



★ TEAM-PRRC ★ ANNUAL SUMMIT

SECOND EDITION

PRRC'S MEETING ORGANIZED BY TEAM-PRRC :



Round Tables



Workshops



Presentations



Networking

NOVEMBER 16 & 17 2023

HILTON HOTEL

1, avenue Herrenscheidt - 67000 STRASBOURG / FRANCE

WWW.TEAM-PRRC.EU - INFORM@TEAM-PRRC.EU



★ PROGRAMME ★

1ST DAY PROGRAM: THURSDAY 16 NOVEMBER, 2023

8.00 – 9.00 AM

WELCOMING ALL ATTENDEES

9.00 – 9.15 AM

**TEAM-PRRC welcoming presentation
And intervention of RAPS (sponsor of the event)**

9.15 – 10.30 AM

**OPENING PRESENTATION AND DISCUSSION BY
STAKEHOLDERS' ORGANIZATION AND NOTIFIED BODIES**

What is the impact of the changes regarding MDR/IVDR due to regulation 2023/607 and the extension of the transitional period? **Round table moderated by Bassil AKRA**

Presenters:

- Orla DALY - Policy and Legal Officer, MDCG (To be Confirmed-TbC)
- Alexey SHIRYAEV - Global Head of Clinical and Regulatory Affairs, DNV
- Other guests - TbC

10.30 – 11.00 AM

Q&A

11.00 – 11.30 AM

COFFEE BREAK / NETWORKING

11.30 – 12.30 AM

**LEGAL INTERPRETATION OF THE ARTICLE 15
FROM THE COMPETENT AUTHORITIES**

What they expect from a PRRC?

Presenter: Thierry SIRDEY – Co-chair CAMD

12.30 – 14.00 PM

LUNCH BREAK

14.00 – 14.45 PM

THE DIFFICULTIES MET BY START-UPS and SMEs

How they hired their PRRC and understand their organization

Presenters:

- Nihal Engin VRANA - CEO, SPARTHA MEDICAL
- Another company (IVD sector) - TbC

14.45 – 16.15 PM

ISSUES AND SUCCESSES AS A PRRC – Round table

Sharing experiences as a PRRC

Presenters:

- Anne-Laure BAILLY - Internal PRRC, CERAVER
- Anne-Sophie GRELL - External PRRC, QBD Group
- Emile UNK - AR PRRC, Certification Experts

16.15 – 16.45 PM

COFFEE BREAK / NETWORKING

16.45 – 18.00 PM

WORKSHOP/SHARING EXPERIENCES

How can I protect myself in critical situations?

With Erik VOLLEBREGT – Lawyer, AXON Lawyers

& Dr Volker LÜCKER – Lawyer, Medical Device Law Lückner

18.00 – 19.00 PM

FREE

19.00 – 23.00 PM

SPECIAL NETWORKING DINNER



★ PROGRAMME ★

2ND DAY PROGRAM: FRIDAY 17 NOVEMBER, 2023

9.00 – 10.00 AM

HOW SHOULD A PRRC ASSESS ACHIEVING THE COMPLIANCE OF ARTICLE 15?

Technical documentation / conformity assessment – what majors they apply regarding the requirements of the regulations?

Presenter: an auditor from a Notified Body (TbC)

10.00 – 10.45 AM

MANUFACTURERS IMPLEMENTATION

Views and implementation

Presenter: Melissa FINOCCHIO – PRRC of Sophia Genetics

10.45 – 11.15 AM

COFFEE BREAK/NETWORKING

11.15 – 12.00 AM

WHAT KIND OF STATEMENT IS EXPECTED BY COMPETENT AUTHORITIES REGARDING THE REQUIREMENTS OF THE CLINICAL INVESTIGATIONS?

Clinical evaluation, clinical investigation, sufficient clinical data

Presenter: Nebojsa SERAFIMOVIC – Assessor Medical Devices, Austrian and Medical Device Agency

12.00 – 12.45 PM

CLOSING SESSION WITH THE BOARD OF TEAM-PRRC:

- Summary
- Advice to PRRCs
- Q&A

12.45 – 14.00 PM

LUNCH BREAK

AFTERNOON

FREE (VISITING STRASBOURG)