

TEAM-PRRC ANNUAL SUMMIT

FIFTH EDITION

PRRCs' MEETING ORGANIZED BY TEAM-PRRC:

Round Tables | **Workshops** | **Presentations** | **Networking**

OCTOBER 29 & 30 2026

HOTEL HILTON OLD TOWN

V Celnici 2079/7,

PRAGUE / CZECH REPUBLIC

PROGRAMME

1ST DAY: THURSDAY 29 OCTOBER, 2026

8.15 – 9.00 — **REGISTRATION - WELCOMING ALL ATTENDEES**

9.00 – 9.10 — **TEAM-PRRC welcoming presentation by Elem AYNE**

9.10 – 11.00 — **ROUND TABLE: MDR & IVDR Simplification Proposal: Shaping the Next Generation of the European Regulatory Framework, moderated by Bassil AKRA**

- Overview of the European Commission's MDR & IVDR Simplification Proposal
- Perspectives from Key Stakeholders
- Interactive Panel Discussion and Audience Q&A

- *Françoise SCHLEMMER – Director, Team-NB*
- *Nelli KARHU – Senior advisor, Healthtech Finland*
- *Helena DZOJIC – Senior leader, Swedish Medical Products Agency*
- *Christopher KIPP - Manager Regulatory Affairs Medical Devices, BVMed*
- *Cyrille FLEURY – President of GALMEON & SNITEM Administrator*

11.00 – 11.10 — **PHOTO WITH ALL ATTENDEES**

11.10 – 11.40 — **COFFEE BREAK / NETWORKING**

11.40 – 12.30 — **HEMARINA : Regulatory Journey of an Innovative French Medical Device Manufacturer**

- Challenges encountered under the MDR
- Feedback and strategic insights from the CEO

- *Franck ZAL – CEO, HEMARINA*

12.30 – 14.10 — **LUNCH BREAK**

14.10 – 14.15 — **Sponsor speech**

RAPS – RCC Program

14.15 – 15.00 — **Workshop: Post-Market Surveillance (PMS) Under the MDR & IVDR From Requirements to Implementation**

- Overview of applicable guidance documents
- Developing an effective PMS system
- Practical examples and case studies

- *Tatsiana RIPICH – Head of Regulatory Affairs, Enmodes GmbH*
- *Tonia JEITER – Sr Manager Clinical Evaluation, Alcon*

15.00 – 15.45 — **Proposed Changes to Clinical Data Requirements Under the MDR & IVDR**

- Impact on Class III and implantable medical devices
- WET (Well-Established Technologies): regulatory implications

- *Carine COCHEREAU – Regulatory International VP, Integra LifeSciences*
- *Tonia JEITER – Sr Manager Clinical Evaluation, Alcon*

15.45 – 16.15 — **COFFEE BREAK / NETWORKING**

16.15 – 17.00 — **Proposed Changes to Quality Management System Audits and Recertification Principles**

- Overview of the proposed changes to QMS auditing and recertification
- Notified Body perspective
- Q&A

- *Ilkka JUUSO – Lead Auditor, SGS*

17.00 – 17.45 — **Proposed Changes to Articles 11 and 15 of the MDR & IVDR: Practical Implications for Economic Operators**

- Overview of the proposed amendments to Articles 11 and 15
- Benefits and challenges of the proposed changes
- Impact on manufacturers
- Impact on Authorized Representatives

- *Katerina SVAMBERGOVA - Expert consultant, OBELIS (Belgium AR company)*
- *Aida ILKHECHOIE - PRRC, ASCILION (Sweden Manufacturer)*

19.30 – 20.00 — **MEETING AT THE LOBBY TO GO TO THE RESTAURANT BY WALK (15 min)**

20.00 – 23.00 — **GALA Dinner**

DEER Restaurant, Michalská 436/19 - Prague

TEAM-PRRC

PROGRAMME

2ND DAY: FRIDAY 30 OCTOBER, 2026

9.30 – 10.15

The Future of Regulatory Compliance: The Role of AI under the EU AI Act for PRRCs

- *Thais SALA - PRRC, CergenX*
- *Cecile VAN DER HEIJDEN - Senior Legal Counsel, AXON LAWYERS*

10.15 – 11.00

Impact of the Proposed Reduction in Reporting Obligations on the Healthcare System

- Overview of the proposed changes to reporting obligations
- Manufacturer and Notified Body perspectives
- Q&A
- *Jenifer HANNON - Senior Regulatory Lead for PMS, BSI UK*
- *Franck ZAL - CEO, HEMARINA*

11.00 – 11.30

COFFEE BREAK / NETWORKING

11.30 – 12.00

New Conformity Assessment Pathways: Supporting Innovation Under the MDR & IVDR

- Breakthrough Device Pathway
- Orphan Device Pathway
- Regulatory Sandboxes
- *Richard HOLBOROW – Global Head Clinical Compliance, BSI*

12.00 – 12.30

Preparing for IVDR Certification: Strategies for a Successful Conformity Assessment

- Key steps in preparing for certification
- Common challenges and pitfalls
- Best practices from manufacturers and Notified Bodies
- *Melissa FINOCCHIO – QA/RA Advisor, QA Lion*

12.30 – 14.00

LUNCH BREAK

14.00 – 14.30

EUDAMED Implementation: Timelines, Registration and Practical Experience

- Current implementation timeline and key milestones
- Registration process and lessons learned
- *Patrick PILLE - Senior Consultant Director EUDAMED, MDSS GmbH*
- *Amber HARRISON-CRUDGE – EUDAMED Lead at Johnson & Johnson*

14.30 – 15.15

The PRRC as a Whistleblower: Responsibilities and Liability Implications for Manufacturers and Authorized Representatives

- PRRC obligations and escalation responsibilities
- Potential liability implications for manufacturers
- Impact on Authorized Representatives
- *Erik VOLLEBREGT - Partner, AXON LAWYERS*
- *Alex DENOON - Partner, Bristows Law Firm*

15.15 – 15.45

COFFEE BREAK / NETWORKING

15.45 – 17.00

ROUND TABLE WITH NOTIFIED BODIES moderated by Bassil AKRA
Changes on Annex VII: Pros and Cons related to those changes

- Impact on assessment timelines and capacity
- Increased transparency: expectations and implications
- Benefits and Challenges for SMEs
- *Maddalena PINSI - Head of MD, BSI Italy*
- *Richard HOLBOROW - Global Head Clinical Compliance, BSI UK*
- *Thomas LOMMATZSCH - Head of MD, AFNOR Certification*
- *Marta CARNIELLI - Head of certification IVD, TÜV SÜD*
- *Béatrice LYS - Technical Director, GMED*
- *Alexey SHIRYAEV - Global Head of Clinical and Regulatory Affairs, DNV*

17.00 – 17.15

CLOSING SESSION WITH THE BOARD OF TEAM-PRRC

"A special thank you to our sponsors for
their generous support of the TEAM-PRRC Annual Summit"

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EAAR European Association of Authorised Representatives