Seminar on European Pharma & Medical Device Regulation and Overseas Clinical Trial Strategies

All relevant companies:

With the rapid development of China's pharmaceutical and medical device industries, more national enterprises are aiming at the vast international market. It is crucial to develop a rigorous and pragmatic global development strategy. In order to help pharmaceutical and medical device companies understand the EU clinical regulatory requirements and clinical trial regulatory environment, and provide feasible solutions for them to go to Europe. To this end, the Beijing Advanced Medical Device Industry Innovation Alliance, together with Summer Atlantic Capital, organized a Seminar on European Pharma & Medical Device Regulation and Overseas Clinical Trial Strategies. Details of the conference are as follows.

Time and Venue

13:00-17:00 (China Time) **April 03, 2023**

Conference Venue:

Zhongke Electric Business Valley
(No. 20, Guangde Street, Daxing District, Beijing, 900 meters southwest of Wufutang Station, Subway Line 8)

Organization

Organizer

Co-organizer

Participants Pharmaceutical company managers, clinical teams, registration teams, etc.

Agenda

13:30-13:40
Opening Remarks by Alliance leaders

13:40-13:50
Introduction

13:50-14:00
Company Profile

14:00-16:30

- Quality Management Systems in clinical trials (electronic versus paper)
- ePRO solutions in clinical trials
- Clinical trial strategy development
- Study approval and conduct specifics in EAEU
- Study approval and conduct specifics in Europe
- EMA inspection in clinical trials, practical aspects of preparation, conduct, and follow-up

16:30-17:30
Specialized consultation

01

Sebright Chen

Founder of Summer Capital and Chief Representative of Smooth Drug Development China.

Mr. Chen has extensive experience in investment management, healthcare and technology industries. He holds a BA in Economics from the State University of New York at Binghamton and a Certificate in Innovation and Entrepreneurship from Stanford University, and is pursuing an Executive MBA from the nationally ranked University of Chicago Booth School of Business. After graduating from Stanford, he began his career as an analyst at Signalert Asset Management, followed by executive positions at asset management and technology companies in China, where he developed extensive contacts in China and the U.S., as well as significant international relationships in the asset management and investment banking industries. Prior to founding Summer Atlantic Capital, the artificial intelligence startup he served as CFO was acquired by one of the world's largest technology companies. Mr. Chen is also a venture advisor to Spike Ventures, a Stanford alumni fund, and an advisor to several technology companies. He was selected as a GCIF USA Global Finance 100 Leader for 2020 and a Global Finance 100 for 2021. Mr. Chen is a key member of the Horasis global community, a member of the International Trade Council and Chairman of the China region, and has been invited as a keynote speaker at several global conferences organized by the ITC, covering topics such as technology, trade, and finance. Mr. Chen's team focuses on the areas of medical technology, life sciences and regulatory technology.

02

Alexandra Trofimova

Head of Quality Assurance and Training Department

Alexandra Trofimova is Head of Quality Assurance and Trainings Department in Smooth Drug Development CRO. Alexandra has 8 years of experience in the field of clinical trials. Her job at SDD is to coordinate work of QA department, hold internal and host external audits, maintain and develop QMS of the company and develop and and perform trainings for the company employees. Her passion is continuous improvement of all the company processes.

03

Anna Azheganova

Head of Data Management Group

Anna graduated from the Chemical and Pharmaceutical Institute with a degree in biotechnology. She has 10 years of experience in clinical research. Anna is the Head of the Data Management Group at Smooth Drug Development and responsible for data management activities from 2016.

04

Alexey Ladutko

M.D., PhD is the Scientific Department Director

Dr. Ladutko has wealth of experience in scientific research, as well as twelve years of experience in clinical trials and drug safety. Dr. Ladutko is responsible for the development of clinical trial documentation, biostatistics, data management and pharmacovigilance.

05

Alina Semenova

Head of Support Group

Alina Semenova has a university degree in pharmacy and journalism. Alina work experience in clinical trials is about 7 years. Alina experience includes global multinational trials in India, Europe and EAEU.

06

Anton Seleznev

MD, Clinical and Regulatory Operations Department

Anton Seleznev is an MD with over 20 year of professional experience in pharmaceutical industry in different roles with increasing responsibilities across CIS, EU, South-East Asia and Africa within Clinical Operations and Medical Affairs. His roles assumed local, regional and global responsibilities at companies like Roche, Boehringer-Ingelheim, Sandoz, Takeda.

07

Maria Zaitseva

Global Quality Assurance Specialist

Biography: Independent auditor, candidate of medical sciences, specialist in clinical trials / preclinical testing and quality assurance with 24 years of experience in clinical / preclinical testing, including 18 years in QA in international companies (OCT, Accel Clinical Research, Cromos Pharma) as head of quality assurance, and, trainer in GxP standards. Since 2014, she has been a national industry inspector of good laboratory practice in EAEU region. Specializes in independent GCP/GLP/GCLP/GDP audits in CIS, EU, regular consultations on complex elements of GCP/GLP/GCLP/GDP, development, organization and implementation of GCP, GLP, clinical/-clinical quality management programs, including courses, webinars for clinical research specialists (CRA), clinical trial managers (CTM). Provides quality oversight at the project level (Phases I-IV and bioequivalence studies), including development of quality assurance and risk management plans.

Conference Contact and Registration

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bmi2014@163.com

ChinaBD@smoothdd.com

info@summeratlantic.com

Please scan the QR code below to register

Other Matters:

The conference fee is waived, and transportation and accommodation will be provided at your own expense.

Beijing Medical Equipment Innovation Alliance

February 21, 2023