they are revised by the UK Competent Authority.

2. Requirements for PRRC in the Regulations and in the MDCG 2019-7

Both the manufacturers and the Authorized Representative are required to have within their organisation, or at their disposal, at least one PRRC who possesses the proper expertise and qualification in the field of medical devices or in vitro medical devices, as applicable, in the European Union. The responsibilities of the PRRC are also set in the Regulations and interpreted in the MDCG Guidance 2019-7, which may be reviewed in due course.

The following sections analyse in detail the requirements of this new role within medical device organizations.

2.1. Qualifications of the PRRC

The sum of required qualifications and professional experience of the PRRC are either of the following as specified in Article 15 and as clarified by the MDCG Guidance 2019-7.

Table 1: Summary of the required qualifications for the PRRC

OPTION.	QUALIFICATION	PROFESSIONAL EXPERIENCE
1	<p>"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"¹</p> <p>"Any qualification acquired outside the EU, including any university diplomas or certificates, should have been recognised by an EU Member State as equivalent to the EU corresponding qualification*."²</p>	<p>"At least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices [in vitro diagnostic medical devices]"³</p> <p>(the professional experience in regulatory affairs or in quality management systems should be related to the EU requirements in the field – MDCG Guidance 2019-7)</p>
2		<p>"Four years of professional experience in regulatory affairs or in quality management systems relating to medical devices/ in vitro diagnostic medical devices"⁴</p>
<p>* The MDGC Guidance 2019-7 interpreted this in relation to PRRC within a manufacturer: it is opinion of the authors of this white paper that these could be extended to the PRRC within an AR.</p>		

The professional experience in regulatory affairs or in quality management systems is expected to be recent in relation to EU medical devices regulation, therefore this has to be taken into consideration when appointing the PRRC.

As per MDR Article 15(1), manufacturers of custom-made devices may simply demonstrate the requisite expertise described in the first option with at least two years of professional experience within a relevant field of manufacturing.

¹ MDR / IVDR

² MDCG Guidance 2019-7

³ MDR / IVDR

⁴ MDR / IVDR

2.1.1. Recognition of qualifications acquired outside the EU

As outlined in Table 1, the MDCG Guidance 2019-7 states that any qualification acquired outside the EU, including any university diplomas or certificates, should be recognised by an EU Member State as equivalent to the EU corresponding qualification.

Individual governments of EU countries may apply their own rules in terms of whether to recognise academic qualifications obtained elsewhere.

The website for ENIC (European Network of Information Centres in the European Region) and NARIC (National Academic Recognition Information Centres in the European Union)⁵ enables the user to find information on procedures for the recognition of foreign qualifications in the different EU member states.

As per the ENIC-NARIC website, in order to know the details about an official national credential evaluation centre or service, the first step is to contact the national authority in charge of higher education issues in the member state where the PRRC needs an evaluation, as each country has specific rules and procedures to evaluate foreign qualifications.

Once logged into the above website, there is a box entitled “Individual wishing to study/work abroad”, where individuals will find the possibility to select “I need to have my qualification(s) evaluated” or “I need Professional recognition” pages to obtain more information or to directly select the proper member state. Once on the country’s section of the ENIC-NARIC website, they will find a section for “Policies and procedures for the recognition of qualifications” with a link redirecting to the member state’s local webpage.



⁵ <https://www.enic-naric.net/>

2.2. Organisations who need to appoint a PRRC

2.2.1. Manufacturers

As per the Regulations Article 15(1) and as interpreted by the MDCG Guidance 2019-7, manufacturers are required to have available within their organisation at least one PRRC with proper expertise in the field of medical devices or in vitro medical devices, as applicable, in the European Union. This is valid for enterprises which employ at least 50 persons and whose annual turnover and/or annual balance sheet total exceeds EUR 10 million⁶.

The MDCG Guidance 2019-7 explains that “within their organisation” means that the PRRC appointed to larger manufacturers would need to be an employee of the organisation. In cases where an organisation has more than one legal manufacturer under the parent company, it would need to ensure that each legal manufacturer has its own PRRC.

In the case of micro and small manufacturers, defined by the Commission Recommendation 2003/361/EC as enterprises which employ fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million, the PRRC are required to be “permanently and continuously at their disposal” as opposed to “within their organisation”. Therefore, micro and small manufacturers are permitted to designate an external subcontractor as their PRRC.

