TEAM-PRRC

The European non-profit organization of Persons Responsible for Regulatory Compliance

Position Paper N°1 on qualifications required to become a PRRC - the practical application of Article 15 §1

For Persons Responsible for Regulatory Compliance according to article 15 of MDR (EU) 2017/745 and IVDR (EU) 2017/746

The information summarized in this document reflects the current understanding of the EU Requirements and may be subject to a regular change over the upcoming years.

Contents

I. Abbreviations

AR: Authorised Representative

CA: Competent Authority

CV: Curriculum Vitae (resume)

EU: European Union.

IVDR: *In Vitro* Diagnostic Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on medical devices

MDR: Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

MD: Medical Device

MDCG: Medical Devices Coordination Group

PRRC: Person Responsible for Regulatory Compliance

QMS: Quality Management System

II. Presentation of TEAM-PRRC association

TEAM-PRRC was established in April 2020 and is the only European (EU) non-profit organization dedicated to Persons Responsible for Regulatory Compliance (PRRC), which originated from Article 15 of the Medical Device Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR) and *In Vitro* Diagnostic Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on medical devices (IVDR).

As mentioned in these regulations, the PRRC is a new role ensuring compliance of manufacturers and/or authorized representatives. This role is known from other regulations where a similar position is described:

- General Data Protection Regulation with the Data Protection Officer
- The pharmaceutical industry with the Qualified Person
- The cosmetics industry with the Responsible Person

The new requirement significantly impacts the resources and quality management system (QMS) of the previously mentioned economic operators.

Therefore, TEAM-PRRC is working on reasonable and practical solutions to support its members in implementing the requirements. The focus of this association is to share knowledge and experience on issues faced daily by PRRCs, develop and maintain a high level of professionalism and encourage harmonization in the interpretation of the requirements.

If you are fulfilling the minimum qualifications required by article 15, you can join the association as an active member and benefit from:

- A secure professional practice because of the association's Code of Ethics;
- Proposals for solutions to your professional problems;
- Access to conferences and specialized training;
- Access to templates reflecting the minimum requirements;
- Access to a library of regulatory texts;
- A regulatory watch.

This position paper aims to:

- Explain the intent behind the role of the PRRC
- Describe the roles and responsibilities of the PRRC
- Explain the type of qualifications and extent of experience required
- Define the place of a PRRC in the QMS of the various organizations
- Describe potential methods to fulfill the legal obligations described in the MDR and IVDR
- Acknowledge the liabilities of the PRRC
- Give our position on article 15, and Medical Devices Coordination Group (MDCG) guidance

III. The qualifications of the PRRC

The MDR states that:

"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 recognized 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.

Position of TEAM-PRRC:

1) Demonstration of the qualifications:

The manufacturer or the authorised representative (AR) is responsible for defining the PRRC qualification criteria for his organization by considering the applicable law(s). The PRRC is required to deliver sufficient evidence of qualification for this role providing details of fulfilling the job description of the manufacturer or authorised representative by including along with the Curriculum Vitae (CV) the relevant copies of certificates. Those documents showing evidence of compliance shall be recorded, maintained and, when requested, made available to relevant Notified Body(ies), during their assessment activities, or Competent Authority(ies) (CA), during Market surveillance and vigilance activities.

The file includes:

Diploma - Certificate - formal Qualification	**Professional experience in regulatory affairs or in quality management systems relating to medical devices (MD)**
Copy of any relevant diplomas (note: if this diploma is not in law, medicine, pharmacy, engineering or another relevant scientific discipline, please refer to Art 15.1.b)	An up-to-date detailed resume/CV. The update should be done yearly or whenever relevant new training is conducted.
Copy of relevant training certificate(s)	The job description/work attestation for each position is mentioned in the resume/CV. It should precisely describe all the assignments and the relevant experience gained in regulatory affairs or in quality management systems relating to medical devices when occupying this position.

2) What is "Relevant experience":

It is essential to demonstrate based on documented evidence that the qualification and competence criteria are met.

The description of the experience acquired (at least one year or four years[1]) should provide:

- the evidence that the person has exercised a professional function in the field of MDs and/or IVDs
- and that this function involved duties and responsibilities in either regulatory affairs or quality management systems.

