TEAM-PRRC

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

TEMPLATE FOR THE PRRC JOB DESCRIPTION

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1. Introduction and Background

According to the Recital 34 of the EU Medical Device Regulation 2017/745 and Recital 33 of the EU *In Vitro* Diagnostics Regulation 2017/746, the PRRC is intended to perform supervision and control of the manufacture, post-market surveillance and vigilance activities concerning the medical devices in the portfolio of ***Insert Company Name***. It is not directly required that the PRRC should carry out the tasks outlined below him / herself. The purpose of this Job Description is to define the main responsibilities of the PRRC and describe how they are implemented within the QMS at ***Insert Company Name***.

Note: Article and Annex references in the following text are from EU Medical Device Regulations 2017/745.

Article 15 §3 states:

"*The PRRC shall at least be responsible for ensuring that:*

(a) The conformity of devices is appropriately checked in accordance with the QMS under which the devices are manufactured, before a device is released;
(b) The technical documentation and the EU declaration of conformity are drawn up and kept up to date
(c) The post-market surveillance obligations are complied with in accordance with Article 10(10);
(d) The reporting obligations referred to in Articles 87 to 91 are fulfilled;
(e) *In the case of investigational devices, the statement referred to in section 4.1 of Chapter II of Annex XV is issued*".

2. Abbreviations

MDR – Medical Device Regulation (EU) 2017/745

IVDR – In Vitro Diagnostics Regulation (EU) 2017/746

SOP – Standard Operating Procedure

WI – Work Instruction

QMS – Quality Management System

TD – Technical Documentation

PMS – Post-Market Surveillance

PMCF – Post-Market Clinical Follow Up

PSUR – Periodic Safety Update Report

SSCP – Summary of Safety and Clinical Performance

FSN – Field Safety Notice

FSCA – Field Safety Corrective Action

CAPA – Corrective and Preventive Action

SRN – Single Registration Number – All economic operators are required to register their details in order obtain this number which forms part of the Unique Identification Number as required to be used for device identification and consequent registration in EUDAMED.

3. Objectives

This job description is written to define the role of the Person Responsible for Regulatory Compliance (PRRC) as specified in article 15 of MDR and IVDR within ***Insert Company Name***.

4. Associated documents

- "Human Resources" Procedure.
- Letter of appointment or amendment of the contract of the employee
- Other, if any (according to the QMS of the company)

5. Management

A Deputy PRRC may be appointed, and / or there could be a team of different persons covering the requirements requested by Article 15. In this case, the individual roles should be outlined here along with their reporting structure and communication interfaces as appropriate.

The PRRC(s) report directly to *insert the function to which the PRRC reports*

6. Qualifications and expertise

Art.15 §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 (preferably ISO 13458:2016) relating to EU requirements for medical devices;

Insert qualifications and summary of experience which fulfils this requirement:

Requirements	Documentary evidence
Insert formal qualification held	
Insert professional experience	

7. Skills and Competencies

The PRRC has a central role in the organization. He/she must work closely with all departments of the company. It is therefore desirable that he / she has the following specific skills.

- Leadership
- Project management – including good organization of regulatory intelligence
- Critical thinking – prepared to speak out and ask questions
- Good communication within the organization and proactive cooperation with the organization's team(s)
- Diplomacy to handle situations where nonconformities may be discovered
- Good problem solving
- Competence to analyse data and decisiveness to act on conclusions

8. Tasks and Activity Requirements

The following Table 1 reviews each subparagraph of Art.15 §3 and lists:

- Documents that must be made available to the PRRC by the Manufacturer/ Authorized Representative
- Description of the tasks to be performed by the PRRC;
- Accesses and information which must be made available by ***Insert Company Name***
- Activity periodicity & duration/sampling & Audit Plan(s) – statistical techniques used to determine this should be justified, where possible, by reference to relevant standards or guidelines.