The MDCG Guidance 2019-7 interprets that the micro or small enterprise may subcontract the responsibilities of a PRRC to a third party, as long as the qualification criteria are met, and the manufacturer can demonstrate and document how they can meet their legal obligations. Therefore, in these cases, the PRRC may be part of an external organisation with which the manufacturer has established a contract laying down provisions to ensure the permanent and continuous availability of that party. The contract should also mention the relevant person’s qualifications demonstrating compliance with points a) or b) of Article 15 (1).

Each micro and small manufacturer is supposed to evaluate its needs and define in the contract with the subcontracted PRRC how the availability requirements are intended to be met (e.g. two PRRCs or deputies might be needed to cover the availability obligations, or the contract could state to inform the client if the PRRC will be out of contact for more than two business days etc.).

2.2.2. Importers, distributors and other persons acting as manufacturers (Article 16)

Where Article 16 (1) of the Regulations applies, importers, distributors or other natural or legal person assume the obligations incumbent on manufacturers. If it is assumed that the obligations incumbent on manufacturers include Article 15, then these types of organisations are required to designate a PRRC in certain cases. The types of organisations or persons that need to appoint a PRRC include those who do any of the following:

- Make available a device on the market under their own name where there is no other manufacturer identified on the label (Article 16 1a)
- Change the intended purpose of a device already placed on the EU market (Article 16 1b)
- Modify a device which has already been placed on the market to the extent that its compliance with the regulations may be affected (Article 16 1c)

In any of these situations the importer, distributor or other person is considered to be a manufacturer and needs to appoint a PRRC.

⁶ Commission Recommendation 2003/361/EC of 6 May 2003

2.2.3. Systems and procedure packs (Article 22)

Companies who put devices together into systems or procedure packs using devices which do not already bear the CE marking, or where the combination of devices is not compatible in view of their original intended purpose, or where sterilization has not been performed in accordance with the manufacturer's instructions, are the subject of Article 22 (4). Such systems and procedure packs are treated as a medical device in their own right, and therefore such organisations assume the obligations incumbent on manufacturers and are required to designate a PRRC.

2.2.4. Authorised representatives

As per the Regulations Article 15(6), authorised representatives shall have permanently and continuously at their disposal at least one PRRC with proper expertise in the field of medical devices or in vitro medical devices, as applicable, in the European Union.

The MDCG Guidance 2019-7 states that the authorised representative may subcontract the responsibilities of a PRRC to a third party, as long as the qualification criteria is met, and the authorised representative can demonstrate and document how they can meet their legal obligations.

Therefore, the PRRC may be part of an external organisation, with which the authorised representative has established a contract laying down provisions to ensure the permanent and continuous availability of that party. The contract should mention the relevant person's qualifications demonstrating compliance with points a) or b) of Article 15 (1).

The MDCG Guidance 2019-7 underlines that the PRRC for an authorised representative and for an 'outside EU' manufacturer cannot be the same person. The guidance justifies this position as the aim is 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".

Table 2: Summary of the required availability for the PRRC

ECONOMIC OPERATOR.		PRRC WITHIN THE ECONOMIC OPERATOR'S ORGANISATION	PRRC PERMANENTLY AND CONTINUOUSLY AT DISPOSAL (SUBCONTRACTOR)
MANUFACTURER Including importers, distributors or other persons per Article 16 (1) and manufacturers of systems and procedure packs per Article 22 (4)	Employs at least 50 persons and whose annual turnover and/or annual balance sheet total exceeds EUR 10 million	✓	✗
	Employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million	✗	✓
AUTHORIZED REPRESENTATIVE		✓	✓

2.3. Where can the PRRC be located?

The regulations do not mention where the PRRC has to be located with respect to the economic operator. The MDCG Guidance 2019-7 provides some information about where the PRRC can be located.

2.3.1. Manufacturers

MDCG Guidance 2019-7 underlines the importance of establishing a close linkage of a permanent and continuous nature between the PRRC and the manufacturing activities. For this reason, for manufacturers located outside the EU it is assumed that the PRRC should also be located outside the EU. On the other hand, for manufacturers within the EU it is assumed that the PRRC should also be located in the EU.

