



European Confederation of  
Pharmaceutical Entrepreneurs AISBL

**EUCOPE  
Regulatory/Pharmacovigilance/Medical Device  
Working Group Meeting**

Date: 16 January 2019  
2 pm – 4 pm

Venue: Teleconference

Rue Marie de Bourgogne 58  
1000 Brussels  
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Date: 23 Nov 2018

- TOP 1**            **Welcome / Next Events / Working Groups**
  
- TOP 2**            **Brexit implications on Regulatory Affairs**
  - Latest news, Update of EUCOPE check list
  
- TOP 3**            **Safety Features**
  - Achievements so far and challenges ahead (TBD)
  
- TOP 4**            **Medical Devices**
  - EUCOPE advocacy on Combination Products acc to Art 117 MDR (Lars Hyveled-Nielsen, Zealand Pharma)
  - Changes to ISO 14155 standard for medical device clinical investigations expected in 2019 (Thomas Mohr, Miltenyi Biotec)
  
- TOP 5**            **Paediatrics**
  - Industry proposal for improvement of handling PIP applications (Angelika Joos, MSD)
  
- TOP 6**            **Patient disease registries for regulatory purposes**
  - EMA discussion paper for public consultation
  
- TOP 7**            **AOB / Next meeting dates / Closure of meeting**