Jointly organised by

ECA Academy
Your GMP/GDP Information Source

QP Association

+++Urgent Compliance Meeting+++Urgent Compliance Meeting+++

Speakers

Dr Afshin Hosseiny
ECA Foundation, Chairman

Dr Ulrich Kissel
European QP Association, Chairman

Brexit – Consequences for GMP and Supply Chain

Live Online Training on 25 February 2021 from 14.00 to 17.00 h CET

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

What changed for Medicinal Products and APIs coming from and delivery to UK

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 exists 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. No doubt: 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.?

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 while our presenters will answers 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, Quality Assurance etc.

Your Benefit
Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training

Programme

Background of Brexit and its Impact on Medicinal Products and APIs
Dr Afshin Hosseiny, Chairman ECA Foundation

- Introduction – overview about the past developments

Medicinal Products and APIs from EU to UK
Dr Afshin Hosseiny, Chairman ECA Foundation

- What are the new expectations in UK?
- What and how importers from UK should manage these requirements

Medicinal Products and APIs from UK to EU
Dr Ulrich Kissel, Chairman European QP Association

- What are the EMA expectations regarding imports from UK?
- What and how importers from UK should manage these requirements

Questions and Answers Session

Participants are invited to ask questions.

Speakers

Dr Afshin Hosseiny
ECA Foundation, Chairman

Afshin Hosseiny works as a GMP/GDP consultant. Formerly 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.

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GERMANY

Reservation Form (Please complete in full)

Brexit – Consequences for GMP and Supply Chain, Live Online Training on 25 February 2021 from 14.00 to 17.00 h CET

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Thursday, 25 February 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

Via the attached reservation form, by e-mail or by fax message. Or you 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 a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can order the recording of the Live Online Training at the earliest 10 days after the live performance at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

Organisation and Contact

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