Your TEAM-PRRC association

Newsletter N°5

January 31th, 2021

Our president, Elem Ayne, message:

Dear members, partners and all,

This year will mark the beginning of an exciting new chapter by the application date of the MDR (EU) 2017/745 and will be far from restful for MedTech Sector. I wish all of you Health, Energy, Confidence, Perseverance, Hope, Happiness and Success.

To start this new year, we have decided to have an expansion of the formal structure of the organisation by the addition of a management team to more clearly identify roles and responsibilities within the day-to-day management of ongoing activities.

In this regard, we are happy to include a key subject matter expert to our Board: Dr Bassil AKRA, the CEO and Co-Owner of QUNIQUE, former Vice President of Global Strategic Business Development at TÜV SÜD Product Service. Dr. Akra will support us, at least but not limited to, in our external communication with the legislators and relevant associations in Europe, in

guiding our strategical plans and on ensuring that the voice of our members is considered during the preparation of guidance documents.

We have added the Advisory Board, including Mr Denys Durand-Viel, President of DM Experts and the founder member of the association and Mrs Corinne Delorme, Regulatory Intelligence Director of Nexialist.

And finally we have also added the Contributors team, including all the members of the association who want to participate actively to the future projects of the association. The members will have to approve this new structure during the next General Assembly. The date will be communicated later.

We remain committed to drive things forward sharing values of equity, integrity, mutual aid and humanity.

I also take this opportunity to thank all our members and sponsors who supported us reaching our target in 2020 and are still supporting us towards achieving the strategical target of our association.

Dr Bassil Akra, CEO & co-owner of QUNIQUE GmbH

QUNIQUE GmbH is a medical device and in-vitro diagnostic consultancy company, located in Germany and Switzerland. Dr Bassil Akra spent the last decade as a subject matter expert at the biggest notified body in Europe and represented locally and globally the notified body association in the various European discussions. He was the Vice President for strategic business development at the Global Medical Health Services of TÜV SÜD Product Service GmbH in Germany. He has long experience in leadership, business management, research, development, quality management and regulatory approval of medical devices, combination devices and ATMP products. Dr. Akra played an essential role during the implementation of the medical device regulation (MDR 2017/745) in Europe and was involved in the drafting of the several European guidance documents (e.g. MEDDEV, MDCG, etc.). He spent the last years of his career at TÜV SÜD training and educating the various stakeholders on the EU Legislations (e.g. MDD/AIMDD, MDR and IVDR) and their impact on the EU healthcare system.

Editorial

Dear members, bonjour!

As the EUDAMED actor registration module has been recently activated voluntarily (from 1st December 2020), the PRRC must be declared while registering a Manufacturer or an EU Authorised Representative in EUDAMED. This means the names of such personnel are

disclosed in the public European data base which might lead to additional measures in each organization ensuring compliance to data protection rules. For details regarding the released module 1 of EUDAMED, click here EUDAMED.

With this registration in this database, a recurrent question becomes clear. While only PRRC names are now public, who has the responsibility in case of for instance a medical device failure? PRRC identity is the ONLY public name associated with the company or the manufacturer. It is now clear that the PRRC will be the ONLY publicly identified face of the economic operators. Who holds the responsibility? Where should potential harm be addressed, to the manufacturer or to the PRRC or both? TEAM PRRC will help the members getting all these questions clarified. Some historical experience have shown the fateful power of such transparency even within the best of intentions. We would like to influence this interpretation and want to make sure that compliance to the legislation remains reasonable and does not create new issues which could be clarified by countermeasures at an early stage!

This definitively demonstrates the high expectations devoted to that new position by both regulations the MDR and the IVDR. It confirms the need of highly responsible professionals to hold such a major regulatory role in the medical device and in-vitro diagnostic industry.

We join our president to wish all of you our best wishes for this new decade with the hope for more clarity and purpose on what is going to happen in OUR future.

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 a better EU with safer and more effective devices!

The TEAM

In this issue:

Your association:

Our membership remains steady during the last quarter 2020. However, while we are approaching the "Date" we still need to enhance our visibility and promote our influence to become a major stakeholder with the authorities. To that aim, we do need all of you to recruit and spread the word.

