TEAM-PRRC

European Association of Persons Responsible for Regulatory Compliance

"Compliant together"

MDR (EU) 2017/745 & IVDR (EU) 2017/746

- On-demand mediation with other stakeholders
- Pursue mutual assitance & exchange experience on issues faced by PRRC
- Conferences & specialized trainings
- Professional practice secured
- Promote understanding of PRRCs' responsibilities

www.team-prrc.eu

What we are

Team-PRRC is an association that aims to promote active compliance according to MDR & IVDR

A new **not-for profit** European Association dedicated to the profession of « Person Responsible for Regulatory Compliance » (PRRC)

Directed by volunteer experts*in the new EU regulation (MDR/IVDR) with regard to the quality of the association's activities

*independent consultants, directors of SMEs, retired experts

Supported by legal experts in the field of medical device legislation

Who we are

www.team-prrc.eu

Elem Ayne

President

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- Postgraduate degree in MD Regulatory Affairs
- MSc International Business Development
- Sp. Master in Marketing
- 7 years experience in industry

Anne Jury

Vice-President

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- Regulatory affairs consultant for 20 years
- Over 30 years experience in medical technology industry
- Former lead auditor at BSI and TÜV Süd

Who we are

Jean-Louis Divoux

Secretary

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- Over 30 years experience in Active Implantable Medical devices
- Standardisation committees member
- AIMD Expert and Advisor

www.team-prrc.eu

Daniel Petit

Treasurer

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- Sales training manager for pharmaceutical manufacturer
- Regional Manager for different MD manufacturers in France
- Founder and President of a Manager's MD association

ACKNOWLEDGEMENTS
Thank you to our supporters

- Denys Durand-Viel (DM Experts)
- Dario Pirovano (MedTech Europe)
- Gideon Elkayam (Obelis, MD Law)
- Bassil Akra (QUNIQUE)
- Mika Reinikainen (Abnovo, EAAR)
- Florian Tolkmitt (RAPS Germany)
- Corinne Delorme (Nexialist)
- Richard Young (Acclaim Biomedical Consulting)
- Marc Simondi (Protheos)
- Gérard Pelisson (Evolutis)

Our objectives

- **Bring together** all those people with PRRC functions & **pursue mutual assistance**
- Provide a forum for the **exchange of experience** on issues faced by PRRC in their daily activities
- Establish, maintain and **develop a high level of professionalism of PRRC**
- Exchange information with health authorities in charge of regulation and **promote understanding of PRRCs' responsibilities to other stakeholders**
- **Act as a mediator** and **support to PRRCs** in conflicts or disputes encountered during their day-to-day PRRC activities
- Aim for **enhancement of Public Health**

Who may join us & how to join?

- The persons with the following requisite expertise according to article 15 §1 – MDR/IVDR

(a) a diploma, certificate or other […], 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.

- The persons who do not meet the above criteria but have an interest in the role of PRRC can apply to become a supporting member

- These eligible persons can apply directly via our website: http://www.team-prrc.eu/

How to join

TEAM-PRRC Membership process

YOU:
- Register
- Fill in membership form

Team-PRRC:
- Check for eligibility
- Acknowledge (Password…)
- Request for commitment
- Request membership payment

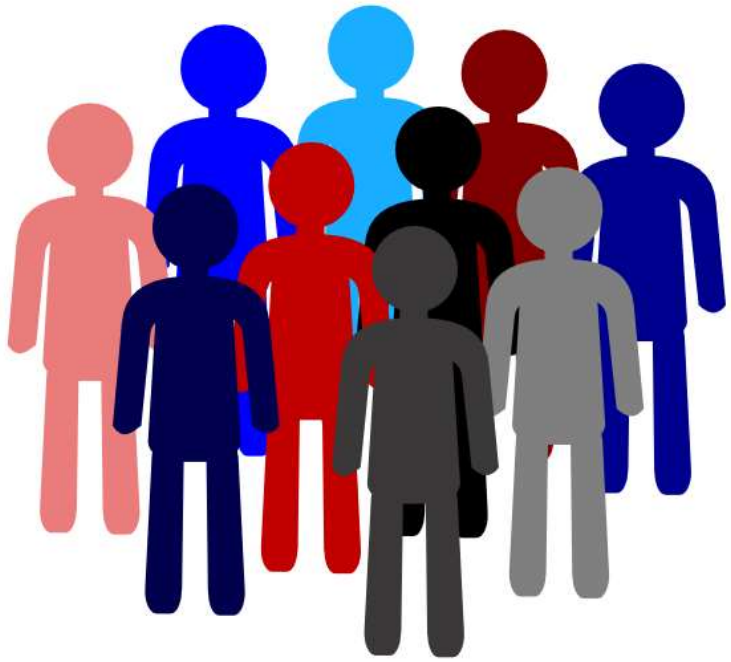
YOU:
- Commit to TEAM-PRRC values
- Pay membership fee

