

Your TEAM-PRRC association Newsletter N°7

October 31th, 2021

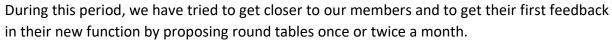
Editorial

Dear members,

Summer has gone and this dreadful virus is still everywhere, but we will resist and survive thanks to medical devices!

It has been 5 months since we entered the era of the Regulations and 5 months since the PRRC function came to life.

5 months that TEAM-PRRC demonstrates its reason to exist according to the numerous contacts and requests we received from you.



We will continue to do this and then write more documents to clarify and harmonize the practices of this function, which is becoming central to medical device manufacturers, agents and importers/distributors who may be required to designate such a function if they perform activities that are the responsibility of manufacturers.

TEAM-PRRC's primary goal is to represent PRRCs throughout the European Union and internationally. We therefore invite all those eligible for this function to become members of the association in order to build together the future of this function.

This association remains YOUR association so feel free to pass on this newsletter to your colleagues and acquaintances in Europe. Stay safe and keep on with compliance strategy towards safer and more effective devices for EU citizens!

The TEAM

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Your association

Our membership has increased during this end of year 2021 with more and more members from a variety of horizons in many countries, which is good news. TEAM-PRRC association and its objectives take on its full meaning. To that aim, we still do need all of you to spread the word and recruit others to the cause.

We continue to maintain our close relationship with the relevant stakeholders including but not limited to EU MDCG. We will represent all PRRCs and provide your feedback by considering the legal text and rules of proportional applications. To make that happen, we do need your support and value your inputs. Please send us your questions, your opinions, and your thoughts regarding the PRRC's duties, responsibilities and any other related topics.

For a reminder, you have 3 ways to join the association:

- You can become an active member for 250 €/year if you fulfil the criteria of Article 15;
- 2. You can join as a supporting member for 500 €/year if you don't fulfil the criteria of Article 15 but you plan to become a PRRC and want to support the association;
- 3. If you are a company which can propose benefits to PRRCs, you can become a sponsor for 500 €/year.

TEAM-PRRC remains committed to supporting its members and continues to work with regulatory authorities to work towards a harmonized interpretation of European requirements.

In that way, the association has restructured its organization, with:

- The Board, including:
 - o Elem Ayne: President
 - Anne Jury: Vice-PresidentBassil Akra: Vice-President
 - o Jean-Louis Divoux: Secretary
 - o Daniel Petit: treasurer
 - Ronald Boumans: Member of the Board
- The Advisory Board, including:
 - o Denys Durand-Viel: founder member
 - Corinne Delorme
 - David R Rutledge

And now, TEAM-PRRC would like to enlarge its organization creating a Contributors team, including interested active members, who can take a part in the development project of the association. Interested active members can reach us by email at inform@team-prrc.eu.

These projects will be led by one member of the Board, and contributors can have some meetings about this later. The topics of these projects are:

- PRRC liability: this will be managed with one of our lawyers
- Job description template
- PRRC's replacement procedure
- **EUDAMED**
- Round Table: the contributor can help us to collect the question
- Representative on Member States: legal issues, insurance, translating
- FAQ: these are the Questions & Answers + Forum

More will follow with your help!

Send us some of your relevant findings on PRRC documentation and support, even specialized press releases including original source references; we will share!

Provide us with requests and ideas about relevant templates that could be drafted and shared together within the PRRC community.

PRRC insurance:

TEAM-PRRC has finally negotiated an insurance dedicated to PRRCs. To start, this one is only proposed for French people, then the contract

can be translated and proposed to European PRRCs.

This insurance contract covers the professional civil liability of PRRCs during the performance of their obligations relating to Article 15 of EU MDR 2017/745 and EU IVDR 2017/746 into European Union.

The members interested can start to subscribe to that insurance by filling out the form thanks to the link provided in their member space.

Position Papers:



TEAM-PRRC planned to publish 4 Position Papers:

N°1: Qualifications of the PRRC

N°2: Contracts and location

N°3: The Responsibilities of the PRRC at a Manufacturer

N°4: The Responsibilities of the PRRC within an Authorised

Representative

We have finished and shared the two first Position papers with our members and the MDCG. We plan now to run some webinars on the Position papers N°1 and N°2 in December and January. Thanks to that, we can have the feedback from the members and improve these documents. We hope that these documents will bring more clarifications to the activities of the PRRCs.

We will share the 2 other Position Papers soon.

New member in the Advisory Board!

We have welcomed during the summer **Mr David R RUTLEDGE**.

He will manage the topics related to PRRC based outside the EU.