We continue to maintain our close relationship with the relevant stakeholders including but not limited to EU MDCG. We will communicate in your name and provide your feedback by considering the legal text and rules of proportional applications. Towards that aim, we do need your support and inputs. Please send us your questions, your opinion, and your thoughts regarding the PRRC's duties, responsibilities and any other related topics.

The "FORUM" is operational in our site, in your member space. Use the opportunity to exchange with PRRCs and CHAT!

Some of you entered the association website but have still not finalized their membership! If you are experiencing difficulties, do not hesitate to contact us: SUPPORT

Just for you (our active members)!

This new tab (**For U**) in our Website includes opportunities and discount from our cherished sponsors reserved for our active members. There are attractive prices on training, news and regulation watches, documents and templates for your everyday activities… and much more!!

New year special from White-Tillet:

25 % Special discount for TEAM-PRRC member on this webinar dedicated to PPRC's rights and duties presented by Pr Anne-Catherine Perroy, Doctor of Pharmacy, Doctor of Law, lawyer.
FORMATION PRRC by White Tillet

Past Events

TEAM-PRRC @ La rentrée du DM

TEAM-PRRC was 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).

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 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 in the flesh.

TEAM-PRRC Q/A webinar 29th October 2020

This two-hour webinar was a great success for with more than 60 attendees including EU and Health Authorities representatives.
We took that opportunity to build our TEAM-PRRC YouTube Channel!!
Sessions were recorded and available at WEBINARS++ in our website.
Thanks to that session, all people can know more about TEAM-PRRC activities and its objectives. We hope that this will be useful and fruitful to all of you. We gathered from this event a list of questions which feeds our actions with the EU commission and the MDCG. This also consolidated our presence as a major stakeholder when talking about PRRCs.

TEAM-PRRC @ La Journée du DM

TEAM-PRRC registered for the face to face event at the "6ème Rencontres Internationales des DM " on 5th November 2020 in Nimes (France). This is one of the major events of the South of France medical cluster Eurobiomed. However, the event had to go to virtual and we were offered and we accessed to B to B meeting + adverts held during Eurobiomed General Assembly on 10th of December together with our sponsor-partner DM-Experts.

TEAM-PRRC @ MedFIT

TEAM-PRRC registered for the face-to-face event MedFIT (France) which rapidly turned to a fully digital online event. This event was organized by Eurasanté, a major development agency dedicated to tech transfer and business development the in-life sciences sector.

TEAM-PRRC @ Regulatory breakfast: PRRC

TEAM-PRRC together with our sponsor-partner OBELIS were invited by Norway Health Tech to give a talk at the last of five regulatory breakfasts addressing important issues for your regulatory work and the role of the PRRC. Thanks to this virtual meeting, TEAM-PRRC had interesting discussions with attendees. Norway Health Tech is a technology cluster facilitating the growth of new and innovative healthcare solutions.
Virtual breakfast Norway Health tech

Virtual 5th EAAR Annual Conference on New Medical Device Regulations (RMD2021). (26-27 January 2021) *>> MORE INFORMATION <<*

To come

DIGITAL WEEK Medtech-summit conference
On 8th March 2021, TEAM-PRRC has been invited to talk about the role of the PRRC and what are the expectations of the manufacturers.

Thanks to our sponsors: visit them on our website!

IFIS DM
Training and Consulting in Medical Device. IFIS group, leader for vocational and professional training in Healthcare Industries (France).
IFIS

Easy Medical Device

Liven up well known Monir El Azzouzi, this site promises:
"All you need to have a better understanding of Medical Devices"
Easy Medical Device

iV PASS

iV PASS is a regulatory consulting company dedicated exclusively to In Vitro Diagnostic Medical Devices.
iV PASS

Short News

- **Position paper – we had some exchanges with the MDCG about this document and we plan to publish it next month**
- **Raising our profile with MDCG**
- **Negotiating insurance dedicated for PRRCs in every member state: still in process for the European insurance, and we succeed to get some insurance agreement from French insurance companies.**
- **Templates (these documents will be published after the approval of our lawyer)**
- **Letter of appointment**
- **Agreement**
- **Job description**
- **Specialised PRRC topic webinars**
- **Call for interest to our members: which topics for the webinars ? call for contributors about our project (Combined product/pharmacist; national laws; IVD devices; GDPR; …)**

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

Hope you enjoyed. Hear from you very soon.

The TEAM