Global Medical Device Regulation Update and Practice

"Asia Regulatory Training Course" is organized by Asia Regulatory Professional Association (ARPA) and Qualtech Consulting Corporation annually since 2011. This annual event aims to bring practice to schools. By recognizing the situation that existed in medical device industry today, and understanding developmentally practices, both lecturers and students may integrate studies into practices.

This year, we are honored to have a professional from CFDA to guide us through the regulation changes on clinical trials in China and a regulatory expert on European CE&MDR. Join us to learn about the framework for regulation of medical device in Europe and China, get a hold on the updates and trends of medical device regulation, and engage with the professionals from frontiers through this event!

FREE

Friday, 12th January, 2018

4th floor Lecture hall, The School of Biological Science and Medical Engineering, Beijing, China

13:00 ~ 13:10 pm	**Registration**
13:10 ~ 13:15 pm	**Introduction** Dr. Yin-Pen, Chang, General Manager at Qualtech
13:15 ~ 13:45 pm	**Biological Evaluation for Medical Devices** Prof. Tíng Fěi, Xī, Prof. in BUAA
13:45 ~ 14:35 pm	**Clinical Trials Update in CFDA** Xīn Lì, Shǐ, Minister of Supervision III at Center for Medical Device Evaluation (CMDE)
14:35 ~ 14:50 pm	**Break**
14:50 ~ 15:30 pm	**CE and MDR Regulatory Affairs** Dr. Arkan Zwick, Director of Regulatory Affairs, CROMA Pharma GmbH, Austria
15:30 ~ 16:30 pm	**AHWP Introduction, ASEAN Regulatory Update and Practice** Prof. Jack Wong, Secretary, Asian Harmonization Working Party, AHWP
16:30 ~ 17:00 pm	**Discussion**
17:00 pm	**End**

Organized by:

ARPA
Asia Regulatory Professional Association

The Asia Regulatory Professional Association

北京航空航天大学 BEIHANG UNIVERSITY 1952

The School of Biological Science & Medical Engineering

Co-organized by:

QUALtech
MEDICAL DEVICE REGULATORY & CRO

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