Team-PRRC:
- Receive your commitments and membership payment
- Open full access for you to Active Member space

YOU ARE WELCOMED AS MEMBER

Member types

- **Active members**
  - Individuals
  - Those who meet the criteria to become a PRRC
  - NOTE: you do **not** need to already be in a PRRC job
- **Sponsorship**
  - Corporate entities
  - NOTE: No voting rights



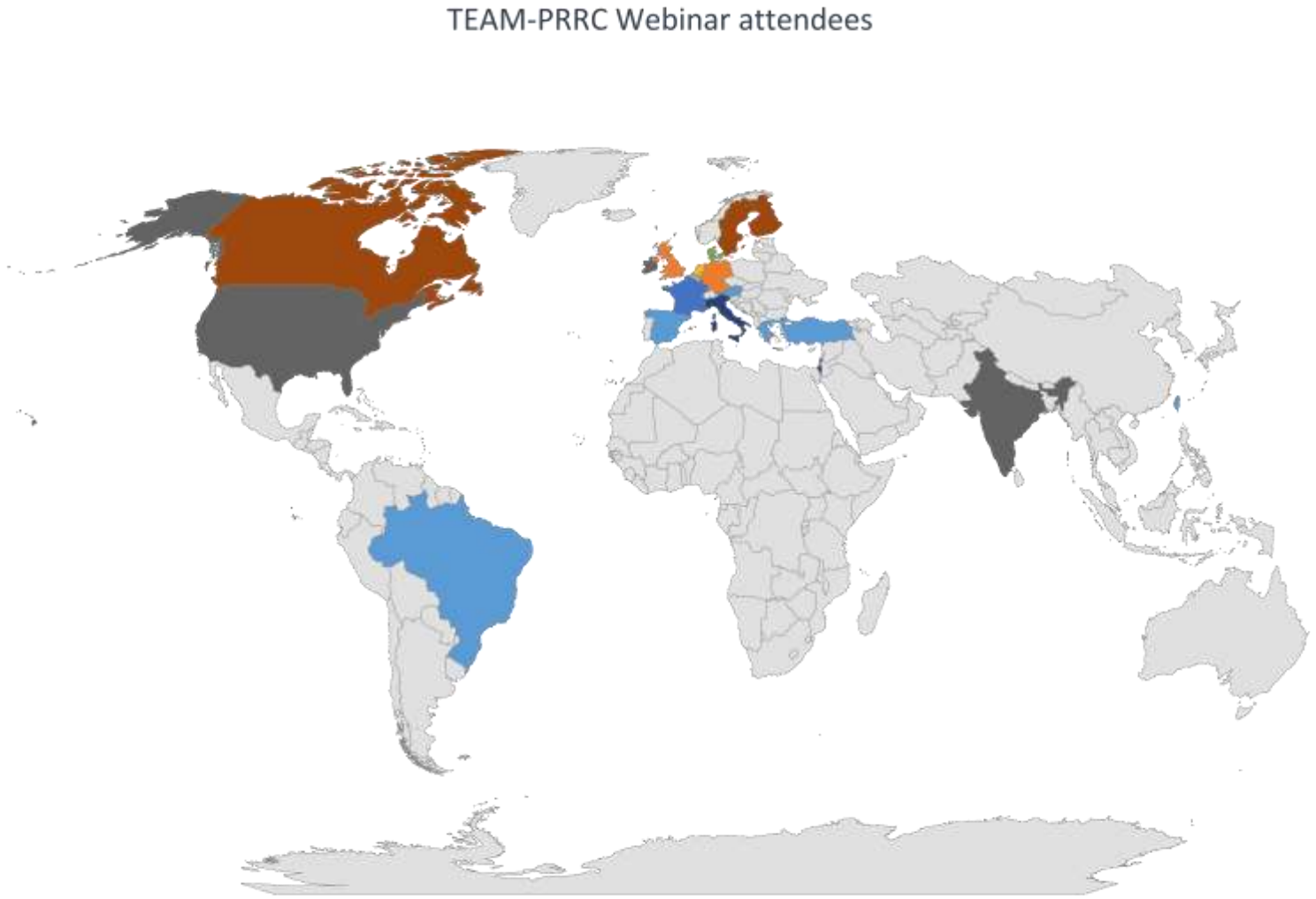
Our members

- **163 members (today) in 18 countries**
- **From different backgrounds**
  - Employees from manufacturers (SMEs in majority)
  - Employees from Authorised Representatives
  - Independent consultants

- **13 sponsors**
- **Gender equilibrium**
- **70 PRRC within organization / 35 contracted**

Today's attendance:

- 106 registrants in 18 countries (86 from EU member states)
- 20 TEAM-PRRC active members
- 50 PRRC within organization
- 10 PRRC contracted
- 6 Sponsors



Responsibilities of the PRRC - reminder

Article 15 (3) a to e

Checking device conformity for release
Art. 10(9)

Ensuring Technical file is drawn up and kept up to date
Art. 10(4) & (6)

Ensuring Post-market surveillance obligations are met
Art. 10(10)

Ensuring Vigilance reporting obligations are met
Art. 10(13)

Issuing Investigational devices statement of conformity with GSPRs
Annex XV
Chapter II

What are the practicalities?

Task list for appointment of PRRC

Recruitment – Demonstrate evidence of qualifications; generate letter of designation; define the job description including split of responsibilities if more than one PRRC and location(s)

Insurance – Decide who insures who for what

Methods – Define in procedures how the PRRC ensures all the requirements of Art. 15 are met, including the frequency of checks and what objective evidence should be reported to whom

Management of data – Decide who registers what information in EUDAMED and when (EUDAMED will be available for actor registration from 1st Dec 2020)

How Team-PRRC can help you

A professional practice

- Every member must agree to the Code of Ethics when joining
- Goal: To work towards recognition of this by Notified Bodies

Support in finding solutions to your professional PRRC problems

- Member Forum: Use it to share questions / thoughts
- Goal: Expand the Member Forum into topic areas – organise webinars or online meetings to discuss particular issues as they arise

Member Space

How Team-PRRC can help you

Conferences and specialized trainings

- We are working with partner organisations to provide training
- GOAL: Negotiate more discounts for training
