



Your TEAM-PRRC association

Newsletter N°3

June 26<sup>th</sup>, 2020

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## EDITORIAL

Dear members, bonjour!

Here is a new challenge! Providing an attractive editorial every month to PRRCs community when you are an expert in Active Implantable Medical Devices and associated technologies! Economic activities are gently recovering from that devastation which even impacted us in our deep and secret life philosophies. Yes, for sure there will be another life “after” and we are main actors of its “better” integration. Our activities, in the medical field, have shown in the front line response these last weeks. The need for relevant technologies based on strong clinical evidences and supported by solid regulation has been definitively demonstrated, starting from simple face protections up to “smart” life sustaining respiratory systems. Here is our reason for existence in that long chain of responsibilities and commitments.

PRRCs are responsible for compliance of devices delivering priority *services* to the Human community and providing patients with better lives, if not simply survival!

This association remains YOUR association so feel free to pass on this newsletter to your colleagues and acquaintances in Europe. They are all welcome.

Stay safe and keep on with compliance! With our kind regards.



## **The TEAM**

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### Your association:

We now blithely surpassed 100 active members since we launched the TEAM-PRRC association in March. Still good news which so, call for more care and activities with all of you! Still some bugs from our website platform but the handful of laypersons we are, together with your solidarity and patience, is rather proud of our team enterprise.

The long-awaited “FORUM” is now operational in our website and we believe it will be one of our major collective resource to feed Q/A and knowledge and reference database. So [CHAT!](#)

We also welcome Marc Simondi at the TEAM-PRRC board. He brings is strong experience in Class III Regulatory affairs.

We added new features in your profile which you could also use to advertise your activities. So please update your profile (image could be your company logo...) and LinkedIn remains a major professional network.

If you are experiencing difficulties, do not hesitate to contact us: [inform@team-prrc.eu](mailto:inform@team-prrc.eu)

## NEW SECTION : Just for you!



[MDlaw, Information Platform on EU Medical Device Regulations](#) offers a system that helps you identify and monitor relevant regulatory requirements and related changes, as per the ISO 13485:2016. At **one place**, all relevant regulatory documents, guidelines, case-law and regulatory updates are gathered and published when released. Additionally, different MDR and IVDR implementation tools can be found. Guidance, templates and checklists on clinical evaluation, GSPR, post-market surveillance, and others were exclusively prepared by our experts to help you comply with the new Regulations. TEAM-PRRC members will enjoy a **50% discount** on the MDlaw three membership options. Detail on your member space.

Links: [MDlaw in 1 minute!](#) **Become [MDlaw member](#) today!**



Audit and Risk Solutions, insurance broker, has agreed to propose Civil Responsibility Insurance contracts dedicated to PRRCs with special discount to our members. A specific version for those PRRC practicing within companies will be proposed. More details on your member space to come soon.

## Events



### TEAM-PRRC Webinars

TEAM-PRRC successfully lead two “inaugural” webinars about the most important things to know regarding the Persons Responsible for Regulatory Compliance according to the article 15 of MDR & IVDR. Two 2 sessions were planned:

- An English session on 17<sup>th</sup> June 2020 presented by our Vice-President, [Anne Jury](#)
- Session en Français le 19 juin, presented by our President, [Elem Ayne](#)

These webinars lasted 1 hour and were free for our members. Numerous guests including EU commissioners, institution and stake-holder representatives joined and appreciated our presentation enhancing the impact of our association.

Attendees: 15 people joined on 17<sup>th</sup> June 2020 while over 40 people attended on the 19<sup>th</sup> of June.

The members could add their questions either prior to or during the event. Questions and Answers will be soon published in our new FORUM space for further discussions and precisions.

For those who could not attend, these free webinars were recorded and are available on member space together with the slides.

## To come



### MedtecLIVE

TEAM-PRRC association is registered at [MedTecLIVE](#) Summit Congress which will be held virtually from 30 June to 2nd July 2020 in that particular period. Visit !

### Easy Medical Device Podcast



Team-PRRC has been invited to Easy Medical Device Podcast organized by [Monir El Azzouzi](#). We will be interviewed about the role of the PRRCs and their liabilities. The video of that podcast will be released around the 13th July. You will know more about us by following this podcast. More details in our next Newsletter.



### TEAM-PRRC Q/A webinar sept/oct 2020

Preparing the questions for that particular session:

Team-PRRC is preparing a new session of webinar in the form of Q&A, and it will be open to all people interested to attend. You can ask your questions as from now by sending them to our email address [inform@team-prrc.eu](mailto:inform@team-prrc.eu) (please insert TEAM-PRRC Q/A webinar sept/oct 2020 in title) or sharing them in the forum (for our members). Thanks to that session, all people could know more about what Team-PRRC activities and its objectives. We hope that this will be useful and fruitful to all of you.

We aim to outcome this event with a list of questions clearly formulated to be forwarded to the EU commission and the MDCG. This will establish our presence as a major stakeholder when talking of PRRCs.



### TEAM-PRRC @ La rentrée du DM

TEAM-PRRC will be present in its first face to face event at the “8ème Édition de la rentrée du DM” on 29-30 September 2020 in Besançon (France).

Join and meet us in our booth during this major event dedicated to Medical Devices.

Our sponsors: visit them on our website!



Soon to join us:



## News

*We talk about us!*



In its last digital issue, Devicemed magazine and Patrick RENARD promote again our association: [READ MORE](#)

### Medtech Insight **New EU Association Supports EU Regulatory Compliance Role As Responsibilities Take Shape**

Informa Pharma Intelligence

How will the new, not-for-profit European association, TEAM-PRRC, support the many regulatory experts – perhaps more than 50,000 individuals - who take on the new weighty responsibilities that come with the role of Person Responsible For Regulatory Compliance (PRRC) under the EU MDR?

Elem Ayne, president of TEAM-PRRC and Anne Jury, vice-president, talked to Medtech Insight about the uncertainty that remains around this role and how TEAM-PRCC hopes to influence EU guidance that is being developed for the PRRC role in an interview with Medtech Insight.

Issues covered include: the biggest challenges ahead for the PRRC; where the PRRC should be located; liability; the overlap with the authorized representative role; recruitment challenges; and the UK position. The full interview with Medtech Insight's Amanda Maxwell is available to MI subscribers [HERE](#)



TEAM-PRRC association has launched "THE Forum" in our website, a space for questions, reflections, discussions, exchanges & .... answers dedicated to our members and addressing PRRC daily life and questioning. Visit the forum [HERE](#)

## To review and decide We (still) need your opinion

To promote your TEAM-PRRC Association, we need a striking motto such **as 'Compliant together'** (not complaint together!). To help us to decide, we offer you to voted here: [TEAM-PRRC motto poll](#) . Our motto will be disclosed and announced in our next issue!

That's all for that issue of YOUR association newsletter. Hope you enjoyed.

Hear from you very soon

**The TEAM**