Invitation to the MEGRA seminar

Regulatory Environment and Reforms in China

20 May 2021
01:00 – 05:30 pm

Purpose of the seminar

This seminar provides an overview of the pharmaceutical drug market and the regulatory landscape in China. 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. 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, 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.

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

Speakers

Yingying Liu, GRA CMC Lead Plasma Fractionation, Global Regulatory Affairs CMC, CSL Behring AG, Bern, Switzerland
Dr. Christina Juli, Head of Tech RA Germany, Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, Germany

Program

Regulatory Environment and Reforms in China

20 May 2021
01:00 – 05:30 pm

01:00 – 01:15 p.m.	**Welcome and introduction of speakers**	
01:15 – 02:00 p.m.	**Overview of the Chinese regulatory authorities and regulatory landscape** • Structure of the Chinese regulatory authorities (NMPA, Provincial Medical Products Administration (PMPA) CDE, Center for Medical Device Evaluation (CMDE), NIFDC, Center for Food and Drug Inspection (CFDI), Acceptance Center, Information Center etc.) and their duties • Overview on Chinese legislation, regulatory guidelines, and requirements covering CTA, NDA/MAA, post-approval change management, annual report, MAH program etc.	Yingying Liu
02:00 – 02:15 p.m.	**Break**	
02:15 – 03:00 p.m.	**Clinical trial application (CTA)** • CTA process (incl. Ethical Committee and human subject samples importation application by Human Genetics Resources Administration of China (HGRAC)) • CTA relevant topics (incl. dossier preparation, CMC requirements, CTA `Silent approval`, change management during CTA, foreign clinical trial data acceptability, clinical trial registry, etc.)	Dr. Christina Juli
03:00 – 03:15 p.m.	**Break**	
03:15 – 04:00 p.m.	**Marketing authorization application (MAA)** • MAA pathways overview: Standard MAA pathway, and accelerated approval pathways and timeline • MAA relevant topics (incl. dossier preparation, CMC requirements, MAH system, etc.) **Specific China requirements regarding MAA approval:** • Testing and Inspection • Bundling review regulation for APIs, excipients and packaging materials ('China DMF') • Harmonization of ChP with international pharmacopoeias	Yingying Liu
04:00 - 04:15 p.m.	**Break**	

04:15 – 05:00 p.m.	**Life cycle management** • Post-approval change management: Post-approval change regulations and guidance documents; Change classifications, reporting categories and consultation with authorities, manufacturing site change, MAH change, review timeline etc. • Renewal procedure • Annual report **Specific CMC requirements – Challenges for industry:** • Module 1 CMC requirements (e.g., batch records, CoAs, chromatograms, Raw Materials, excipients and packaging materials information) • Module 3 requirements (e.g., Manufacturing Testing Specification/ Protocol (MTS/P))	Dr. Christina Juli
05:00 - 05:30 p.m.	**Questions and discussion**	all
		Responsible for the program: Dr. Christina Juli

Registration

See our Homepage: www.megra.org/Veranstaltungen

Fees: € 350,-- for MEGRA members

The MEGRA membership is mandatory for all participants. In case you are not yet member of MEGRA you can apply for membership when registering for this webinar. Cost of membership normally is € 140,-- per calendar year**. In 2021 the MEGRA membership will be free of charge.**

Cancellation fees:

until 4 weeks prior to the event: 10 % handling fee

until 2 weeks prior to the event: 50 % cancellation fee

until 1 week prior to the event: no refund