  Hold our own Conference….eventually!

Information Source

- Access to a library of regulatory texts
- A regulatory watch
- List of service suppliers E.g. insurance & law companies, training suppliers
- GOAL: Negotiate more discounts for members

How Team-PRRC can help you

Representation

- We have already opened dialogues with regulatory authorities to represent the individuals performing the role of PRRC
- GOAL: To clarify our position on the requirements of MDR/ IVDR and pursue mutual understanding with EU, Competent Authorities and Notified Bodies

On-demand mediation

- If the worst happens and you find yourself in a dispute relating to PRRC's activities with an employer or regulatory authority
- GOAL: We aim to provide a mediation service to support PRRCs

Events

TEAM-PRRC	March 2020 – Established the Association
Medtech Insight	June 2020 - Article about Team-PRRC appeared in Medtech Insight
MedtecLIVE Connecting the medical technology supply chain	June 2020 – Team-PRRC attended Medtec Live (virtual)
	June 2020 - Webinars in French and English on the Role of the PRRC
La rentrée du DM 8ème édition	September 2020 – Team-PRRC exhibited at La Rentree du DM (in person!)
MEDI'NOV CONNECTION 2020	September 2020 – Team-PRRC exhibited Medi'Nov (in person!)
	September 2020 – Exploratory meeting with MDCG
	October 2020 – 2nd Webinar
6e RENCONTRES NATIONALES DES DISPOSITIFS MÉDICAUX 2020	November 2020 – Exhibit at Rencontres Nationales des Dispositifs Médicaux
MedFIT Fostering Innovation in medTech	7 -10 December 2020 – Attend MedFIT

Work in progress

We are currently working on

- Position paper
- Raising our profile with MDCG
- Negotiating insurance dedicated for PRRCs in every member state
- Templates
  - Letter of appointment
  - Job description
- Notified Body recognition of membership status
- Specialised PRRC topic webinars

Our sponsors

AIMD
Advice in Medical Device

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Question 1

Question	Team-PRRC opinion
I have heard that it may be possible to transfer "personal" responsibility for the PRRC to the "company" responsibility. Do you have any information on that?	Responsibility cannot be “transferred”. If you are talking about liability here rather than responsibility, then, yes, it might be possible to ask the company to insure the named individual as part of their overall liability insurance if that individual is an employee. This might not be possible if the PRRC is an external contractor. In this case, the contractor should have their own insurance.

