



# ★ TEAM-PRRC ★ ANNUAL SUMMIT

## FOURTH EDITION

PRRC'S MEETING ORGANIZED BY TEAM-PRRC:



Round Tables



Workshops



Presentations



Networking

# OCTOBER 23 & 24 2025

**HOTEL CARDO ROMA, AUTOGRAPH COLLECTION**

Viale del Pattinaggio, 100  
ROME / ITALY



# ★ PROGRAMME ★

1<sup>ST</sup> DAY: THURSDAY 23 OCTOBER, 2025

13.00 – 14.00

**REGISTRATION - WELCOMING ALL ATTENDEES**

14.00 – 14.15

**TEAM-PRRC welcoming presentation by Elem AYNE with the Board**

14.15 – 15.00

**AUTHORITIES EXPECTATIONS FROM A PRRC**

*Presenter: Alessandra BASILISCO – Servizio Sanitario Nazionale, Ministry of Health*

15.00 – 16.15

**DISCUSSION WITH STAKEHOLDERS**

State of Play EU MDR & EU IVDR

Overview about the potential future legislative changes and their potential impact on the role of the PRRC

**Round Table moderated by Bassil AKRA**

*Guests :*

- *Alessandra BASILISCO – Servizio Sanitario Nazionale, Ministry of Health*
- *Giulia MAGRI – Quality & Regulatory Affairs Director, Confindustria Dispositivi Medici*
- *Merlin RIETSCHER – Senior Manager, MedTech Europe*
- *Christina ZIEGENBERG – Deputy Managing Director, BVMed*

16.15 – 16.20

**PHOTO WITH ALL ATTENDEES**

16.20 – 16.40

**COFFEE BREAK / NETWORKING**

16.40 – 17.15

**EUDAMED: updates**

*Presenter: Richard HOULIHAN – Founder, EirMed*

17.15 – 18.00

**LIABILITY**

An example of a concrete case

*Presenters:*

- *Erik VOLLEBREGT - Partners, Axon Lawyers*
- *Alex DENOON - Partner, Bristows Law Firm*

19.30 – 01.30 am

**MEETING AT THE LOBBY TO GO TO DINNER ALL TOGETHER IN THE CENTER OF ROME by BUS**  
**RETURN TO THE HOTEL by VANS (by small group as from 00.00 until 1.30 am)**  
**RESTAURANT : RIPA GRANDE SALOTTO – Lungotevere Ripa 3, 00153 Roma RM**



# ★ PROGRAMME ★

2<sup>ND</sup> DAY: FRIDAY 24 OCTOBER, 2025

9.30 – 10.30

## ROUND TABLE WITH PRRCs

Feedback from daily activities, their feeling in the position

**Round table moderated by Anne JURY**

*Guests:*

- Silvia ZANCOLA, PRRC from a MF (Theras Lifetech)
- Lyudmila DASHDAMIROV, PRRC working within an AR (HOYA Surgical Optics GmbH)
- Adam RAE, Outsourced PRRC (Founder of The Other Consultants)

10.30 – 11.10

## REGIONAL UPDATES

PRRC requirements in the various Member States

*Presenters:*

- Sandra FERRETTI - Lead Representative PRRC, TEAM-PRRC
- Piero COSTA - Representative for Italy, TEAM-PRRC

11.10 – 11.30

## COFFEE BREAK / NETWORKING

11.30 – 12.00

## IMPACT OF THE IMPLEMENTATION STUDY ON SHORT-TERM REGULATORY CHANGES

Changes foreseen within the regulations

*Presenter: Françoise SCHLEMMER – Director, Team-NB*

12.00 – 12.30

## CLINICAL EVALUATION & CLINICAL INVESTIGATION:

What is expected by the PRRC to fulfil the requirements?

*Presenter:*

- Amie SMIRTHWAITE – MedTech consultant, Clinical & Regulatory Strategy, BTInternet

12.30 – 13.30

## LUNCH BREAK

13.30 – 14.15

## PMS & VIGILANCE: How the PRRC can ensure the compliance?

*Presenter: Breda KEARNEY - Clinical Regulatory Lead, BSI Ireland*

14.15 – 15.00

## A CASE STUDY presenting real examples from a SaMD manufacturer who used their role to support the continuous safety of the devices on the Union market

*Presenter:*

- Alice RAVIZZA - Founder, InsideAI

15.00 – 15.20

## COFFEE BREAK / NETWORKING

15.20 – 16.45

## Q&A and DISCUSSION WITH NOTIFIED BODIES

MDR & IVDR Certification experiences, Transitional provisions, overview of the future legislations and impact on the MDR & IVDR

**Round table moderated by Bassil AKRA**

*Guests:*

- Maddalena PINSI - Head of MD, BSI Italy
- Daniele BOLLATTI - Technical Manager, IMQ
- Carlo GHERARDI - Lead Auditor, TÜV SÜD
- Alessia FRABETTI - Head of MD, KIWA CERMET Italy
- Selene MALVICINO - MD Manager, BUREAU VERITAS Italy

16.45 – 17.00

## CLOSING SESSION WITH THE BOARD OF TEAM-PRRC