

TEAM-PRRC ANNUAL SUMMIT FOURTH EDITION

PRRC'S MEETING ORGANIZED BY TEAM-PRRC:











HOTEL CARDO ROMA, AUTOGRAPH COLLECTION

Viale del Pattinaggio, 100 ROME / ITALY



1ST DAY: THURSDAY 23 OCTOBE





TEAM-PRRC welcoming presentation by Elem AYNE and the whole Board





DISCUSSION WITH STAKEHOLDERS (MDCG, Authorities, NB, MedTech Europe ...) State of Play EU MDR & EU IVDR Overview about the potential future legislative changes and their potential impact on the role Round Table moderated by Bassil AKRA

Guests :

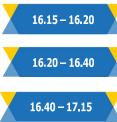
- Orla DALY Policy and Legal Officer, MDCG (tbc)
- Alessandra BASILISCO Servizio Sanitario Nazionale, Ministry of Health
- Giulia MAGRI– Quality & Regulatory Affairs Director, Confindustria Dispositivi Medic
- Merlin RIETSCHEL Senior Manager, MedTech Europe
- BVMed (tbc)

EUDAMED: updates

PHOTO WITH ALL ATTENDEES

COFFEE BREAK / NETWORKING

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



MEETING AT THE LOBBY TO GO TO DINNER ALL TOGETHER IN THE CENTER OF I By BUS TRANSFER RETURN TO THE HOTEL by VANS (by small group)



2[№] DAY: FRIDAY 24 OCTOBER

9.30 - 10.30	ROUND TABLE WITH PRRCs Feedback from daily activities, their feeling in the position Round table moderated by Anne JURY <i>Guests</i> :	13.30 - 14.15	PMS & VIGILA Presenter: Brea
	 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) 	14.15 - 15.00	A CASE STUD who used thei on the Union I Presenter:
10.30 - 11.10	REGIONAL UPDATES PRRC requirements in the various Member States <i>Presenters</i> :		- Alice RA
	 Sandra FERRETTI - Lead Representative PRRC, TEAM-PRRC Piero COSTA - Representative for Italy, TEAM-PRRC 	15.00 – 15.20	COFFEE BREA
11.10 - 11.30	COFFEE BREAK / NETWORKING	15.20 - 16.45	Q&A and DIS(MDR & IVDR (overview of th
11.30 - 12.00	IMPACT OF THE IMPLEMENTATION STUDY ON SHORT-TERM		Round table n Guests:
	REGULATORY CHANGES Changes foreseen within the regulations		- Madd
	Presenter: Françoise SCHLEMMER – Director, Team-NB		- Danie - Carlo
12.00 - 12.30	CLINICAL EVALUATION vs CLINICAL INVESTIGATION: What is expected by the PRRC to fulfil the requirements? <i>Presenter:</i>		- Anoth
	- Amie SMIRTHWAITE – MedTech consultant, Clinical & Regulatory Strategy	16.45 – 17.00	CLOSING SE
	· · · · · · · · · · · · · · · · · · ·		

12.30 – 13.30 LUNCH BREAK