Legal entities may have more than one PRRC, each with defined responsibilities based on the company's needs and structure (e.g., one PRRC responsible to ensure that the technical documentation is kept up to date, another PRRC responsible to ensure that the conformity of the devices released is appropriately checked, in accordance with the quality management system under which the devices are manufactured, or different PRRCs appointed in manufacturing sites that are geographically separated). Manufacturers are expected to document the competencies and respective areas of responsibility and to register in EUDAMED each person who has been appointed as PRRC (see paragraph 2.4).

It is important to note that each legal manufacturer under a parent company must have its own PRRC.

In case of multiple manufacturing sites, the manufacturer might consider, using a risk-based approach, where and how many PRRCs might be needed in order to comply with the requirements. The risk-based approach might consider the number and range of types of devices to be covered as well as the classifications involved. For example, in case of many similar types of low risk devices, one PRRC might be able to handle all the responsibilities but, for multiple types of higher risk products, more than one PRRC might be needed to cover everything.

In case of virtual manufacturers – *organisations that fully source their own named product from another company (sometimes known as the 'original equipment manufacturer' (OEM)) which has designed and manufactured an identical CE marked product⁷* – they must meet the requirements of the MDR/IVDR as legal manufacturers and are responsible to ensure that the PRRC requirements are met within the relationship with the OEM.

2.3.2. Micro and small manufacturers

MDCG Guidance 2019-7 states that, for micro or small enterprises located in the EU, it must be assumed that the PRRC, to be permanently and continuously at disposal of the enterprise, should be also located in the EU.

The MDCG Guidance 2019-7 does not clearly state if micro or small enterprises located outside the EU are expected to have the PRRC located outside the EU. So unless clarified in a future edition of the guidance, it is assumed that the same concept applies as that for medium and large manufacturers, that is, the PRRC should be in proximity to the manufacturing site.

2.3.3. Authorised representatives

Taking into account that the AR is located in the EU, the MDCG Guidance 2019-7 states that it must be assumed that the PRRC (to be permanently and continuously at disposal of the AR) should be also located in the EU.

⁶ MHRA guidance "Virtual manufacturing of medical devices" V2.0 April 2019

2.4. Registration in EUDAMED

The name, address and contact details of the person or persons responsible for regulatory compliance shall be registered in EUDAMED (MDR Article 31 and Annex VI, Part A, clause 1.4; IVDR Article 28 and Annex VI, Part A, clause 1.4), whose actor registration module includes an optional field to list the responsibilities of a specific PRRC. This option is useful in case a manufacturer decides to divide the responsibilities among different people.

MDCG Guidance 2019-5, Registration of legacy devices in EUDAMED, states that legacy devices must be registered in EUDAMED with different timelines depending on classification and validity of existing certificates. Therefore, it is possible that an organisation will need to obtain a Single Registration Number, which requires actor registration in EUDAMED and the the PRRC's contact details, before or by the date of application.

2.5. Roles and responsibilities of the PRRC

The Regulations (Article 15, clause 3) define the roles and responsibilities of the PRRC within a manufacturer, while the MDCG Guidance 2019-7 identifies the single responsibility of the PRRC within an Authorised Representative.

Manufacturers

The responsibilities of the PRRC within a manufacturer can be associated with 3 main areas of the Quality Management System:

- Product release under the manufacturer's Quality Management System,
- Compliance of technical documentation and declaration of conformity with regulation requirements
- Post Market Surveillance (PMS)/Vigilance

There is also a specific requirement related to compliance of investigational devices and in vitro diagnostic devices for performance studies.

