Center for Pharmaceutical Information and Engineering Research
Peking University, Beijing, China
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July 5, 2006

Dear Sirs,

We are glad to announce the upcoming "2006 EU-Swiss GMP China Training Workshop", which is to be held at Peking University in Beijing China from September 19th to 21st of 2006. For details, please visit www.cpier.pku.edu.cn.

This important initiative has the support of the European Commission's Pharmaceutical Unit and is sponsored by Swissmedic. Peking University and International Society for Pharmaceutical Engineering (ISPE) are also sponsoring the event.

The Workshop will focus on GMP of both APIs and dosage forms, covering toll manufacturing, GMP for herbal medicinal products, impurity profiles of APIs, and APIs manufactured by cell culture and fermentation. It will also explain the law-making system in the EU and provide information about licensing procedures in the EU and Switzerland. As in the past, each attendee can receive a Certificate of Attendance. Those who pass the exam can each also receive a Certificate of Completion. The certificates will be jointly issued by College of Engineering of Peking University and ISPE.

Should you need any assistance, please do not hesitate to contact me or my colleagues at gmp@cpier.pku.edu.cn.

We welcome your participation, and look forward to seeing you in Beijing.

Sincerely,

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Agenda

Day 1

- Law-Making in the European Union and Legal Background for the Regulation on Pharmaceuticals
- ICH Q7A / GMP Part II – Basic Requirements for Active Substances
- Inspection / Audit Programs
- API's Manufactured by Cell Culture / Fermentation
- Impurity Profiles of APIs
- The Role of QC / Production / QA in Relation to Batch Release

Day 2

- GMP for API vs. GMP for Dosage Forms
- Toll Manufacturing
- Packaging Materials, Labeling and Distribution
- GMP for Herbal Medicinal Products
- MRA's and PIC/S – How Regulatory Authorities Exchange Information on GMP Inspections
- ICH Q9 (with a Brief Introduction into Q10)
- Exam

Day 3

- Award Ceremony and ISPE Presentation
- The Process to Apply for Marketing Authorisation in the EU and in Switzerland
- Round Table Discussion / Q&A

Speakers

- Emer Cooke, Head of inspection sector, EMEA
- Susanne Keitel, Head of EU and international affairs, BfArM
- Lionel Viornery, Head of the starting materials for pharmaceutical use inspection unit, Affssaps
- Ruedi Ackermann, GMP inspector, the regional inspectorate for central & eastern Switzerland
- Michel Keller, GMP/GDP inspector, Swissmedic
- Eckhart Wildi, Deputy Head, complementary and herbal medicines department, Swissmedic
- Paul D'Eramo, Executive Director, quality and compliance worldwide at J&J, Former ISPE Chairman