Your TEAM-PRRC association

Newsletter N°6

May 26th, 2021

(Copyright EU Commission)

Editorial

Dear members, bonjour! "MDR DAY": HERE we are!!!

The countdown reached zero so we have to find something else to animate our website front page now 😉. Why not something about IVDR??

We have observed a remarkably high and sometimes sudden agitation from all sides with recommendations, guidance and guidelines, last-minute webinars and posts. Even some improbable combinations of lobbyists are still hallucinating a possible adjournment of the MDR application … no chance!

Of course, not all economic operators are fully ready and we are even facing some strange situations with the very low number of Notified Bodies along with the disappearance of many of them.

It even appeared in a very recent event in which TEAM-PRRC participated (Medi'Nov Connection 2021) that 61% of the attendees had not appointed their PRRC to date. This is both disturbing and a strong motivation to mobilize our association.

However, we have to continue and you, the PRRCs, will be the lead climbers in this ascent to conformity. We are here with you and for you.

TEAM-PRRC has been launched and built to support you and help you in your daily duties. In addition, we also aim to have long-haul activities on the positioning of the PRRC role in the value chain and to weigh as much as we can on authorities and other stakeholders to recognise the criticality and importance of these responsibilities. For that we must increasingly present ourselves as an alternative, relevant and representative actor on this all too frequent battlefield.

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

In this issue:

Your association:

Our membership has increased during this first quarter 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 communicate in your name 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.

The "FORUM" is operational in our website in your member space. To encourage exchanges between active members, some of us are experimenting with a dedicated closed group in LinkedIn. If successful, we plan to extend it to all members.
Let us know if you would like to participate (TEAM-PRRC).

We are delighted to see so many members have agreed to contribute to the projects of the association in the future.
We are still more than happy to receive more on our members interests along with other new contributors. We are waiting for further applications, all of you are most welcomed!

PRRC insurance:

The negotiations carried out for months have made it possible to deepen knowledge of the professional responsibility of PRRCs and to develop a specific contract for them, in particular when they exercise this profession within the framework of a contract for the provision of external services.

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.

You will receive soon more explanation and find a dedicated link in your member space to apply.

For those who provide external PRRC services, ask yourself this question: Has my professional responsibility, when I worked for a manufacturer as a consultant before MDR, changed since I am working for the same manufacturer as PRRC under the MDR?

Obviously, the answer is yes, because now I am responsible for ensuring… (Article 15, paragraph 3).

Therefore, I need specific liability insurance as a PRRC "responsible for ensuring that ...".

Not sure it is the same work, but surely not same liability.

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

Specials MDR day!

To celebrate this special day, we asked some leading figures to provide with their comments and to understand what is expected for PRRCs:

Interview of TEAM-PRRC Advisory

The Advisory Board is composed by experts in different fields and they help us with specific tasks such as legal advice, insurance matters, and other relevant topics to manage. This Advisory Board includes Mr Denys Durand-Viel, President of DM Experts and the founder member of the association and Mrs Corinne Delorme, Regulatory Intelligence Director of Nexialist.

Corinne Delorme

Since March 2020, Corinne Delorme is the Regulatory Intelligence Director at Nexialist, a consulting company dedicated to medical devices (including IVDs) compliance based in France and Canada.

She held various operational and management positions, first at the French Ministry of Health, then at GMED (MD Notified Body/MDSAP Auditing organisation). She has been particularly involved in the implementation of medical device regulations in Europe, US, Canada, Australia, Brazil, Japan and Taiwan. Making a pragmatic contribution to the regulatory ecosystem is constantly one of her top priorities. She is an active member of the AFNOR S95B Commission "Quality Management and Related General Aspects of Medical Devices" and of the associated CEN and/or ISO standards working groups.

Denys Durand-Viel

Engineer from Centrale Lille, graduate of the "IBMH" cycle from the University of Compiègne and graduate of the IAE of Paris (MBA), Denys DURAND-VIEL has devoted his entire career to medical devices.

He has held various positions, working in hospitals as a biomedical engineer, in a test laboratory for French homologation (before CE marking), in hospital engineering companies, and finally as an auditor for two internationally renowned German notified bodies. He also held the position of Quality and Regulatory Affairs Director in an orthopaedic company specialised in spine. Since 2014, he has been managing "DM Experts", a network of independent consultants that he created and of which Muriel GONIDEC is the Managing Director.