The activities listed in Table 1 may be performed by the PRRC exclusively for the scope of devices agreed between the PRRC and ***Insert Company Name.*** *(This could be documented in the appointment letter or an agreement appended to this Job Description.)*

Table 1 Tasks and responsibilities relating to PRRC activities

PRRC Responsibility with Ref. to Article 15 §3 **Requirement**	**Documents that are required by the PRRC to Manufacturer/ Authorized Representative**	**Description of task to be performed by PRRC**	**Access and information which must be made available by *Insert Company Name***	**Activity periodicity & duration/Sampling & Audit Plan(s)**
1. Art 15 §3(a)	• Quality Manual • Company SOPs • Device specifications	Ensure that the QMS includes a process for checking conformity of devices before release. *This may include activities throughout the device(s) life cycle, comprising R&D, purchasing, production and post-production.* Ensure existence of device specification(s) and corresponding SOPs covering the monitoring and measuring of processes and product.	PRRC must have FULL access to ALL the documents related to the ***Insert Company Name*** QMS at all times, upon request. PRRC must have access to production, storage and test areas for unannounced audit / inspection at any time. ***Insert Company Name*** must inform PRRC about e.g. production plans and/or of expected timing for batch release(s). ***Insert Company Name*** must inform PRRC about any significant change in the QMS.	Depending on the risk class(es) of device(s), and the number of different types of devices at the company the extent, scope and duration of audit(s) should be scheduled to cover the processes throughout the device(s) life cycle that contribute to confirming conformity of production output (e.g. Research & Development, Production, Purchasing, Quality Control). To determine the extent, scope and duration of audit(s) ISO 19011:2018 may be used.
	• Production and Post Production plans • Batch / Lot Record(s).	Review product conformity records, e.g. batch or lot records, for evidence of conformity with device specification(s). *This may be done as part of the release process or after release.* Audit internal process for batch record review and final product release.		Every batch release OR per sampling plan on batches, that must be agreed between the PRRC and the company**.** A sampling plan for this may be defined according to e.g. production volumes and/or risk class of devices, size and locations of organisation. MDCG 2019-13 may be useful to assist with prioritisation where a manufacturer or AR is dealing with a large number of types of devices.

PRRC Responsibility with Ref. to Article 15 §3 **Requirement**	**Documents that are required by the PRRC to Manufacturer/ Authorized Representative**	**Description of task to be performed by PRRC**	**Access and information which must be made available by *Insert Company Name***	**Activity periodicity & duration/Sampling & Audit Plan(s)**
2. Art 15 §3(b)	• Technical documentation (according to Annex II and Annex III) • Declaration of Conformity • SOP(s) and WI(s) for the generation of technical documentation (with reference to MDR requirements)	Review each technical documentation upon completion for placing product on the EU market. Check contents are complete according to MDR 2017/745 Annex II and III, plus Annex XIV. Check each Declaration of Conformity exists and is complete according to Annex IV.	***Insert Company Name*** must make all technical documentation available to the PRRC for devices for which the PRRC must ensure conformity to the MDR.	Upon initial market launch and upon any significant changes to product and 1x per annum thereafter for Technical Documentation. All the contents of the TD should be examined according to Annex II and III. Depending on the risk class of the medical devices, and the number of TD to be covered, the PRRC can follow a sampling approach e.g. according to the suggested approach of MDCG 2019-13. A summary of technical documentation could be made available by the company in order to simplify the initial assessment by the PRRC.
3. Art 15 §3(c)	SOP(s) and WI(s) about Post market surveillance activities (PMS) For each device covered by the PRRC Activity: - PMS Plan(s) - PMCF Plan(s) - PSUR - PMS Report (for Class I devices only) - SSCP if applicable	Review process and procedures for PMS ensuring that they cover all the requirements in MDR Chapter VII, Section 1. Check for existence and completion of PMS records.	***Insert Company Name*** must make all QMS procedures available to the PRRC and related records for devices for which the PRRC must ensure conformity to the MDR.	PMS related records should be reviewed upon initial market launch and thereafter at least once per annum. Depending on the risk class of the medical devices, and the number of different device types to be covered, the PRRC can follow a sampling approach, (e.g. grouped per basic-UDI).

