



EUCOPE

European Confederation of
Pharmaceutical Entrepreneurs AISBL

2 May 2019

EUCOPE offices
Rue Marie de Bourgogne, 58
1000 Brussels

EUCOPE

REGULATORY / PV / MEDICAL DEVICE

WORKING GROUP MEETING

2 May 2019 at EUCOPE offices 11am – 2pm CET

Meeting agenda

TOP 1 **Welcome / next events**

TOP 2 **Priorities 2019**

TOP 3 **Brexit implications on Regulatory Affairs - current status and latest news**

TOP 4 **Registries for regulatory purposes - EMA discussion paper for public consultation**

TOP 5 **Research & Development (R&D) - EMA focus groups**

- Focus group on opportunities leading to a more integrated R&D product support (Lucia D'Apote, Amgen)
- Focus group on qualification of digital technologies for medicines development (João Duarte, Alexion)

TOP 6 **Medical Device Regulation – progress in implementation**

- Report from the Medical Device Coordination Group (MDCG) and working groups

TOP 7 **ISO IDMP (Identification of Medicinal Products) implementation**

- Current status of the SPOR (Substance, Product, Organization, Referential) Implementation Guide (Karl-Heinz Loebel, PharmaLex)

TOP 8 **AOB / End of meeting**