

# TEAM-PRRC ANNUAL SUMMIT FOURTH EDITION

#### PRRC'S MEETING ORGANIZED BY TEAM-PRRC:











#### HOTEL CARDO ROMA, AUTOGRAPH COLLECTION

Viale del Pattinaggio, 100 ROME / ITALY



### 1<sup>ST</sup> 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 :

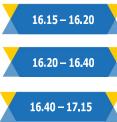
- Orla DALY Policy and Legal Officer, MDCG (tbc)
- Alessandra BASILISCO Servizio Sanitario Nazionale, Ministry of Health
- Giulia MAGRI– Quality & Regulatory Affairs Director, Confindustria Dispositivi Medic
- Merlin RIETSCHEL Senior Manager, MedTech Europe
- BVMed (tbc)

**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<sup>№</sup> DAY: FRIDAY 24 OCTOBER

9.30 - 10.30	<b>ROUND TABLE WITH PRRCs</b> Feedback from daily activities, their feeling in the position <b>Round table moderated by Anne JURY</b> <i>Guests</i> :	13.30 - 14.15	<b>PMS &amp; VIGILA</b> Presenter: Brea
	<ul> <li>Silvia ZANCOLA, PRRC from a MF (Theras Lifetech)</li> <li>Lyudmila DASHDAMIROV, PRRC working within an AR (HOYA Surgical Optics GmbH)</li> <li>Adam RAE, Outsourced PRRC (Founder of The Other Consultants)</li> </ul>	14.15 - 15.00	A CASE STUD who used thei on the Union I Presenter:
10.30 - 11.10	<b>REGIONAL UPDATES</b> PRRC requirements in the various Member States <i>Presenters</i> :		- Alice RA
	<ul> <li>Sandra FERRETTI - Lead Representative PRRC, TEAM-PRRC</li> <li>Piero COSTA - Representative for Italy, TEAM-PRRC</li> </ul>	15.00 – 15.20	COFFEE BREA
11.10 - 11.30	COFFEE BREAK / NETWORKING	15.20 - 16.45	<b>Q&amp;A and DIS(</b> 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	<b>CLINICAL EVALUATION vs CLINICAL INVESTIGATION:</b> 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
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12.30 – 13.30 LUNCH BREAK