



★ TEAM-PRRC ★ ANNUAL SUMMIT

INAUGURAL EVENT

PRRC'S MEETING ORGANIZED BY TEAM-PRRC :



Round Tables



Workshops



Presentations



Networking

NOVEMBER 3 & 4 2022

BRUSSELS MARRIOTT HOTEL GRAND PLACE

3-7 RUE AUGUSTE ORTS/GRAND PLACE - BRUSSELS, 1000 BELGIUM



★ PROGRAMME ★

1ST DAY PROGRAM : THURSDAY 3 NOVEMBER, 2022

8.00 – 9.00 AM

WELCOMING ALL ATTENDEES

9.00 – 9.10 AM

TEAM-PRRC presentation

9.10 – 10.30 AM

OPENING PRESENTATION AND DISCUSSION BY STAKEHOLDERS' ORGANIZATION AND NOTIFIED BODIES

Round table

Who is the PRRC and what can we learn from real life regarding 'ensuring compliance'?

What are the expectations from a PRRC?

Presenters:

- Orla DALY – MDCG
- Mario GABRIELLI-COSSELLU – MDCG
- Françoise SCHLEMMER – Team-NB
- Christopher KIPP – BVMed

10.30 – 11.00 AM

Q&A

11.00 – 11.30 AM

COFFEE BREAK / NETWORKING

11.30 – 12.30 AM

ISSUES AND SUCCESSES AS A PRRC; A PERSONAL REPORT

First experience as a PRRC

Presenters:

- Sandra FERRETTI – CCO & PRRC of OBELIS
- Piero COSTA – Representative PRRC Italy of TEAM-PRRC

12.45 – 14.00 PM

LUNCH BREAK

14.00 – 14.45 PM

HOW MANUFACTURERS SELECT THEIR PRRC?

How they chose their PRRC and difficulties met

Presenters: 2 manufacturers

- Kees MAQUELIN - ABBOTT for IVD sector
- Fabian SPÄNIG - J&J for MD sector

14.45 – 15.45 PM

HOW CAN A PRRC DEMONSTRATE THEY HAVE ENSURED CONTINUOUS COMPLIANCE?

Presenters:

- Erik VOLLEBREKT - Partner lawyer, Axon Lawyers
- Cécile THEARD-JALLU - Partner lawyer, De Gaulle & Fleurance

15.45 – 16.15 PM

COFFEE BREAK / REGISTRATIONS FOR THE SPEED DATING WITH EXPERTS

16.15 – 17.30 PM

SPEED DATING/EXCHANGE/NETWORKING/SHARING EXPERIENCE

Every 10/15 minutes, all people can have a face-to-face discussion about their experience and MDR/IVDR with one expert

17.30 – 17.45 PM

COFFEE BREAK / COLLECTING DATAS FROM THE SPEED DATING

17.45 – 18.00 PM

INFORMAL MEETING: FEEDBACK FROM SPEED DATING

19.00 – 23.00 PM

SPECIAL NETWORKING DINNER



★ PROGRAMME ★

2ND DAY PROGRAM : FRIDAY 4 NOVEMBER, 2022

9.00 – 9.30 AM

HOW CAN A PRRC ENSURE THE LEVEL OF COMPLIANCE OF THE TECHNICAL DOCUMENTATION?

Technical documentation / conformity assessment

Presenter: Lucia FORTE – EUROFINs Italy

9.30 – 10.00 AM

HOW CAN A PRRC ENSURE IF PMS/PMCF/PMPF ARE SUFFICIENTLY IN COMPLIANCE?

Presenter: Elisabeth GFOELLER - Regulatory Affairs Director, MED-EL

10.00 – 10.30 AM

COFFEE BREAK/NETWORKING

10.30 – 11.30 AM

HOW DOES A PRRC ENSURE CLINICAL DATA COLLECTION IS ADEQUATE?

Clinical evaluation, clinical investigation, sufficient clinical data

Presenter: Tom MELVIN - Professor, Trinity College Dublin

11.30 – 12.45 AM

CLOSING SESSION:

- Do we really understand what 'ensuring...' means?
- As a PRRC, can we make clear how important we are?
- Advise to PRRCs
- Q&A

12.45 – 14.00 PM

LUNCH BREAK

AFTERNOON

FREE (VISITING BRUSSELS)