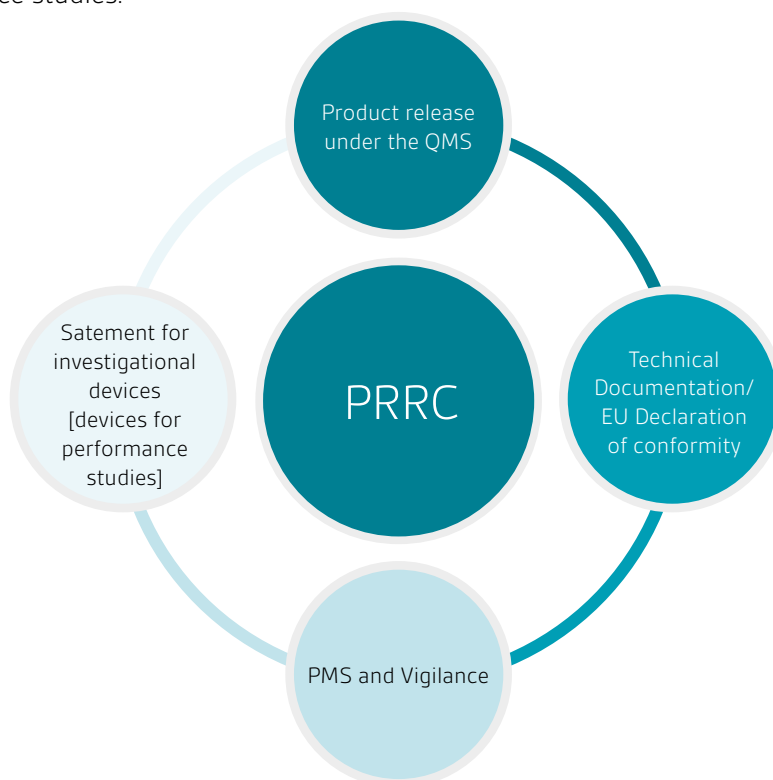


Figure 1 Areas of responsibilities of the PRRC within a manufacturer

The first column of Table 3 lists the responsibilities of a PRRC within a manufacturer (as per the Regulations Article 15, clause 3), while in the second column the responsibilities have been cross-referred to the roles and responsibilities of a manufacturer.

It is worth highlighting that the MDR and the IVDR require the PRRC to be at least responsible for ensuring that these duties are performed, meaning that there is no requirement for the PRRC to actually perform these tasks herself or himself. The PRRC therefore has responsibilities in terms of verification and oversight.

The PRRC is required to ensure that certain activities occur and are in compliance with the regulations. However, the manufacturer is already required to perform these activities under their obligations listed in Article 10. Table 3 demonstrates the relationship between the PRRC's tasks and those of the manufacturer.

Table 3: PRRC responsibilities within a manufacturer

MDR [IVDR] Article 15 text	Roles and responsibilities of a manufacturer
3(a) 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	"The quality management system shall cover all parts and elements of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It shall govern the structure, responsibilities, procedures, processes and management resources required to implement the principles and actions necessary to achieve compliance with the provisions of this Regulation" (Article 10(9)) [10(8)].
3(b) 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)) [10(5)]. The requirements for the Technical Documentation are in Annex II and Annex III of the MDR and IVDR, while Annex IV of the Regulations lists the information to be included in the EU declaration of conformity.
3(c) the post-market surveillance obligations are complied with in accordance with Article 10(10) [10(9)]	Manufacturers "of devices shall implement and keep up to date the post-market surveillance system" (Article 10(10)) [10(9)]. The requirements for the post-market surveillance system are described in Article 83 [78] and Annex III.
3(d) the reporting obligations referred to in Articles 87 to 91 [82 to 86] 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 [82 and 83]" (Article 10(13)) [10(12)].
3(e) in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV is issued [in the case of devices for performance studies intended to be used in the context of interventional clinical performance studies or other performance studies involving risks for the subjects, the statement referred to in Section 4.1 of Annex XIV is issued]	Manufacturers shall ensure that "a signed statement by the natural or legal person responsible for the manufacture of the investigational device [for performance study] that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical investigation [performance study] and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subject." (Annex XV 4.1) [Annex XIV 4.1]

Moreover, the Regulations state (Article 15, clause 4) that, if a number of persons are jointly responsible for regulatory compliance as per Table 3, their respective areas of responsibility shall be stipulated in writing.

2.5.1.1. Relation between PRRC and the manufacturer's QMS

As indicated in paragraph 2.5.1, each PRRC is responsible for carrying out the tasks for which they have been designated under an established QMS.

As per Article 10(9) of the MDR and Article 10(8) of the IVDR, 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”.

Therefore, an established QMS is vital for supporting the PRRC in this role, including appropriate procedures to be in place to control the execution of the responsibilities. For example, internal audits and/or periodic sampling of documentation/records could be a method to ensure the proper tasks are conducted.

Some enterprises might find it more appropriate to list the PRRC responsibilities in a dedicated procedure, while others might include the PRRC role in the already existing QMS documentation.