PRRC Responsibility with Ref. to Article 15 §3 **Requirement**	**Documents that are required by the PRRC to Manufacturer/ Authorized Representative**	**Description of task to be performed by PRRC**	**Access and information which must be made available by *Insert Company Name***	**Activity periodicity & duration/Sampling & Audit Plan(s)**
4. Art 15 §3(d)	Vigilance reporting SOP(s)/WI(s) Trend reporting SOPs Any SOPs relating to the analysis of such data e.g. CAPA SOP(s) Records of vigilance reports, FSN, FSCA issued by ***Insert Company Name*** CAPA records	Review procedures for compliance with MDR Chapter VII, Section 2. Check that complaint data suggesting that vigilance reporting criteria have been met is being accurately captured as vigilance reports. Review vigilance reports and trend reports to see if they have been correctly filled in and submitted within stated timeframes. Check CAPA arising from vigilance reports is appropriate.	***Insert Company Name*** must make all procedures related to vigilance and CAPA, along with related records and associated analysis, available to the PRRC, for devices for which the PRRC must ensure conformity of the device to the QMS of its company and MDR requirements	The activity should be performed upon appointment as PRRC and at least 1x per annum thereafter (or timescale appropriate for risk class of device(s) covered).
5. Art 15 §3(e)	Procedure(s) related to process for management of a clinical investigation (where applicable)	Ensure that a statement is prepared *"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*". Ensure that this statement is signed by the natural or legal	***Insert Company Name*** must make this statement available to the PRRC prior to filing an application to run a clinical investigation. All the documentation needed to perform the clinical investigation(s) must be made available to the PRRC.	PRRC must check the described statement for every clinical investigation device within the scope of their appointment as PRRC.

PRRC Responsibility with Ref. to Article 15 §3 **Requirement**	**Documents that are required by the PRRC to Manufacturer/ Authorized Representative**	**Description of task to be performed by PRRC**	**Access and information which must be made available by *Insert Company Name***	**Activity periodicity & duration/Sampling & Audit Plan(s)**
		person responsible for the manufacture of the investigational device.		

9. Additional responsibilities

Insert Company Name *may require a PRRC to perform other tasks in addition to those in Art. 15.3 which should be outlined here.*

Other responsibilities may include :

- Check the languages of the IFU and labels of the devices
- If the Legal Manufacturer is based outside the EU, that an AR is appointed with a mandate and has its own PRRC and is registered in EUDAMED.
- Ensure that procedures are in place to assign UDI codes, and BASIC UDI-DI. The UDI carrier is affixed on the label in compliance with the MDR/IVDR requirements.
- The PRRC cooperates with the Competent Authorities and Notified Bodies, and remain available in case of unannounced audits.
- The PRRC participates in defined audits (some internal audits, Notified Bodies audits and /or Competent Authority inspections (Class I devices))
- Take part in regulatory intelligence processes– to keep abreast of changes in regulatory requirements and new standards and guidance as they are published

10. Resource Requirements

The resources and time required to complete the above tasks are dependent on the range of devices covered, the number of different devices and quantity produced thereof per week/ month or year and the size of ***Insert Company Name*** (e.g. number of personnel involved and number of sites and processes managed directly or subcontracted). In order to ensure this role is properly resourced, the PRRC and the company should agree the target time to be dedicated to ensuring that the requirements of this role are properly fulfilled.

The following table may be used to estimate the time associated with the adequate fulfilment of the PRRC's activities according to Article 15. In case of an external PRRC, this can be used as a starting point for a cost calculation.

Table 2 Resource requirements associated with PRRC activities

Article 15 §3 **Requirement** (see Table 1)	Time required for PRRC activities outlined in Table 1 at ***Insert Company Name***
1. Art 15 §3(a) – conformity of product release	
2. Art 15 §3(b) – Technical Documentation & DoC	
3. Art 15 §3(c) - PMS	

4. Art 15 §3(d) - Vigilance	
5. Art 15 §3(e) – Statement in Annex XV	

Approval	Signature	Date
PRRC ***Insert Name***		
Insert Company Name ***Insert Name***		

11. References

- Medical Device Regulation (EU) 2017/745
- *In Vitro* Diagnostic Medical Device Regulation (EU) 2017/746
- MDCG 2019-07 - 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)