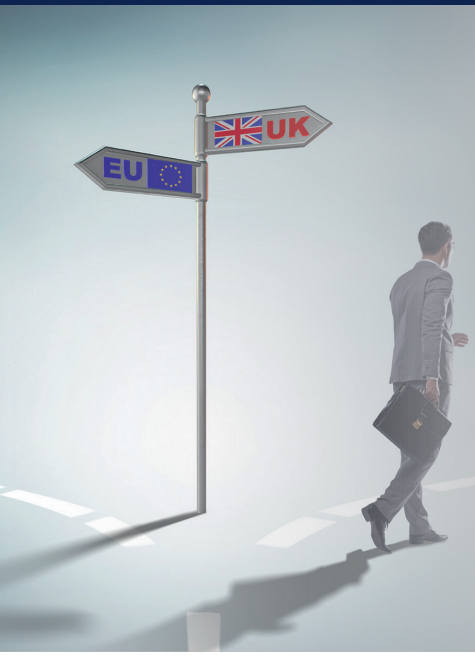
Seminar and Webcast

FORUM



BREXIT Countdown – Q&A Focus Pharma

Topics

- New marketing authorisations in the EU (including the UK)
- Maintaining existing marketing authorisations
- Assuring the supply chain (GMP certificates and imports)
- Maintenance of European databases and portals
- Customs and VAT

Including a live webcast to ensure you have the latest Brexit information three months after the seminar

Your Speakers

Dr Peter Bachmann

Senior Expert Regulatory Affairs, Bonn, GERMANY

Dr Bachmann has many years' experience in regulatory affairs. He contributed significantly to establishing the European DCP system and is currently deeply involved in Brexit-Affairs.

Dr Dr Adem Koyuncu

Partner, Lawyer and MD, Covington & Burling LLP, Brussels, BELGIUM

Covington & Burling LLP, one of the leading law firms for life science companies, with subsidiaries in Brussels and London amongst others, has established a Brexit Task Force to support healthcare companies.

Seminar: 6 July 2018, Frankfurt Airport; Webcast: 1 October 2018*

*This date may change if essential news is expected after 1 October.

BREXIT Countdown – Q&A Focus Pharma

Aims and objectives

Twenty-ninth March 2019 is fast approaching. What are your essential things to do prior to this date:

- To maintain your products on the UK market?
- To make sure your EU supply chain still functions after this date?

Two experts provide you with first-hand knowledge and help you to secure your marketing authorisations, supply chain and product availability on the EU and UK markets.

Who should attend

This seminar addresses the needs of specialists and executive staff in pharmaceutical companies who:

- maintain marketing authorisations in the UK
- perform batch releases or batch testing in the UK

Keeping you updated

The two speakers will update you with the latest Brexit news in an additional live webcast on 1 October.

Your programme from 10:00 - 17:30

The negotiations so far: Is a further transition period envisaged?

- The UK under the EU's acquis by December 2020?

Existing marketing authorisations – urgent things to do

- National marketing authorisation in the UK (after the DCP or MRP): change of the RMS prior to 29 March 2018
  - Is there a formalised procedure?
- Centralised marketing authorisation: Any things to do so far?
- Existing Art 126a authorisations
- Open variations, renewals – your things to do!

Applying for a new marketing authorisation in the EU (including the UK) now

Marketing authorisation holder in the UK

- Transfer of the marketing authorisation holder and the QPPV
- Consequences for PV: the PSMF and the summary of the PharmVigSystem
- Consequences for packaging and labelling

What to keep in mind to assure the supply chain

- Batch testing in the UK? Batch releases?
- Importing to the EU from the UK (API, finished drugs, etc.)
- GMP certificates and inspections

European databases, portals and clinical trials

- Maintenance of the XEVMPD
- The CESP and CESSP
- CTAs
- Bioequivalence studies and the reference medicinal product for the generics application

What else needs to be kept in mind?

- Customs and VAT import procedures in the UK
- Parallel imports
- Intellectual property
- Implications for contracts
- Investments in the UK

Registration: +49 6221 500 555 or email: service@forum-institut.de

Yes, I will attend the seminar

☐ **BREXIT Countdown – Q&A Focus Pharma**

Name

Position/Department

Company

Street address

Postal Code/City/Country

Tel. No.

E-Mail

Contact person at the office

Date/Signature

- **Registration: +49 6221 500-500**
- **Conference-No. 18 07 231**

- **Date/Venue:**

Seminar: 6 July 2018
09:30 registration; 10:00 - 17:30 seminar

Steigenberger Airport Hotel
Unterschweinstiege 16 · 60549 Frankfurt
Tel. +49 69 6975-0 · Fax +49 69 6975-2505

Live-webcast: 1 October 2018
14:00 - 15:30

- **Fee:**

€ 1,290.00 (+German VAT) incl. course documentation (incl. free download) as well as mid-session refreshments, lunch, certificate and webcast.

- **Questions and information:**

Dr Henriette Wolf-Klein
Tel. +49 6221 500 680 · h.wolf-klein@forum-institut.de

- **Cancellation Policy:**

Our general terms and conditions apply (as of 1 January 2016) and are available upon request. We can send them to you anytime or you can find them on the internet at www.forum-institut.com/t&c