Moreover, in order to define the specific responsibilities and scope of activities for each individual PRRC in a contract or letter of appointment with a PRRC, whether internal employee or external resource, it might be helpful to use a risk-based approach, considering the risk class and the range and type of devices involved.

It is expected that the responsibilities of the PRRC are documented and accepted by the person and that evidence of his/her fulfilling the qualification requirements are provided. It is also expected that the PRRC has full access to relevant documents and records, in order to fulfil the tasks best. This might be even more important in cases where the PRRC is outsourced.

Correlation between the PRRC and the Regulatory and quality function in the company

Under the MDD and IVDD, 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 and IVDR is the requirement to name a specific person or persons as PRRCs to ensure that these tasks happen properly.

This means that the individuals performing these tasks will have a more prominent visibility within an organisation than ever before. So, it is critical that the role of PRRC is not only recognised within the organisation chart of a company but also has the executive power and organisational freedom to request any information they need from any other member of the company. It is likely that most PRRCs will only be able to fulfil their role if they report directly to senior management. The rest of the management team are also encouraged to assist the PRRC by thinking about how they can foster a culture of compliance awareness throughout the organisation.

The PRRC is not the same as the Management Representative as required by EN ISO 13485 clause 5.5.2, although it may make sense for the same person to fulfil both roles.

2.5.1.2. Checks in proportion to the risk class of the device

The extent to which the PRRC should be directly involved in the activities for which they are responsible, as opposed to supervising others, is best determined according to the risks presented by a number of factors. In particular, when planning the quality management system in this regard, the following should be taken into consideration:

- the type and risk class of devices concerned. For example, it would seem sensible to require a greater degree of direct involvement of the PRRC for high risk devices than might be necessary for Class I devices where a sampling or auditing approach might be sufficient
- the number of devices or generic device groups to be covered by a PRRC
A company with, for example, just a handful of different medical devices may find it easier to require the PRRC to directly sign off every batch for release than a multi-national company with hundreds of different product groups where a supervisory approach using other staff might be more appropriate.
- the number of manufacturing locations in which the manufacturer has premises
A manufacturer with sites in several different countries and many different product types may well require a number of PRRCs who perhaps need a section of the QMS all to themselves to describe their activities and reporting requirements.

Taking these factors into account should also help a manufacturer to determine how many PRRCs should be appointed to ensure that there is always one, whether internal or external, “permanently and continuously” available.

2.5.1.3. How to check the conformity of the devices at release

The purpose of this task is to ensure that the devices being released from routine manufacturing have been manufactured in accordance with the appropriate QMS documentation and that quality control (QC) release criteria are traceable to the device specification. This does not necessarily need to be carried out directly by the PRRC but, in the case they are not, checks and balances need to be in place to ensure it happens correctly and the related methods of verifications are expected to be stated in the QMS documentation. This could take the form of one or a combination of:

- instruction of particular staff whose job includes the release of devices
- internal audits of release procedures and batch history/ release documentation
- periodic sampling of batch release documentation by the PRRC

This is not a finite list, and it is the responsibility of the manufacturer with the PRRC to determine an appropriate process and document it such that it can be subject to external audit.

2.5.1.4. How to check that the Technical Documentation and the EU declaration of conformity are drawn up and kept up-to-date

This might be approached in different ways, depending on the number of technical files (called "Technical Documentation" in the Regulations) and EU declarations of conformity impacted. If relatively few, the PRRC could check that each item of technical documentation has been drawn up and kept up-to-date, and then sign the EU Declaration of conformity. If the number of technical files is large, the PRRC might approach this task in a different way. For example, by auditing, sampling, or being an approver of the procedure for this activity.

It should be remembered that upon signing the EU declaration of conformity, the signatory makes a binding commitment on behalf of the manufacturer that the device covered by the declaration is in compliance with the relevant legislation, and therefore could be held liable. However, Article 15 does not go as far as saying that the PRRC must sign the EU declaration of conformity, only that they should ensure it is drawn up and kept up to date.

2.5.1.5. Checks to fulfill PMS obligations

In order to fulfill this requirement, the PRRC must have a detailed understanding of post-market surveillance requirements. The MDR Articles 83 to 86 and the IVDR Articles 78 to 81 are quite prescriptive about the documentation required to be generated by a post-market surveillance system. So, for example, it will be quite easy for the PRRC to request to be part of the approval for a Post-market Surveillance Plan, Report, or the Periodic Safety Update Report. However, if there are hundreds of different product types or even a small range of products that vary widely in their intended use, then the PRRC(s) might have to take a sampling or auditing approach, or act as an approver of the procedures.