The PRRC shall provide documented objective evidence supporting their assignments. This might include internships.

TEAM-PRRC recognises that the work experience of the PRRC can be very diverse, so it is not possible to clearly define professional experience in this context. Therefore, the PRRC must declare their expertise and provide evidence of compliance with the job description posted by the manufacturer or the authorised representative. The manufacturer or authorised representative must confirm the fulfilment of the pre-defined criteria via internal processes allowing the PRRC to conduct their role. The NB and CA can verify if compliance with the applicable requirements of the MDR or IVDR is shown.

IV. Custom-made devices (article 15 §1):

Regarding custom-made devices, the MDR states that:

"Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing.

Position of TEAM-PRRC:

The situation for many manufacturers of custom-made devices is that they make devices one at a time in very specific areas of technology and clinical needs for a specific single patient. Therefore, the requirement to demonstrate at least two years of professional experience should be interpreted as meaning that two years

[1] These should be considered calendar years. Part-time work would qualify exactly the same as full-time jobs.

professional experience in the technology of the manufacturing field of the device produced by the manufacturer are sufficient. This professional experience does not therefore need to be exclusively in regulatory affairs relating that technology but should show an understanding of what regulatory requirements apply to that particular technology.

V. Non-EU Qualifications

The MDCG guidance 2019-07 notes that:

"For the purpose of fulfilling the requirement laid down in point "a" of Article 15 (1), 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."

Position of TEAM-PRRC on how to get a non-EU qualification accepted by the EU Member States:

Although the MDCG Guidance state that '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,' Article 15§1(a)only requires this recognition for 'a course of study.' If the legislator had intended EU Member States to have a process for recognizing non-EU university degrees, there would be a comma between 'study' and 'recognised' in article 15§1(a). In any case, all diplomas or certificates must be recognised if they are in line with the applicable local laws qualifying the person to act in their country as a qualified professional person e.g., a lawyer with a degree in law or an engineer with a degree in engineering, etc.

TEAM-PRRC recommends that manufacturers critically evaluate all relevant diplomas and certificates regarding their similarity to EU requirements and document the justification in all cases.

A university degree obtained in a non-EU country might be recognised as equivalent by the Member States concerned if supported by objective evidence such as the course content.

ENIC and NARIC are networks that supports the recognition of qualifications. The website is https://www.enic-naric.net/. One of the purposes of this initiative is to help interested parties find information on procedures for the recognition of foreign qualifications within EU member states.

In case of doubt, it is highly recommended to approach the responsible competent authority of the member state to understand their expectation and check for any formal procedures for recognising foreign qualifications.

It is our interpretation that the regulator intends to steer the role of PRRC towards a professional status. It would seem sensible to require that "evidence of formal qualification" is based on a long course of study validated by an academic institution and not a simple short training course. Such training courses are potentially valuable and could be recognised as evidence of continuous education and knowledge update in a specific regulatory, clinical, or quality field for example in filling a gap in a person's experience; however, they cannot be used solely to justify the fulfilment of the minimum qualification requirements of a PRRC.

VI. Knowledge management

Regulatory requirements and standards evolve constantly in the medical device and the *in-vitro* diagnostic sectors. The PRRC will undoubtedly be expected to demonstrate how they evaluate and take the necessary actions, such as additional training, to prove that they have kept their knowledge and competence up-to-date. A documented record such as a learning journal or spreadsheet would be a way to achieve this.

Position of TEAM-PRRC:

TEAM-PRRC highly recommends PRRCs to maintain up-to-date qualifications and knowledge relating to regulatory affairs and quality management systems. For example, this can be done by:

- Attending training sessions. Those with a final examination resulting in a certificate with pass/fail criteria are useful evidence of training effectiveness.
- Reading articles, white papers, journals in subjects related to the tasks of the PRRC and to the changes in regulatory affairs and quality management systems.
- Attending conferences, seminars, and other events focused on medical device or *in-vitro* diagnostic regulatory affairs and quality management systems.
- Becoming a member of professional organizations whose focus is on regulatory affairs and quality management systems.

