DIA

Brexit Summit: Final Steps in Preparing for Day 1

Join the Group Discussions with UK and EU Authorities

16 January 2019 | London, UK

Objectives

Update on the steps that are taken in deal or no deal situation (EU & UK)

- Offer the opportunity for small group exchange on specific areas with the key regulators or policymakers
- Ensure your organization is fully informed on impact of Brexit on operations in pharmacovigilance, marketing authorization & lifecycle management, clinical trials and supply chain.
- Benchmark your readiness against the advice from the regulators and policymakers.

Who Will Attend

The event is developed for those in the Brexit preparedness teams or task forces in their respective Organisation at various levels (policy & operational). Topics are structured around the main areas that are impacted: pharmacovigilance, marketing authorization & lifecycle management, supply chain and clinical trials.

08:00 REGISTRATION AND WELCOME COFFEE

09:00 SESSION 1

UK UPDATE (DEAL / NO DEAL)

Moderator for the whole day:

Virginia Acha, Executive Director, Global Regulatory Policy, MSD, UK

Industry Preparedness and Response to the Consultation

Steve Hoare, Head of Quality, ABPI, UK

- Ongoing Work
- Looking at Preparations for the No deal Scenario
- The Withdrawal Agreement
- Work on the Future Relationship

Laura Collister, Brexit Lead, The BioIndustry Association (BIA), UK

Questions and Answers

10:30 COFFEE BREAK

11:00 SESSION 2

EU UPDATE (DEAL / NO DEAL)

Centralised Activities, Ireland Particular challenges and general preparedness

Rita Purcell, Deputy Chief Executive, HPRA, Ireland

Decentralised And Mutual Recognition Pathways And Transition

Kora Doorduyn-van de Stoep, CMDh member (EU-representative)/Policy adviser, Medicines Evaluation Board, the Netherlands

Industry's Preparedness And Key Considerations

Vicki Edwards, Vice President, Pharmacovigilance Excellence and QPPV, AbbVie, UK

Questions and Answers

12:30 LUNCH

13:30 SESSION 3

GROUP WORK – STEPS TO TAKE FOR PREPAREDNESS IN THE UK

PHARMACOVIGILANCE **Vicki Edwards, AbbVie**	MARKETING AUTHORISATION & PAEDIATRIC INVESTIGATION PLAN (PIP) & CLINICAL TRIALS **Steve Hoare, ABPI** **Kora Doorduyn-van de Stoep, MEB**
Presentation (20 min) Including UK QPPV Status PSUR ICSR UK PMSF Discussion	Presentation (20 min) Including Supply Chain Challenges Clinical Trials Existing MAs & New Applications Discussion

15:30 REFRESHMENT BREAK

16:00 CLOSING PANEL

Wrap up the discussions in the small working groups & generally
Panel with Representatives from HPRA, CMDh and ABPI

17:00 END OF THE CONFERENCE

Hotel Information

Park Plaza Westminster Bridge London
200 Westminster Bridge Road
London SE1 7UT
+444 (0) 333 400 6112
View directions
View directional map

The hotel offers complimentary Wi-fi

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for 6 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

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