Mrs Corinne Delorme has provided us with relevant recommendation:

“Article 15 quite legitimately leads us to seek precise answers and pragmatic solutions to our questions on how to exercise the regulatory function in a modified context. In doing so, we inevitably highlight the rough aspects of this function.

Nevertheless, let's remember the PRRC occupies one of the most interesting positions in a company because it has a 360° view on the product lifecycle with interactions with most of the services from design to post market surveillance. Article 15, which sets an obligation for manufacturers and authorized representatives, is also an opportunity to promote all the milestones to build and maintain regulatory compliance within the company.

One could recommend to implement Article 15 provisions in 3 steps:

1) Examine the different missions described in the Article 15 §3 and how they are distributed today in the organization of the company. If the organization of the company is satisfactory, it is important to take it into account. There is no need to modify what is working, especially regarding clinical investigations and IVD performance studies. We should also ask ourselves the question of the number of people needed to properly conform to each subject.

2) For each person, whose profile is considered to be appointed as PRRC (alone or jointly with others), it is necessary to make an inventory of his/her education and professional experience, and to compare it to the requirements of article 15. This analysis leads to a realistic GO / NO GO potentially followed by the search of an alternative solution.

3) Once the choice has been made, it will be necessary to formalize and keep available a robust and detailed record of qualifications evidence as it can be audited by a notified body or inspected by a national competent authority.

TEAM-PRRC membership brings a very valuable resource in term of experience sharing when implementing those 3 steps.

For Mr. Denys Durand-Viel, the PRRC role represents "an exciting new challenge!"

"We are faced with a new profession: the **"PRRC"**. Everything must be explored, which is very motivating and stimulating Said M. Durand-Viel.

We will have to combine French creativity and ingenuity with German rigor and pragmatism. The PRRCs should find "financially viable" solutions, smart and practical, to be compliant to MDR/IVDR requirements. PRRCs should also communicate and share all their experience and ideas with each other: this is where all the interest of the Team-PRRC association lies.

Above all, any ideas and decisions should be guided by the fact that all the actors are responsible and are at the service of the patient.

PRRCs are an integral part of businesses and they shall demonstrate that they are not police officers blocking business by opposing the CEO's decisions; it should be the opposite: they should facilitate business by finding smart and compliant solutions through the mobilization of collective intelligence within the company.

To ensure that all the human resources of a company are working towards MDR/IVDR compliance, the PRRC must not only be competent in matters of regulation, but also combine human qualities to be accepted, to be heard, to dialogue and to mobilize resources. They should not hesitate to call upon external resources that may be needed for training and support.

In summary, the PRRC must combine technical knowledge, people skills, and the ability to analyze training and support needs to be a force for business success. This is an exciting new challenge for anyone who is ready to take it on!"

Quotes from Notified Bodies

Robert Dostert, DNV Sales Director

*"*The PRRC requirement sets the bar for regulatory competence level and adds a layer of scrutiny that was not there before. A PRRC must have a minimum of 4 years experience in EU regulatory affairs or QMS for medical devices and cannot be simultaneously your Authorized Representative's PRRC. To ensure compliance, please review guidance document MDCG 2019-7 on the PRRC requirements."

Suzanne Halliday Regulatory Director at BSI Group and Co-Chair NBCG-Med:

TEAM-PRRC and BSI co-wrote a white paper you can find it here: BSI Whitepapers
NBCG have written to DG Sante with open questions that we hope will be used to update MDCG 2019 7.
BSI and NBCG look forward to working with TEAM-PRRC

Dr. Andreas Stange, Vice President IVD at TÜV SÜD Product Service GmbH

"An important topic with the application of both MDR and IVDR is that manufacturers have a person responsible for regulatory compliance either as part of their organization or at their disposal. It is important not only to implement the requirements as described in Art 15 of the regulations, but to also observe the MDCG guidance 2019-7, which contains additional crucial clarifications. Notified bodies have to assess the implementation of these requirements during the conformity assessments.

Just for you (our active members)! and more

This tab (**For 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).

On line **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-PRCC members.
Find it here :
Language requirements & sanctions under the MDR: Belgium
Pdf file will be available in the Active member space.

