Day 1 – Thursday 11 September 2014

09:00 – 11:00  Registration
11:00 – 11:05  Welcome
11:05  13:00  Doing business in China
    • Christian Goedel (SinaLingua)
      Cultural awareness: things can be confusing, pitfalls, keeping face, etiquette
    • Yang Liu (Yang Liu Design)
      East meets West – Yang Liu’s personal experience on cultural differences
    • Discussion
13:00 – 14:00  Lunch
14:00 – 15:30  Quality systems and Regulatory Processes
    • Jianan Wang (CFDA)
      Submissions and inspections
    • Andrew Gray (MHRA)
      Is GLP an appropriate standard for laboratories that analyse samples from human clinical trials? – A European perspective
    • Philip Timmerman (Janssen R&D)
      Bioanalysis in China: working in the intersection of global regulations and OECD-GLP
    • Discussion
15:30 – 16:00  Tea Break
16:00 - 18:00  Bioanalytical Guidelines
    • Daniel Tan (ICON)
      Introduction
    • Dafang Zhong (Shanghai Institute of Materia Medica)
      Guideline on bioanalytical method validation in China
    • Daniel Tang (ICON)
      CBF activities and involvement in guideline conception and review
    • Discussion
18:00 – 19:00  Reception

Day 2 – Wednesday 12 September

8:30 – 10:30  Clinical studies
    • Peter van Amsterdam (Abbott Established Pharmaceuticals Division)
      Introduction to Clinical Trial Applications
    • Pei Hu (Peking Union Medical College Hospital)
      Early Phase clinical studies
AGENDA

- Huafang Li (Shanghai Mental Health Center)
  Late Phase Clinical Trials
- Discussion

10:30 – 11:00  Coffee Break

11:00 – 12:50  Learning by doing
- Margarete Brudny-Klöppel (Bayer Pharma AG)
  How to get the business started
- Fan Ji (Covance)
  Operational and Compliance challenges of setting up Bioanalytical Lab in China
- Johanna Beekman (Bayer Pharma AG)
  Bayer’s experience in sample exportation from China
- TBD
  Central lab perspective
- Discussion

12:50 – 13:00  Reflections and Close out

13:00 – 14:00  Lunch