We are very pleased to strengthen our association with key experts.



David R Rutledge, Pharm.D., FCCP, FAHA is an accomplished and results-oriented global consultant for clinical evaluations, clinical risk management, regulatory, quality, and clinical investigations. He brings 25 years of experience and exceptional knowledge in product-level analysis, clinical protocol and eCRF development, scientific data analysis, organizational design, integration of science with business needs, quality management systems, signal detection, global clinical evaluations, clinical risk management, and regulatory affairs. He has direct experience developing and leading international regulatory presentations, submissions, and reports to agencies such as US FDA, Brazil ANVISA, Mexico COFEPRIS, NMPA (China FDA), S Korea Ministry of Food and Drug Safety, Hong Kong, Malaysia, Health Canada, Australia TGA, Thailand FDA, Japan PMDA, EMA, Saudi FDA, CDSCO of India, UK MHRA, and several Notified Bodies, e.g., BSI, DEKRA, GMED, MEDCERT, NSAI, and TÜV SÜD. He has participated in the FDA COVID-19 Emergency Use Authorization program.

He has management and professional experience in pharmaceutical and device program teams involving products within the cardiovascular, gastrointestinal, respiratory, and AIDS therapeutic areas. As a former tenured Professor/Chairman in academia, IRB member, and clinical investigator, he understands the role of a PI as a sponsor-investigator in clinical trials. He has published over 100 manuscripts. He was inducted as a Fellow of the American Heart Association in 1995. Dr. Rutledge served on two FDA panels which led to publishing a device-drug combination Guidance Document on Coronary Drug-Eluting Stents (March 2008). He was a speaker for FDA's Post-Approval Studies for Medical Devices Workshop (June 2009) and then served as a panel member for the Methodologies for Post-Approval Studies of Medical Devices Workshop (September 2009). In 2010, he accepted a 4-year appointment from the United States Department of Health & Human Services to serve as the Industry Representative on the FDA's General Hospital and Personal Use Devices Advisory Committee in FDA's Center for Devices and Radiological Health (CDRH). He also served on the June 27th, 2013, Gastroenterology-Urology Devices Panel of CDRH. He was certified in the Abbott Compliance Development Program, Abbott Guest Auditor, and 21CRF820 Quality Systems. He is Six Sigma and CAPA certified along with being an ISO 13845 lead auditor. Dr. David R Rutledge was formerly a Director with Abbott Medical Devices in Global Clinical Research and Global Regulatory Operations, where he managed budgets up to \$23.3 million. He is currently President & CEO (Founding Partner) at Global Strategic Solutions, LLC within the Biotech, Med Device, Clin Evaluations, Clinical Risk, PMS/PMCF, R&D, Clinical Trialist, and Biologic Compatibility sectors within the Global Clinical, Regulatory, and Quality areas.

Just for you (our active members)!

This tab (<u>For U</u>) in our Website includes opportunities and discounts from our cherished sponsors, specifically reserved for our active members. There are attractive prices on training, news feeds and regulation watches, along with documents and templates for your everyday activities... and much more!!



MDlaw annual membership: 43 EUR – 125 EUR – 330 EUR

TEAM-PRRC member promotion: **50% on all membership levels**, starting at 23 EUR per month! The discount coupon is shared in membership area {to be used at the checkout of the Store}.



20% Special discount for all the webinars to any Team-PRRC member (up to date with his membership fee).



Online MDR (EU) 2017/745 training course (French only); 6 months continuous access and including 2-hour-live session of Questions and Answers: TEAM-PRRC members special rate: 750€ (instead of 1000 €).

Special 20% discount on one year "Premium" subscription to "Flash de DM Experts" articles.

And more!



Our sturdy partner MDlaw wrote a very interesting article, on language requirements and sanctions under MDR in Belgium.

They exceptionally agree to share it only for TEAM-PRRC members. Find it here :

<u>Language requirements & sanctions under the MDR: Belgium</u> Pdf file will be available in the Active member space.



We have also delivered useful templates such as "<u>Template agreement for external PRRC services for Manufacturers</u>" and also "<u>Letter of appointment model for PRRC</u>".

Some other interesting reference documents are also included, such as "<u>Dutch penalty clauses</u> <u>under MDR</u>" and available on the page titled: **Reference Documents**.

Past Events

TEAM-PRRC was at "La Rentrée du DM" in Besançon from 6th to 7th October



du DM".

