TEAM-PRRC
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Code of Ethics

TEAM-PRRC

1. INTRODUCTION

1.1. The concept of the PRRC has been established in 2017 in Article 15 of the Regulation 2017/745 and in Article 15 of the Regulation 2017/746 of the European Parliament and the Medical Devices Council, specifying the conditions of training and/or professional experience necessary to practice the profession of "Person responsible for regulatory compliance" (PRRC). It is a unique regulatory requirement that applies only within the European Union (EU). The only comparable situation exists within countries with whom the EU has reciprocal agreements.

1.2. Each legal manufacturer of Medical Devices, within Member States of the EU, must name a person or persons who are eligible to act in the capacity of PRRC.

1.3. If an organisation has more than one legal manufacturer, each of them needs to have its own PRRC.

1.4. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC are not required to have the PRRC within their organisation, but shall have such person permanently and continuously at their disposal.

1.5. Authorised representatives need to have their own PRRC.

1.6. The wider technical, ethical and professional obligations in terms of patient safety, quality and efficacy must also be considered. Hence this professional Code of Ethics is designed to take account of these issues.

2 . REGULATORY BASIS FOR THE PRRC

For ease of reference the key regulatory documents concerning PRRCs are as follows:

2.1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on Medical Devices.

2.2. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC.

2.3. Commission Decision 2010/227/EU

2.4. Commission recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (notified under document number C (2003) 1422) (Text with EEA relevance).(2003/361/EC).

2.5. 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).

This document has been endorsed by the Medical Device Coordination Group (MDCG)

established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document MDCG 2019-7 is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

TEAM-PRRC has adopted the recommendations of this document.

2.6. TEAM-PRRC Internal Regulations.

3 PURPOSE OF THIS CODE OF ETHICS

3.1. The purpose of this Code of Ethics is to provide guidance to PRRCs on how to comply with European Regulations on Medical Devices and in vitro diagnostic Device Regulation.

3.2. It aims to provide guidance on how an individual PRRC can safeguard him or herself, aspects a PRRC needs to be aware of when working with other PRRCs, and where a PRRC can obtain support in difficult situations.

3.3. It also aims to make people understand that the PRRC in its professional activities works for the good of Public Health.

4. TERMINOLOGY

4.1. The terminology used in this Code of Ethics for TEAM-PRRC members corresponds with that used in the current versions of the regulations as detailed in the Chapter 2 "Regulatory basis for PRRC".

4.2. Within the EU, the terms clinical investigations are generally used and shall henceforth be referred to throughout this Code of Ethics.

5. QUALIFICATIONS OF THE PRRC

5.1. The requisite expertise of a PRRC shall be demonstrated by either of the following qualifications:

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;

b) four years of professional experience in regulatory affairs or in quality management systems

relating to medical devices.

5.2. Professional experience in regulatory affairs or in quality management systems relating to medical devices defined in point 5.1 should be related to the EU requirements in the field.

6. GENERAL PRINCIPLES

6.1. Manufacturers of medical devices or in vitro diagnostic devices and the Regulatory Authorities of each Member State must ensure that patients are protected and that all medical devices or in vitro diagnostic devices, whether for sale or supply, meet the appropriate requirements for safety, quality and efficacy.

6.2. The PRRC plays a unique role in patient health and the confidence of the regulatory authority when it verifies that all regulatory requirements are met in the Organisation or sector of the Organisation for which he or she works.

6.3. The PRRC is responsible for ensuring that the Organisation is in compliance with laws in force in the Member State where medical device or in vitro diagnostic device certification takes place.

6.4. The PRRC's legal roles and responsibilities apply regardless of where the final product will be sold and/or supplied.

6.5. The PRRC must understand the requirements of the clinical investigations and ensure that the Quality Management System in place is fit for purpose for the activities being performed and types of products involved.

6.6. The PRRC must use risk-based principles and apply sound knowledge and understanding of the relevant steps of manufacturing and placing on the market.

6.7. The PRRC needs to refer to all applicable guidance and ensure he/she is fully conversant with the requirements detailed in the Chapter 2 Regulatory basis for PRRC.

6.8. All PRRCs should ensure adequate professional indemnity insurance arrangements are in place inside the Organisation or for himself or herself.

6.9. The PRRCs reserve the right to refuse to certify compliance with the regulations for the types of products for which they do not have the relevant experience and / or knowledge.

6.10. PRRCs should ensure that this Code of Ethics is brought to the attention of senior management and, where practical, the Chief Executive Officer/Site Head so they are aware of the requirements and expectations detailed within.

7. PRACTICAL DUTIES OF A PRRC

7.1. Before certifying any document, the PRRC should always ensure that all requirements have been met.

7.2. The PRRC should also recognise the need to consult other experts to reinforce

knowledge where required (for example new technology, import of medical devices, designation of authorized representative).

7.3. The PRRCs should also take account of the nature and size of the operations being performed. In large organisations, the PRRCs will typically be dependent upon the knowledge and expertise of colleagues. It is of paramount importance that the PRRC is assured that the tasks allocated are being performed satisfactorily. Hence the duties of a PRRC depend upon a team effort.

