



Your TEAM-PRRC association

Newsletter N°2

May 26th, 2020

Editorial:

Dear members, bonjour!

Here we are, May 26th, 2020, all right! But what else? Nothing has happened on this particular day. Three years that this date has been calling for so much energy from so many of us. A date feared by so many MD manufacturers including QA and RA managers. A date so expected by those who spent so much time and efforts to 'square' their organisation and devices.



And a microscopic organism able to devastate lives and disrupt the planet for a long time is all will remain from this sad spring 2020; Who could have predicted such a disaster!... C'est la vie!

Be that as it may, The Show Must Go On sang Freddie carried off by a virus and a lung inflammation so many years ago.

At least, it will demonstrate our need for more Europe all together with more consensual and structured regulation. PRRC will be one major link of that value chain in the Medical Device field and our association aims to be the flagship of that occupation.

Our brisk activity and the increasing number of you joining us strengthen our belief in our project. We work hard on it and invite you to participate more and more in spreading our actions all over Europe. 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



Membership:

We now passed 50 active members within our two months existence. Good news.

Our registration process is now bedded in and so we have more time for reflections. We still have some of you in the system who have not yet completed the registration form or agreed the statutes and Ethical code, or simply paid their membership fee. Please proceed!

Our board has grown and we welcome Gérard PELISSON to the TEAM. He brings us his long experience in task force organisation.

We continued to add new features in member profile such as LinkedIn link.

Please update your profile.

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

Events to come

TEAM-PRRC Webinars



Free webinar: All you need to know about PRRC (Person Responsible for Regulatory Compliance)

Date: 17th of June 2020	Date: 19th of June 2020
Time: 16:00h - 17:00h CEST	Time: 16:00h - 17:00h CEST
Location: Virtual	Location: Virtual
Language: English	Language: French
Trainer: Anne JURY, Regulatory Affairs Expert	Trainer: Elem AYNE, Regulatory Affairs Consultant

Introduction
During this one hour webinar **dedicated to our members**, our President & Vice-President tell the most important things you need to know about the role of a PRRC, according to the article 15 of MDR & IVDR.

Free for our members but registration required : please go to the link just below

TEAM-PRRC proposes an introductory webinar about the most important things to know regarding the Persons Responsible for Regulatory Compliance according to the article 15 of MDR & IVDR.

Two sessions are planned:

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

These webinars will last 1 hour and are free for our members.

Register in our website: www.team-prrc.eu.

The members can add their questions, as from now, in the FAQ in the member space.

For those who could not attend, these free webinars will be recorded and be available on member space for further access.

OBELIS Webinar:

As announced in Your TEAM-PRRC monthly newsletter Issue N°1, we are happy to invite you to the webinar “MDR Advanced- What any PRRC must know” organized by Obelis



Powered by OBELIS group:
SPECIAL OFFER reserved to TEAM-PRRC members
50% discount for this in deep two days course

WEBINAR- MDR ADVANCED: What any PRRC must know

Register

JUNE 24 - 25, 2020

REGISTER NOW!

The aim of this online comprehensive course is to provide the knowledge and train attendees to be able to act as "Person Responsible for Regulatory Compliance" within their organisations under the **Medical Device** and **In-Vitro Diagnostic Regulations** (MDR & IVDR).

A huge [PROGRAM](#) with some of the most qualified Keynote Speakers in that field including our Vice-President Anne Jury!

Special discounts reserved to TEAM-PRRC active members:

- 50% off for any TEAM-PRRC member*
- 100% off for any TEAM-PRRC member* that referred another person to register and they both registered

→ **Check in member space on our website** [TEAM-PRRC](#)

* Active TEAM-PRRC membership will be verified

News




We welcome Mrs Barbey as Honorary member. Advocate highly specialised in Medical Devices business law, she will support TEAM-PRRC association and active members in that particular topic: [Contact her](#)





Our historic sponsor White-Tillet cabinet proposes special discounts for TEAM-PRRC association active members in regulatory expertise and training [IFEP](#). White-Tillet invites you also to join a free Webinar on June 23rd 2020: “WEBINAR IFEP 1ère Rencontre Règlementaire WHITE-TILLET (RRWT)” in French : [RRWT](#)





We welcome S4M Europe, our new sponsor. As EU-Authorised Representative company, it offers services such as registrations, Post Market Surveillance & auditing.

 TEAM-PRRC is closely collaborating with Obelis Group and MDlaw.eu and building a strong relationship to offer its members with solid opportunities in terms of training, education and regulatory tools and watch.

 TEAM-PRRC association just registered in the “EU Transparency register”. The transparency register is a database that lists organisations that try to influence the law-making and policy implementation process of the EU institutions. A little first step [\(read\)](#)

 TEAM-PRRC association aims to participate at MedTech Summit Congress & Partnering Event which will be held virtually from 30 June to 2nd July 2020 in that particular period. More details to come.

 TEAM-PRRC will add a “FORUM” in our website, a space for questions, reflections, discussions, exchanges & ... answers dedicated to our members and addressing PRRC daily life and questioning. Suggestions welcome to [Team-PRRC](#)

 A PRRC guidance document is ongoing. It will include all the information a PRRC need to know about its responsibilities and tasks.

Under construction

TEAM-PRRC has always had the ambition to officially launch our association at a major event, mainly in Brussels inviting EU commissioners and MDCG representatives. We are still working on it. All proposals and offers of support are welcome: [President](#)

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 vote 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. This is YOURS so feel free to provide us with any news, event or subject you think to be relevant to share with us. We will be glad to publish it. Hope you enjoyed. Hear from you very soon.

The TEAM