Jointly organised by

ECA Academy
Your GMP/GDP Information Source

QP Association

Speakers

Dr Afshin Hosseiny
ECA Foundation, Chairman
Afshin Hosseiny works as a GMP/GDP consultant. Formerly he was Director of Quality Assurance for the Global Supply Network of GlaxoSmithKline. He is Chairman of the ECA Foundation and of the European GDP Association.

Dr Ulrich Kissel
European QP Association, Chairman
Ulrich Kissel works as a GMP consultant and contract QP to the Pharmaceutical Industry. Previous to his current role he held leadership positions in Quality and Supply Chain and served for many years as QP for Roche.

After Brexit – Consequences for GMP and Supply Chain

- An Update -

Live Online Training on 7 December 2021

Highlights

- QP Certification
- Import Testing (in UK and in EU)
- Approval of Manufacturing Sites Located in Each Territory
- GMP Certificates and Inspections
- Manufacturing Sites Outside EU Which Have Been Inspected by MHRA
- The Special Situation in Northern Ireland
- Available Guidance from MHRA and EU/EMA

Medicinal Products and APIs coming from and delivery to UK - the current situation

Programme

Objectives / Background

The decision of the United Kingdom to leave the EU has caused a high uncertainty throughout industry in general and in the pharmaceutical industry more specifically. Since January 1st the UK has become "third country" from an EU perspective. Currently no MRA exist between UK and EU.

Up to now, there are many questions about the exact procedure and consequences. However, pharmaceutical companies must prepare to ensure supply continuity of critical medicines in UK and EU. The procedures and regulations applicable to medicinal products and APIs coming from or going to UK since 1st of January are no longer the same. Further, third countries outside the EU are impacted as well. MHRA has performed many inspections on behalf the EU outside the EU, and has issued GMP certificates.

Delays in delivery, challenges in the supply chain and even drug shortages are scenarios that are very likely to happen. Companies in EU importing medicines from UK must have provisions in place for to the QP certification of all batches received from UK. Additional questions are: How will companies approve the UK sites? Who is going to audit these sites? How do companies get their GMP certificates etc.? And finally: How do companies cope with the Northern Ireland Protocol?

The ECA and EQPA have therefore designed this online meeting to provide the latest updates from EU Commission and MHRA. Two presentations will cover the challenges: Delivery from EU to the UK and Delivery from UK to the EU. In addition plenty of time will be granted for discussion whiles our presenters will answer delegates questions.

Target Audience

The online meeting addresses all colleagues in pharmaceutical industry who have to deal with consequences from the Brexit, e.g. Quality Assurance, Qualified Persons, Regulatory Affairs, etc.

Programme

The Status Quo after Brexit – Current Requirements for Trade and Movement of Medicinal Products and APIs

- Introduction – overview about the past developments

After Brexit – What QPs Have to Consider

- Role of the QP in the approval process
- QP declaration
- Clinical trial material

Specific Challenges for Manufacturers of Medicinal Products and APIs – Examples and Case Studies

- What are the EMA expectations regarding imports from UK?
- What and how importers from UK should manage these requirements?
- Specific challenges related to the NI protocol

Questions and Answers Session

Participants are invited to ask questions.

Date of the Live Online Training

Tuesday, 7 December 2021, 14.00 to 17.00 h CET

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 490
European QP Association Members € 490
APIC Members € 490
Non-ECA Members € 590
EU GMP Inspectorates € 490
The fee is payable in advance after receipt of invoice.

Registration

Please register register online at **www.gmp-compliance.org**.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering Recordings

Independent from the Live Online Training Courses, you can also order recordings of selected Live Online Training Courses at the same conditions – at www.gmp-compliance.org/recordings. These recordings will be provided on our media server. All you need to watch it is an Internet browser – no additional software.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.
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