2.5.1.6. Reporting obligations for incidents and FSCA

The requirements on manufacturers for vigilance reporting and related activities have been incorporated in much greater detail in the MDR and IVDR than they were in the previous directives.

The PRRC should be fully conversant with every aspect of these requirements under section 2 of Chapter VII of the articles of Regulations. For example, it will not be sufficient for the PRRC simply to be copied into any vigilance reports raised by other staff. The PRRC could audit the related procedures and make sure that all requirements are adequately covered, including for trend reporting described in Article 88 of the MDR and Article 83 of the IVDR as well as having sight of all serious incidents.

2.5.1.7. What to do as PRRC if there are devices undergoing clinical investigation (MDR) or performance studies (IVDR)

In the case of investigational devices, or devices for performance studies for IVDs, the PRRC should ensure that a signed statement is issued by the natural or legal person responsible for the manufacture of the investigational device or for the performance study. This statement shall declare that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical investigation or performance study, and that with regard to those aspects, every precaution has been taken to protect the health and safety of the subject.

According to the MDR and IVDR there is no specific requirement for the PRRC to fulfill other clinical investigation related tasks, such as being involved in the release of investigational devices or devices for performance studies.

2.5.1.8. What to do if the PRRC encounters a situation which does not conform to expectations

The Regulations do not explicitly state what the PRRC should do (or who they shall notify) in case they encounter a situation which does not conform to expectations.

When a non-conforming situation is encountered by the PRRC, the QMS procedure(s) defining their responsibilities and tasks should also address the actions to be taken. It is important that senior management understand the full scope and responsibilities of the PRRC's role, and give them the necessary authority and cooperation to resolve any nonconformities that arise.

2.5.2. Authorised representatives

The MDCG Guidance 2019-7 clarifies that the PRRC of an authorised representative is responsible for ensuring that the tasks of the authorised representative as specified in the mandate referred to in Article 11(3) of the Regulations are fulfilled. This means that the AR's PRRC is responsible for ensuring whatever tasks the manufacturer and AR have agreed in the mandate have been fulfilled. Table 4 lists the minimum tasks of an AR.

Table 4: PRRC responsibilities within an Authorised Representative

MDCG Guidance 2019-7	Minimum tasks of an AR as specified in MDR/IVDR Article 11(3)
The PRRC of an AR should be responsible for ensuring that the tasks of an AR as specified in the given mandate, in accordance with Article 11(3), are fulfilled	Verification that the declaration of conformity and technical documentation have been drawn up and that, where applicable, the appropriate conformity assessment procedure has been conducted
	Keeping available a copy of the technical documentation, the declaration of conformity and, if applicable, the relevant certificate issued by the Notified Body at the disposal of competent authorities
	Complying with the obligations to register the following information in EUDAMED AR and AR PRRC details (Article 31 [28] and Annex VI Part A, Section1)
	Verification that the manufacturer has registered UDI information as per Article 27 and details of devices registered (Article 29 [26])
	In response to a request from a competent authority, providing that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned
	Forward to the manufacturer any request by a competent authority of the member state in which the authorised representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device
	Cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices
	Immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated
	Terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation

As per Article 11(3)(h) and 11(6)s, the AR shall terminate the mandate if the manufacturer acts contrary to its obligations under the Regulations, shall inform the competent authority of the Member State in which the AR is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.

It is opinion of the authors of this white paper that the PRRC in the AR would be expected to ensure that such notification occurs in cases where such issues arise.

2.6. Liability of the PRRC

Article 15(5) of the Regulations states that “The PRRC 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 organisation”.

Article 10(16) of the MDR and Article 10(15) of the IVDR cover a requirement for manufacturers to have “measures in place to provide sufficient financial coverage in respect of their potential liability under Directive 85/374/EEC⁸, without prejudice to more protective measures under national law”.

Article 11(5) of the Regulations also states that “without prejudice to paragraph 4 of this Article, where the manufacturer is not established in a Member State and has not complied with the obligations laid down in Article 10, the authorised representative shall be legally liable for defective devices on the same basis as, and jointly and severally with, the manufacturer.”

