EUROMCONTACT

OVERVIEW OF EUROMCONTACT WORKSHOPS IN 2018: PREPARE FOR IMPLEMENTATION OF THE MEDICAL DEVICES REGULATION

3rd July 2018
Transiting from Medical Devices Directive to Medical Devices Regulation

26th September 2018
Clinical Aspects of the Medical Devices Regulation

15th October 2018
Post-market surveillance and post-market clinical follow-up

Q 3 2018 – Eudamed

Q 4 2018 – Notified Bodies

Workshops include presentations by European Commission, Competent Authorities of Member States; Notify Bodies and Industry leaders, followed by question and answer session with speakers.

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26th September 2018

Clinical Aspects of the Medical Devices Regulation

Presenters:

• **Paul Piscoi, DG GROW, European Commission** will present the MDR requirements on clinical aspect sand on the work on clinical equivalence and sufficient clinical data.

• **Hans Juncker, Vice-Chair of NB Team** will present the expectations of Notified Bodies on clinical requirements and the impacts for future audits.

In a close session, **BizzAffairs**, consultant contracted by EUROMCONTACT, will present the EUROMCONTACT Clinical Reports (Ametropy for soft, rigid and scleral; Astigmatism for soft, rigid and scleral; Presbyopia for soft, rigid and scleral; Ortho K; Irregular cornea) and will guide the participants trough the document, including on how to collect and report manufacturers' own clinical data.

15th October 2018

Post-market surveillance and post-market clinical follow-up

Presenters:

• **Jean-François Roche, DG GROW, European Commission** will present the MDR requirements on post-market surveillance.

• **Hazel Randall, from MHRA, Chair of the task force on Periodic Summary Report and Field Safety Notice** will present the latest state of play on FSN template and PSUR requirements.

• **Andrea Hanson, from IHPRA** will present the Meddev 2-12.1 rev 9 on medical devices vigilance system.

• **Catherine Cochereau, Quality and Regulatory, Clinical Affairs Vice-President at the company Biom'up**, will provide recommendations on how to develop a PMC follow-up.

• **Meddev Solution Ltd** will provide recommendations to prepare for post-market surveillance and how to meet expectations from Notified Bodies.

For more details about the workshop and registration, please contact pascale.rouhier@euromcontact.eu

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