La Rentrée du DM has, over the years, become a major (French) event devoted to the Medical Device industry. Supported by one of the top-rated Engineer Highschool (ISIFC) in the medical device field, this event was mainly dedicated to training by means of talks and presentations from major actors of the selected topics of that edition: Regulatory news and update and Design management. Numerous contacts were made and we had the chance to meet some

of our members face to face during this "9ème edition de La Rentrée

TEAM-PRRC was at "La Journée Méditerranéenne du DM" in Gardanne on 12th October





The objective of the day was to clarify and identify the different steps necessary to obtain or renew the CE marking of medical devices (Pre-clinical - Clinical - Regulation)

TEAM-PRRC was at "Les rencontres nationales des DM" in Nîmes on 21th October



Organised by EUROBIOMED, Openîmes Métropole ADE and the CHU of Nîmes, this 7th Edition was dedicated to strategic partnerships in medical devices: academic, clinical, industrial, from the idea to the finished product and experience sharing from experts in the field.



Webinars and Round Table



Webinar for our members on June 22th, 2021

We invited our members to a webinar to talk about the requirements of the article 15 and get their feelings with their new role as PRRC.

At that time (1 month after the application of the MDR), many of the attendees had not yet formalized their designation nor did they anticipate or prepare for what their activities as a PRRC would entail. Thanks to that session, all people can get a better understanding of the daily activities of a PRRC. We hope that this has been useful and fruitful to all attendees.



Round Tables free of charge and open to all

These round tables are managed by 1 or 2 Members of the Board, and once or twice per month.

These sessions are free of charge, open to all but places are limited to 30 attendees to have a better quality of exchange and experience sharing.

We invite all interested people to follow us on <u>LinkedIn</u> in order to register for each session that will be organized.

For the next sessions, we plan to record them and then make it available in our <u>website</u> and Youtube Channel.

To come

TEAM-PRRC @ "MEDICA" as visitor in Düsseldorf from 15th to 18th November, 2021

TEAM-PRRC will be in MEDICA as a visitor, to visit manufacturers of medical devices.



MEDICA is the world's largest medical trade fair for medical technology, electrical medicine, laboratory technology, diagnostics, physiotherapy, orthopaedic technology and consumer goods. The trade fair takes place once a year in Düsseldorf during 4 days and can only be accessed by trade visitors. Medica takes place at the same time as the world's leading trade fair for medical suppliers, Compamed. Thus, the entire process chain of medical products and technologies is presented to the visitors and makes a visit to both exhibitions necessary for all experts in the industry.

An update on current changes to MDR, IVDR & Role of the Person Responsible (PRRC)



November 17 @ 10:00 am - 11:30 am (GMT) >>>> ATTEND

Our Vice-President, **Anne Jury**, will be speaking at this free-to-attend event on the subject of the role of the PRRC.





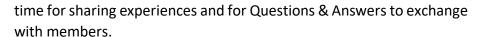
TEAM-PRRC webinar (in <u>GERMAN</u>) planned for 23th
November, 2021 at 5.00 pm CET – <u>free of charge and open to</u>
<u>all.</u> >>>> ATTEND

New webinar about the role of the PRRC presented in German by our vice-president Bassil Akra. There will also be time for Questions & Answers to exchange with members.



TEAM-PRRC webinar (in <u>ENGLISH</u>) planned for 13th December, 2021 and 13th January, 2022 at 6.00 pm CET – dedicated to members.

Two webinars about the Position Papers published by our vicepresident, Anne Jury and our President, Elem Ayne. There will also be





ROUND TABLE (in <u>ENGLISH</u>) planned for 22th November, 2021 at 6.00 pm CET – <u>free of charge and open to all.</u> >>>> ATTEND New Round Table about the role of the PRRC presented by Anne Jury,

New Round Table about the role of the PRRC presented by Anne Jury, our vice-president. This is a great opportunity to exchange with PRRCs and share experiences.



ROUND TABLE (in <u>ENGLISH</u>) planned for 2nd December, 2021 at 5.00 pm CET – free of charge and open to all.

New Round Table about the role of the PRRC presented by Bassil Akra, our vice-president. This is a great opportunity to exchange with PRRCs and share experiences.



ROUND TABLE (in <u>ENGLISH</u>) planned for 11th January, 2022 at 5.00 pm CET – <u>free of charge and open to all.</u>

New Round Table about the role of the PRRC presented by Ronald Boumans, Member of the Board. This is a great opportunity to exchange with PRRCs and share experiences.

Our sponsors

We thank all of our sponsors: visit them on our website!































We wish all medical devices actors a good year ahead for the application of the MDR and all the best for the PRRCs in their new function.

That's all for this issue of YOUR association newsletter.

Hope you have enjoyed it and hope to hear from you very soon.

The MANAGEMENT TEAM