Question 2

Question	Team-PRRC opinion
How do you, in your company, ensure you are living up to Art. 15 Section 5 in MDR. *"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"*	We think this is about ensuring that the PRRC is included in all opportunities for promotion or other work and is not excluded from payment, bonuses or other performance related rewards as a result of their activities. For example if the PRRC stops a batch of product from being released, they should not be penalised in any way.

Question 3

Question	Team-PRRC opinion
a. Does the EC-Representative PRRC need to have a certified QMS-system (either ISO 9000 or ISO 13485) in place?	a. The MDR and IVDR do not specify that the EC Rep (Authorised Representative) should have a certified QMS in place but it might be considered good practice to have some sort of QMS to ensure that processes required occur in a consistent and organised way. This is, however, a decision for the management team and not just the PRRC.
b. Does anyone have a draft checklist to use to check and document regulatory compliance?	Regulatory compliance as a whole is something the whole company should be working towards through the implementation of a QMS and a regulatory strategy. Such a checklist would be huge and vary enormously from organisation to organisation. However, we could think about some sort of template checklist for the specific tasks of the PRRC. Thanks for the idea!

Question 4

Question	Team-PRRC opinion
What would be considered minimum tasks /responsibilities for a PRRC for an AR? How far do the 5 main responsibilities as attributed in general to a PRRC apply for the PRRC for an AR (art 15. 3a-e): only the PMS related ones? or does the PRRC for an AR only needs to review the mandates to ensure the AR fulfills the mandated responsibilities as per MDCG 2019-7?	It is our understanding that the PRRC for an AR must ensure those parts of Art. 15 §3 that could be within the mandate are performed **and** also those things in Art. 11 §3. This could mean, for example, ensuring that there is a process within the AR to ensure that registration obligations have been met or to cooperate with competent authorities on requests for information or samples. **Remember** the PRRC is only checking that the tasks are fulfilled and not necessarily fulfilling them his or herself. The PRRC is looking for relevance, comprehensibility and completeness of records only.

Question 5

Question	Team-PRRC opinion
What is expected/considered minimum documentation to demonstrate that the PRRC for AR acts upon its responsibilities ?	This would depend upon the content of the mandate with the manufacturer but as a minimum, the AR should have procedures in place to address the requirements of Art.11 §3 and the records resulting from their implementation as well as copies of technical documentation including Declarations of Conformity and related certificates of conformity from Notified Bodies.

Question 6

Question	Team-PRRC opinion
Is the PRRC for an AR expected to actively initiate audits / spot checks over time to ensure AR did/continues to fulfill its mandated requirements appropriately?	Not sure if you meant audits /checks of the AR or manufacturer. Each PRRC should work out with their management how their responsibilities should be fulfilled. This means defining in procedures the methods to be used including frequency and location as well as the records to be generated in implementing those methods. Audits / spot checks are two methods but there might be others depending on the size of the company, number of locations, range and volume of devices being produced. The AR might decide that it is necessary to audit / check the manufacturer but it is up to them to decide.

Question 7

Question	Team-PRRC opinion
Are unannounced audits expected at ARs and has this been done yet? If so what type of findings could impact the CE certificate ? And subsequently : If the PRRC for AR executes upon the role's responsibilities appropriately , in which cases , if any , could he be made personally liable ?	The MDR and IVDR do not require Notified Bodies to audit ARs but as suppliers to manufacturers maybe it is possible. However they have a lot to get through in this transition phase without auditing ARs so…… Thirdly, there is no case where the PRRC could be held personally liable if he is fulfilling his role correctly. The question of personal liability is one which concerns a lot of people. The problem is that the penalties for infringement of Art.15 are decided upon by each member state separately as per Art.113. This is something Team-PRRC want to investigate in much more depth and provide additional support on to our members in future.