We have also now delivered useful templates such as "*Template agreement for external PRRC services for Manufacturers*" and also "*Letter of appointment model for PRRC*".
Some other interesting reference documents are also included, such as "*Dutch penalty clauses under MDR*" and available on the page titled: Reference Documents

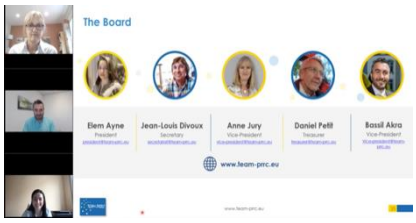
More will follow **with your help!**

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

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

Past Events

TEAM-PRRC Conference 26th March 2021 (in English) and 29th April 2021 (in h)



This two-hour conference was a great success for with more than 40 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 get a better understanding of TEAM-PRRC activities and its objectives. We hope that this will be useful and fruitful to all of you. From this event, we gathered a list of questions which feeds our actions with the EU commission and the MDCG. This event also consolidated our presence as a major stakeholder when talking about PRRCs.

DIGITAL WEEK Medtech-summit conference

On 8th March 2021, TEAM-PRRC was invited to talk about the role of the PRRC and the expectations of the manufacturers.

Our Vice-President Bassil Akra, was interviewed by Amanda Maxwell about the role of PRRC.

The article has been posted on March 8th, 2021: "Harmonization of the EU Regulatory Compliance Role: Many PRRC Issues To Be Clarified". We invite you to read it.

Anne Jury, our Vice-President, was asked by the Notified Body BSI, to write a White Paper about the PRRC.

We are very grateful for the work done by our Vice-President and all BSI's experts reviewers. Anne Jury tried to approach the topic by being as practical as possible, and in particular by comparing the role of the PRRC in a manufacturer and an Authorised Representative. We let you find out the White Paper in this link, and in your member space.

Medi'Nov Connection 2021 Digital fair 19-21 May 2021

Major event of decision makers in the MedTech industry
On 19th May 2021, TEAM-PRRC with his secretary, J.L. Divoux, was invited to moderate a roundtable about MDR-IVDR perspectives. During teleconference meetings, TEAM-PRRC had the chance to talk about the role of the PRRC and present the association to the visitors.

To come

As part of our legal association obligations and statutes, TEAM-PRRC will hold its annual general meeting in order to present and adopt its financial position and to confirm or elect the managing board including the bureau.

FIRST ANNUAL AND EXTRAORDINARY GENERAL MEETING OF TEAM-PRRC

GENERAL ASSEMBLY will take place on June 24th, 2021 at 4 p.m. (CET) by videoconference.
An invitation has been sent to active and voting members to save the date.
We hope many of you will attend to approve our past activities and to know about the future.
Modifications of the statutes, the internal regulations and the code of ethics will be presented for approval.
There will also be time for Q&A on TEAM-PRRC.

TEAM-PRRC @ "Le RDV du DIV" on June 29th, 2021

TEAM-PRRC will be present at the "1st Édition of RDV du DIV" on June 29th, 2021, in Aix-en-Provence (France).

Organized by Nexialist, this event, which will take place over one day, on site (no webinar) is important to understand what is the current situation for the actors of In Vitro Diagnostic Medical Devices and the impact on organizations. There will also be a session about the PRRCs and animated by Corinne Delorme, from our Advisory Board. More information for the subscription here: http://nexialist.fr/rdvdudiv

TEAM-PRRC @ La rentrée du DM

TEAM-PRRC will be present at the "9ème Édition de La Rentrée du DM" on 6 & 7 October 2021 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 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 during the "8ème edition de La Rentrée du DM".

LATER

TEAM-PRRC webinar (in GERMAN) planned in October 2021

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.

Thanks to our sponsors: visit them on our website!

Short news & Ongoing projects

- **Position paper – we continue to exchange views 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 <u>every member state</u>: still in process for the European insurance, and we have succeeded in getting an insurance agreement from French insurance companies.**
- **Templates (these documents will be published after the approval of our lawyer)**
    - **Job description**
- **Specialised PRRC topic webinars**
- **Call for interest to our members: which would you like to see topics for the webinars?**
- **Call for contributors about our projects (Combination products / pharmacist; national laws; IVD devices; GDPR; …)**
- **Website update and upgrade**

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 enjoyed. Hear from you very soon.

It's a new dawn

It's a new day

It's a new life for us , ooh

And we are feeling good

(Nina Simone)

<u>The MANAGEMENT TEAM</u>