Marketing authorisation

– China, Brazil, Eurasian Economic Union –

virtual meeting

05. November 2020
Online Seminar

Course no. 6830

ONLINE SEMINAR

Drug Regulatory Affairs

Target group

The seminar may be supportive for regulators working on CMC approvals for these countries, quality functions to support registrations and authors in Operations and Development who prepare key documents for Emerging Markets.

MAKING SCIENCE WORK

Objectives

The increasing economic importance of the Emerging Markets in Asia and Latin America, for instance, has led to submissions of marketing authorization applications close to submissions in classical 1st wave countries. It is more and more an economic need to be present in these Emerging markets to compensate the slow growth in Europe, Japan and North America, for instance. Under these so called BRIC countries the most promising are China, Russia and Brazil.

These countries do not follow completely the ICH guidelines, although, China and Brazil are ICH members. Instead, country specific requirements are developing rather dynamic and therefore require more attention and resources to fulfil regulatory needs. The overall objective of this seminar is to explain the most important processes and requirements regarding CMC to submit and update a dossier successfully in China, Russia and Brazil. It explains e.g. China's regulatory processes, the review process of National Medicinal Products Administration (NMPA) for MAAs and the tasks of the National Insitute for Drug Control (NIFDC). For Russia and Eurasian Economic Union (EAEU), the regulatory processes and the content of the Normative Document are presented. For Brazil, i.a. the role of ANVISA is explained as well as the most important CMC requirements.

Programme

Thursday, 05. November 2020, 09:00 to 14:30 h

Welcome and introduction
Dr Christophe Girault, Boehringer Ingelheim

International drug approval - an overview
- Basics
- The registration dossier
- CPP dependency

Dr Stefanie Lietsch-Dallwig, PharmaLex

China: submission and maintenance (DMF)
- Background China DMF
- Current regulations
- Drug Substance
- Excipients
- Packaging Material

Dr Susanne Stephan, Boehringer Ingelheim

China: submission and maintenance (CMC documents, Variations)
- Overview Regulatory bodies
- Current Regulatory environment
- CMC related regulations
- Specific Chinese document - CN TS, TMP
- Import requirements
- Variation process

Dr Ingo Ehleben, Boehringer Ingelheim

Brazil: submission and maintenance of Medicine Produsts – A quick overview
- Key Challenges/ Regulatory Challenges of the Pharmaceutical business in Brazil
- CMC documents
- Variations
- Recommendations for successful global regulatory (brief comments)

Fatima Monteiro, PharmaLex

Russia / Eurasian Economic Union: submission and maintenance (CMC documents, Variations)
- Overview Regulatory bodies
- Current Regulatory environment
- CMC related regulations
- Specific Russian document - ND
- Variation process

Dr Ingo Ehleben, Boehringer Ingelheim

Discussion and closing remarks

Moderator

Dr Christophe Girault
Boehringer Ingelheim

Christophe Girault, PhD is pharmacist. He has 25 years of experience in the area of Clinical Trial Supplies and CMC regulatory affairs.

He is currently working as Regulatory Affairs Manager CMC for Boehringer Ingelheim in Ingelheim, Germany.

Speaker

Fátima Monteiro
PharmaLex

Fátima Monteiro is Senior Manager, Regulatory Affairs at PharmaLex.

Fatima graduated in Pharmacy and attending Law School (graduation in 2020/2).

She has more than 11 years of experience in Pharmaceutical Industry, working in Regulatory Department with focus on R&D for obtaining Marketing Authorization approvals in Brazil and Latin America countries.

Furthermore she assumed various positions in multinational companies in Brazil and Andean countries (based in Colombia).

Dr Ingo Ehleben
Boehringer Ingelheim

Ingo Ehleben is Head of a Group of CMC experts, who are responsible for the life cycle of marketed products all over the world. CMC expert operations for some inhalative products.

Dr Susanne Stephan
Boehringer Ingelheim

Susanne Stephan, is food chemist. She has more than 8 years of experience in the area of quality assurance and CMC regulatory affairs. She is currently working as CMC Expert Operations for Boehringer Ingelheim in Ingelheim, Germany.

Dr Stefanie Lietsch-Dallwig
PharmaLex

Stefanie Lietsch-Dallwig, PhD, is a pharmacist by profession.

She has more than 20 years of experience in Pharmaceutical Industry in Regulatory Affairs, with a focus on Emerging Markets for many years.

Since 2013 Stefanie is working at PharmaLex GmbH in different positions, currently as a Director, Regulatory Affairs.

Registration by fax +49 6131 97 69 69 or by email apv@apv-mainz.de

MAKING SCIENCE WORK

Date

Course no.: 6830
05. November 2020
09:00 to 14:30 h

Registration fee

Industry	400 EUR
Authority/University	200 EUR
Students*	50 EUR

(free of VAT according to § 4,22 UStG)

Electronic proceedings included.

* Limited places for full time students available; written evidence must be submitted.

Registration

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
phone: 0049 6131 97 69 0
Fax: 0049 6131 97 69 69
E-mail: apv@apv-mainz.de
Web: www.apv-mainz.de

You will receive a confirmation of your registration with the invoice.

Mainz, July 2020

Marketing authorisation, 05. November 2020, Online Seminar, Course no.: 6830

Registration
As soon as you have found a seminar of your interest, it is very easy to register for it via fax, e-mail or online. We will process your registration promptly and certainly are available for any questions that may arise.

Registration confirmation
After your registration was successfully processed, you will receive a confirmation.

Before the event
A few days before the event starts, you will receive important information about the seminar, such as time, date, addresses etc.

After the event
You will receive a certificate confirming your participation. Furthermore, we would like to ask you to fill-in our evaluation sheet to make sure we get better every time.

Follow-up
After the event, we are open to receive any suggestions and critique that might arise during the seminar and will certainly help you with further questions you may have.

Declaration of consent in respect of data protection

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APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany

Phone: 0049 6131 97 69 0
Fax: 0049 6131 97 69 69
E-mail apv@apv-mainz.de