8. PERFORMANCE OF DUTIES AND REGULATORY COMPLIANCE

8.1. Each PRRC has a personal and professional responsibility for being certain that the regulations for medical devices has been complied by the required person in the Organisation.

Ultimately, the PRRC must be satisfied that manufacturing, packaging and quality control testing comply with the relevant requirements and that any deviations are controlled and managed effectively. These requirements apply whether the work is carried out on site or at a different site.

8.2. The PRRC must scrutinise the operations of many staff within the organisation for the achievement of quality and regulatory compliance in the manufacture of medical devices. It is therefore of paramount importance that the PRRC achieves good working relationships with other people.

8.3. The PRRC should take the necessary steps to inform other functional groups of the legal role and responsibilities of a PRRC and help them to understand how they can provide effective support.

9. PRRCs WITHIN AN ORGANISATION

9.1. Number of PRRC. Legal manufacturer must have permanently sufficient PRRCs available and at least one, to cover all activities involved in medical devices.

9.2. Quality management system. The PRRC shall be responsible for ensuring that 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.

This quality management system for manufacturers of devices, other than investigational [performance study] devices, 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 10.9 of the IVDR).

9.3. Technical documentation and EU declaration of conformity. The PRRC shall be responsible for ensuring that the technical documentation is drawn up and kept up-to-date (Article 10.4 of the MDR and IVDR) and that an EU declaration of conformity is drawn up (Article 10.5 of the IVDR), for manufacturers of devices, other than investigational [performance study] devices.

9.4. Post-market surveillance obligations. The PRRC shall be responsible for ensuring that a post-market surveillance system is implemented and kept up to date within the manufacturer and the post-market surveillance obligations are complied with in accordance with Article 10.10 of the MDR and Article 10.9 of the IVDR.

9.5. Reporting obligations The PRRC shall be responsible for ensuring that a system for recording and reporting of incidents and field safety corrective actions as described in Articles 87 and 88 (Article 10.3 of the MDR and Article 10.12 of the IVDR) and the reporting obligations referred to in Articles 87 to 91 of the MDR and Article 82 and 86 of the IVDR are fulfilled.

9.6. Investigational devices. The PRRC shall be responsible for ensuring that a statement signed by the natural or legal person responsible for the manufacturer of the investigational device is issued and ensure 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 (Section 4.1 of Chapter II of Annex XV of the MDR - Section 4. 1 of Annex XIV of the IVDR).

9.7. The PRRC shall keep up to date any change in European regulation of medical devices.

9.8. The PRRC will regularly inform him or herself of the appearance of any new guidance on post-market surveillance, vigilance, clinical investigations and performance studies, created at European level on what a manufacturer's PRRC should do in these areas.

9.9. The PRRC should be present at the manufacturing site for a sufficient proportion of the working time to discharge their legal duties.

9.10. Where there is more than one PRRC working on the same site, it is an expectation that each PRRC is sufficiently aware of the activities of the other PRRCs.

9.11. It is expected that PRRCs will inform senior management if they believe there are insufficient PRRCs to perform all the required duties.

9.12. PRRCs are typically part of the quality organisation on site. Ideally, the PRRC would also be a member of the senior management team.

9.13. 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.

9.14. Distributors, importers or other natural or legal persons. The above articles of Chapter 9 apply when distributors, importers or other natural or legal persons assume the obligations incumbent on manufacturers in the situations set out in Article 16 of MDR and IVDR.

10. CONTRACTED PRRCs

10.1. The micro or small enterprises which employ fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million (Commission Recommendation 2003/361/EC of 6 May 2003) may subcontract the responsibilities of a PRRC to a third party, so long as the qualification criteria are 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 which allow compliance with points a and b of Article 15 (1).

10.2. In such cases, the duties and responsibilities of a 'Contracted PRRC' are

the same as those for PRRCs who are permanently employed by their company.

The term 'Contracted PRRC' is not a formal title and is used only to describe a PRRC providing an independent service under contract to a company.

10.3. In addition to compliance with the provisions applicable to all PRRCs, contracted PRRCs should observe the following:

- Have a clear written contract, which delineates the duties and responsibilities of the PRRC – as agreed between the company and the 'Contracted PRRC'. Both should sign and retain a copy of the contract;

- Be on site for sufficient time to fulfil all legal and professional requirements;

- Be readily available to the staff of the company for advice and discussion, be present during regulatory inspections and involved in communications with the inspectors;

- Ensure that the company to whom the services are provided will allow free access to any people, information, documentation, premises, systems, etc.

- The PRRC must be informed and aware of any issues arising relating to the PRRC that are relevant to a PRRC, in particular, any events that occur when the PRRC is not on site.

10.4. Particularly for smaller companies, a Contracted PRRC may agree with the company to personally provide some additional services for example, staff training, internal audits and maintenance of authorisations, in addition to performing strictly regulatory compliance duties.

10.5. If any doubt exists between the PRRC and the company concerning the duties and responsibilities of the PRRC, it is recommended that one of them or both contact the TEAM-PRRC Association or the Notified Body of the legal manufacturer for advice.