These articles imply that only the manufacturers and authorised representatives as legal entities carry liability for defective devices.

Article 15 requires a manufacturer to have a PRRC. The obligation of compliance with Article 15 is on the manufacturer and on the authorised representative. The remainder of Article 15 is descriptive, setting out what the PRRC is to do. It does not place personal liability for the organisation’s failure to comply on the shoulders of the individual PRRC. The outcome of failing to comply with Article 15 is that the organisation does not have the person so described in the Article. The outcome of the organisation failing to comply with the regulations depends on the type of non-compliance and the articles concerned.

In neither case is there liability on the PRRC, who would owe duties to the organisation through the employment contract if an employee or the contract for services if a consultant.

Enforcement of the regulations falls entirely to the member states. They are required to determine their own penalties to be imposed on any companies who infringe the requirements of the regulations, at the latest, by 3 months prior to the date of application (MDR Article 113 / IVDR Article 106). Therefore, all member states should make their plans for enforcement known by 25th February 2021 for the MDR and by 25th February 2022 for the IVDR. At the time of writing, still many Member States have not published their plans.

⁸ Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products

2.7. PRRC: similar roles in other industries

PRRC is not a new idea. There are several parallel requirements in other regulated industries. They differ slightly in the scope of their activities but are all involved in regulatory compliance to some extent.

Table 5: Comparison with roles in other industries which are similar to PRRC

Tasks for which person is responsible	PRRC MDR 2017/745 IVDR 2017/746	Qualified Person Pharma Dir 2001/83 ⁹	Responsible Person Cosmetics Reg 1223/2009 ¹⁰	Data Protection Officer General Data Protection Reg 2016/679 ¹¹
Product conformity at release	✓	✓	✗	The DPO has simply to ensure that an organisation complies with the regulation. This is much less well defined than for a PRRC but is still focussed on compliance.
Technical Documentation	✓	✓ for active substances	✓ Product information file	
Post-market Surveillance	✓	✗	✗	
Reporting obligations	✓	✓ pharmacovigilance	✓ Serious Undesirable Event Reporting	

Additionally, the Medical Devices Directive was implemented in Germany under the MPG (Medical Products Law) which requires that manufacturers appoint a "safety officer". It states that *"The safety officer for medical devices shall collect and evaluate existing information concerning risks connected to medical devices and shall coordinate the necessary measures. He/she is responsible for the fulfilment of reporting obligations in so far as they concern risks related to medical devices"*.

Although this role is widely thought to have been the starting point for the new requirement of PRRC within the medical devices regulations, the duties and responsibilities of the safety officer are not the same as those of the PRRC. The safety officer's responsibilities were limited to post-market surveillance and vigilance activities and did not include a requirement to check the conformity of products before release or to ensure that the technical documentation is up to date.

In the pharmaceutical industry, the Qualified Person is now a long-established concept where the role has become a professional qualification which is required to be maintained through ongoing continuous professional development training. Although the medical device and in vitro diagnostic devices regulations make no stipulation about the maintenance of competence for a PRRC, it is foreseeable that this might also be the way that the role of PRRC evolves in the medical device and in vitro diagnostic devices industries.

⁸ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

¹⁰ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

¹¹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation)

3. Conclusion

The Regulations and the MDGC 2019-7 provide some prescriptive requirements and guidance for the PRRC in terms of qualification and responsibilities, but, as outlined in this white paper, some questions are still to be answered.

The manufacturers and authorized representatives are expected to start working on identifying the best person or people to cover this role and to start adapting their own systems to cover the requirements. It will help manufacturers and authorized representatives to truly invest in implementing this requirement thoughtfully and in such a way as to genuinely enhance the compliance culture of the company.

It will not be enough to add the title to the organization chart and give that person a new job description. Senior management have a responsibility to appreciate the importance of defining the role of PRRC correctly and providing the necessary support and resources for the PRRC to be successful in their endeavors.



Further reading

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745>)

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0746-20170505>)

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) (https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_7_guidance_art15_mdr_ivdr_en.pdf)

Authors

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Technical reviewers

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- *The proposed EU regulations for medical and in vitro diagnostic devices: An overview of the likely outcomes and consequences for the market*, Gert Bos and Erik Vollebregt
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