MITTELEUROPÄISCHE GESELLSCHAFT FÜR REGULATORY AFFAIRS e.V.

MEGRA

Invitation to the MEGRA seminar

Regulatory Environment and Reforms in Asia – China and the ASEAN region

Monday, 01. April 2019

09:30 a.m. – 05:00 p.m.
(Registration starting at 09:00 a.m.)

Sheraton München Westpark Hotel, Garmischer Str. 2, 80339 München
Phone: 089-51960

Purpose of the seminar

This seminar provides an overview of the pharmaceutical drug market and the regulatory landscape in China as well as in the ASEAN region. Deeper insights in the regulatory procedures and their challenges for the pharmaceutical industry will be presented during this seminar.

Our competent speakers will inform you about the legal and regulatory framework in China and the ASEAN region. Furthermore, the special requirements regarding the clinical trial authorization application, the marketing authorization application as well as the post-approval life cycle management will be discussed in this seminar.

Our seminar will help you to better understand the regulatory landscape in China and the ASEAN region, to prepare the relevant regulatory documentation for an authority application as well as to avoid any mistakes to receive a fast approval.

Group of participants

This seminar is intended for employees of the pharmaceutical industry dealing with clinical trial application and marketing authorizations in China and/or the ASEAN countries.

- Regulatory Affairs
- Clinical Development
- Medical Affairs / Medical Writing
- Business Development

Speakers

Mrs. Stefanie Faßhauer, MBA, Manager Regulatory Affairs, Pharmalex GmbH, Berlin, Germany
Mrs. Yingying Liu, M.Sc., CMC Regulatory Affairs China Expert, Michor Consulting and Trade Services GmbH, Vienna, Austria

Program

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09:00 – 09:30 a.m.	**Registration**	

09:30 – 10:15 a.m.	**Overview of the Chinese drug market and regulatory landscape**
	• Structure of the Chinese regulatory authorities (NMPA, CDE, NIFDC, etc.) and their duties
	• Regulatory guidelines, legislation and requirements:
	  • China specific vs. ICH requirements
	  • Local manufactured vs. imported drugs
	  • NCEs vs. NBEs
		Yingying Liu

10:15 – 10:45 a.m.	**Coffee break**	

10:45 – 12:30 a.m.	**Regulatory procedures in China and their challenges**
	• Clinical trial application (CTA)
	  • CTA process (incl. Ethical Committee and human subject samples importation application)
	  • CTA relevant topics (incl. dossier preparation, CMC requirements, change management during CTA, foreign clinical trial data acceptability, `Silent approval` database, clinical trial registry, etc.)
	• Marketing authorization application (MAA)
	  • MAA pathways overview: Different strategies for the fast MAA approval
	  • MAA relevant topics (incl. dossier preparation, CMC requirements, master file and bundling review, MAH system, overseas inspection overview)
	• Overview of Post-approval lifecycle management
	• Overview of Pricing and Reimbursement, Data Exclusivity and Patents
		Yingying Liu

12:30 - 01:30 p.m.	**Lunch break**	

01.30 - 02:45 p.m.	**The ASEAN region – Then and Now** **Principals of drug registration and lifecycle management** • New drug application (including ACTD / ICH CTD acceptability) • Post approval regulatory change management • Renewal	Stefanie Faßhauer
02:45 - 03:15 p.m.	**Coffee break**	
03:15 – 04:30 p.m.	**Special requirements in ASEAN countries** • GMP requirements • Halal compliance • Harmonization of standards and technical requirements **Key challenges and regulatory opportunities for ASEAN**	Stefanie Faßhauer
04:30 - 05:00 p.m.	**Questions and discussion**	all
	Responsible for the program: Dr. Christina Juli	

Registration

Please register directly via our homepage www.megra.org/Veranstaltungen
Max. 30 participants

Participation fees

The fees include your attendance at the seminar,
download of the lecture notes, lunch, coffee breaks and beverages.

€ 450,-- MEGRA member
€ 590,-- Non-member*

* Price including € 140,-- for MEGRA membership in 2019.

Early booking discount € 50,-- until 28.02.2019

Information for participants, that are non-members
The membership at MEGRA e.V. is a precondition for the participation in our courses. In order to allow non-members to participate, they can apply for the membership when registering for the course. The membership fee is € 140,-- per calendar year.

Important notice concerning MEGRA membership:
The membership at MEGRA e.V. can be terminated by year end with written notice addressed to the MEGRA board at latest by 15th December. Otherwise the membership will be automatically extended by another year. For further information please refer to your homepage 'MEGRA -> Mitglied werden'.

Cancellation fees:
Up to 4 weeks prior to the seminar: 10 % of the total costs
Up to 2 weeks prior to the seminar: 50 % of the total costs
Up to 1 week prior to the seminar: total costs; no reimbursement

In case a substitute participant will be announced, no cancellation fees have to be paid. In case a MEGRA-member is replaced by a non-member, the difference has to be paid.