

PRRC'S MEETING ORGANIZED BY TEAM-PRRC:









Workshops Presentations



NOVEMBER 16 & 17 2023

HILTON HOTEL

1, avenue Herrenschmidt - 67000 STRASBOURG / FRANCE



PROGRAMME 1ST DAY PROGRAM: THURSDAY 16 NOVEMBER, 2023

8.00 **–** 9.00 AM

REGISTRATION AND WELCOME TO ALL ATTENDEES

9.00 **–** 9.15 AM

TEAM-PRRC welcome presentation
Introduction of RAPS (sponsor of the event)

9.15 – 11.00 AM

OPENING PRESENTATION AND DISCUSSION BY STAKEHOLDERS'ORGANIZATION AND NOTIFIED BODIES

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

Presenters:

Orla DALY – Policy and Legal Officer, MDCG
Françoise SCHLEMMER – Director, Team-NB
Olivier AUDEBERT – International Certification Services of SGS
Purvi PATEL – Auditor, BSI

11.00 - 11.30 AM

COFFEE BREAK / NETWORKING

11.30 - 12.30 AM

LEGAL INTERPRETATION OF THE ARTICLE 15 BY 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 Abdessamad BELHAMDI - PRRC. SPARTHA MEDICAL

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 Lücker

18.00 – 19.00 PM

FREE

19.00 – 23.00 PM

SPECIAL NETWORKING DINNER



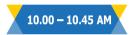


HOW SHOULD A PRRC ASSESS ACHIEVE THE COMPLIANCE WITH ARTICLE 15?

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

Presenters:

Yasmine MOUTON – Auditor, SGS Hakim MEHALBI – Auditor, GMED



MANUFACTURER'S IMPLEMENTATION OF PRRC ROLE

Views and strategy

Presenter: Melissa FINOCCHIO - PRRC, Proud Lion Services



COFFEE BREAK/NETWORKING



CLINICAL INVESTIGATIONS REQUIREMENTS: COMPETENT AUTHORITIES' EXPECTATIONS

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



CLOSING SESSION WITH THE BOARD OF TEAM-PRRC:



LUNCH BREAK

14.00 – 14.45 PM

GENERAL ASSEMBLY WITH TEAM-PRRC MEMBERS