Question 8

Question	Team-PRRC opinion
Clause 3: ” *The person responsible for regulatory compliance shall at least be responsible for ensuring that…*” How is PRRC expected to prove that she/he is filling this responsibility? Should the new role and responsibilities of PRRC be reflected in internal audit process? Is the PRRC person herself/himself expected to perform internal audit to demonstrate that the responsibilities in clause 3 are effectively put in practice in the organization? (Without auditing her/his own work.) Or should the performance of PRRC responsibilities be audited by someone else (not PRRC)?	We think the first part of this question is answered in a previous question. In answer to the second part, yes, the activities of the PRRC are just another part of the QMS which should be included in the internal audit schedule. If the PRRC chooses to use auditing as a method of ensuring that the tasks in Art.15 §3 are completed then this is a different kind of auditing to that of clause 8.2.4 of ISO 13485. But, of course, someone else who is not the PRRC should audit the PRRC’s activities as part of QMS in just the same way that the internal audit process should be audited by someone who is not responsible for the internal audit process.

Question 9

Question	Team-PRRC opinion
I assume that PRRC is responsible for ensuring that there is compliant QMS enabling actions in clause 3, e.g. by writing SOPs. The PRRC herself/himself does not have to directly perform actions in clause 3. In other words, the person performing batch release or making incident reporting does not have to be PRRC. Is this correct?	Yes, this is correct. Again, whether the PRRC performs the batch release themselves or not depends on the size of the manufacturer, the number of locations, the range of products and production volumes as well as the number of PRRCs in the company.

Question 10

Question	Team-PRRC opinion
When the PRRC is working as an employee in an organization, the PRRC responsibility is included in their job description. A separate agreement is not required. Is this correct?	Neither the regulations nor the MDCG guidance 2019-7 make any specific mention of how this should be done. We think you should be cautious of top management (who perhaps do not fully understand the details around Art.15) adding “PRRC” to a person’s job description without any discussion of the methods, time requirements, reporting lines and so on. It is not a requirement but it might be beneficial to the PRRC to insist that there is a separate document to address all the things we have been talking about today.

Question 11

Question	Team-PRRC opinion
Can the Authorized Representative of a non-EU manufacturer be based in EU Member State A, and the PRRC (logistically and with legal contract attached to that AR) be based in EU Member State B? (see paragraph 6 of art. 15 MDR/IVDR)	The MDCG Guidance 2019-7 states that "*it is important that a close linkage of a permanent and continuous nature is established between the PRRC and the manufacturing activities*" and that, for an AR "*it must be assumed that any person to be permanently and continuously at its disposal must be also located in the EU*". It does not say anything about being in the same member state. So we would say, yes, provided the contract addresses how the PRRC will be permanently and continuously available, they could be based in a different member state.

Question 12

Question	Team-PRRC opinion
Can a micro or small enterprise inside the EU have the external PRRC in another EU Member State? (see paragraph 2 of art. 15 MDR/IVDR)	As per the previous question, there is nothing in regulations or guidance about having an external PRRC in the same member state provided there is a "*close linkage of a permanent and continuous nature*". The same practical considerations apply in establishing the contract between the manufacturer and external PRRC to describe how this is achieved. For example, availability in terms of days and hours and response times could be written into the contract.

Question 13

Question	Team-PRRC opinion
Does the PRRC need a legal contract with the AR in regard to Art. 15 §3 c) PMS obligations of the manufacturer under Art. 10§9. As it is stated in Art.11§5 that in case of non-compliance by the manufacturer, the AR is jointly legally liable together with the manufacturer for such non-compliance (under the entire Art. 10).	This question highlights the point that under Art.11, the AR is jointly and severally liable with the manufacturer for defective devices (not just for non-compliance as in the question). In answer to whether there should be a contract between the PRRC and AR, the mandate between the manufacturer and the AR specified in Art.11§3 should cover the subject of PMS obligations along with all the other parts of Art.10 and Art.11 that apply. Therefore we would say that the PRRC does not need to hold an additional contract with the AR but should check that the mandate is clear about the AR's role in PMS.

THANK YOU FOR LISTENING

For more information about Team-PRRC and to find the presentation go to:

www.team-prrc.eu

Please inform your colleagues about Team-PRRC.
The more members we have the greater our voice!