10.6. 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.

11. AUTHORISED REPRESENTATIVES

11.1. Authorised representatives shall have permanently and continuously at their disposal at least one PRRC who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union. The requisite expertise shall be demonstrated by either of the following qualifications:

(a) 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;

(b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

11.2. The authorised representative may subcontract the responsibilities of a PRRC to a third party, so long as the qualification criteria are met and the authorised representative 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 authorised representative 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 which allow compliance with points a and b of Article 15.

11.3. The PRRC of an Authorised representative should be responsible for ensuring that the tasks of an Authorised representative as specified in the given mandate, in accordance with Article 11, are fulfilled.

11.4. Taking into account that the Authorised Representative is located in the EU, it must be assumed that any person to be permanently and continuously at its disposal should also be located in the EU.

11.5. The PRRC 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 performed.

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.

12. OUTSOURCED ACTIVITIES

12.1 Where products are manufactured and/or packed under contract there should be a clearly written Quality/Technical Agreement between the contract giver and the contract acceptor; and such an agreement should be reviewed by a PRRC before signature.

12.2 It may be necessary to consider a direct PRRC/PRRC agreement in addition to any Quality/Technical Agreement(s) where there is a requirement for clarity on division of

responsibilities for PRRCs, or where there are a number of PRRCs in the Organisation.

13 . CONTINUING PROFESSIONAL DEVELOPMENT (CPD)

13.1. PRRCs have a personal and professional duty to ensure they keep their knowledge and experience up to date.

13.2. This should include keeping up to date with all relevant regulatory aspects, regional and international standards and guidelines.

13.3. In addition, PRRCs must also keep up to date with any advances in manufacturing techniques or control technologies relevant to the medical devices.

13.4. Adequate records must be maintained by the PRRC to demonstrate that sufficient CPD is being performed, which also complies with any professional body requirements.

13.5. Where appropriate, these records need to be submitted to the relevant Professional Body and to be available for review during any Regulatory inspection.

13.6. In the event of a PRRC undergoing a significant change in job responsibilities in the same company, e.g. introduction of new technology, or moves company, it is a requirement that the PRRC undergoes formal training. There should be a plan prepared and approved by senior management that details the gaps and training required with timelines. Training must be satisfactorily completed and the PRRC familiar with the new products range before he or she certifies any batches.

13.7. If a PRRC has a break from work and/or temporarily moves away from the PRRC role, the PRRC must ensure he/she is fully up to date before returning to a PRRC role.

14 . PROFESSIONAL CONDUCT

14.1. The PRRC keeps confidential the information of which he or she becomes aware through his or her professional activity.

14.2. PRRCs are subject to the overall jurisdiction of the By-laws, Charters and Regulations, Codes of Conduct, Disciplinary Regulations and any general guidelines of their own Professional Body, and should have access to them.

14.3. PRRCs must ensure that appropriate senior company executives are made fully aware of any manufacturing and/or testing issues that may cause doubt in the regulatory compliance.

14.4. If there is any aspect in the manufacturer or authorised representative operations that is not in accordance with the Directives and Guidelines for Medical Devices then the PRRC has a duty to bring this to the attention of senior management and ensure that appropriate corrective and preventative measures are taken.

14.5. PRRCs should establish a good working relationship with Notified Bodies auditors and, as far as possible, provide information on request during site inspections or technical documentation assessments.

14.6. Manufacturer management has a duty to provide appropriate resources, training and expertise within its organisation to ensure that regulations are not compromised.

14.7. PRRCs may consult TEAM-PRRC for confidential advice in cases where undue pressures to depart from professional obligations cannot be counterbalanced by reference to this and other relevant guidance, preferably having informed their employer first.

14.8. In the event of a difficulty encountered with regard to its employer, its contract giver or the regulatory authorities for medical devices, the PRRC may request TEAM-PRRC to act as mediator.

14.9. Wherever possible before leaving an employer or terminating a contract, the PRRC ensures the continuity of PRRC's functions after his departure or the end of his contract.

15. DISCIPLINARY PROCEDURES

15.1. In case of disrespect of this Code of Ethics, TEAM-PRRC may pronounce a Warning to the TEAM-PRRC member (Article 6 of TEAM-PRRC Internal Regulations).

15.2. As stated in Article 7 of TEAM-PRRC Internal Regulations, a TEAM-PRRC member may be subject to a procedure to exclude him or her from membership TEAM-PRRC for severe violation of this Code of Ethics.

15.3. If a TEAM-PRRC member conducts criminal or penal behaviour, TEAM-PRRC can exclude him from the members.

15.4. TEAM-PRRC may sue a person who has declared to follow the TEAM-PRRC Code of Ethics to obtain an individual or professional advantage, and has not respected it.

16. PERSONAL COMMITMENT

I, the undersigned, declare that I approve this Code of Ethics and that I will respect it:

- either during the manufacture of medical devices or in vitro diagnostic devices as PRRC, or by providing contractual PRRC services;

- either during my current or future professional activity, for the articles which relate to it.

Date, name and signature