Pharmabridge **Updated 28.03.2010**

Offer USA-37 for training courses in industrial pharmacy for manufacturers and inspectors in developing countries.

Michael H. Anisfeld from Globepharm Consulting in Chicago, USA, has offered to Pharmabridge to teach the following industrial pharmacy courses in developing countries:

- Fundamentals and Essentials of Good Manufacturing Practices (1 day)
- Fundamentals and Essentials of Validation (2 days)
- Fundamentals and Essentials of Pharmaceutical Water Systems (1 day)
- Preparing For and Living With 21CFR11 Regulations (Electronic Record/Electronic Signature) (1 day)
- Preparing For, and Passing, an FDA inspection (1 day)
- Managing the QC Lab in a GMP Compliant Manner (1 day)
- GMPs for Pharmaceutical Development Scientists (1 day)

- GMP Week:
  a five day course designed to provide all departments of the company with the GMP information and tools that impacts their daily operations – this course would be perfect for government inspection agencies

These courses are designed for 25 – 50 people in attendance; more than 50 is possible, but spoils the intense interactive nature of the courses.

Detailed course descriptions of all these courses can be found at Mr Anisfeld's website at http://www.globepharm.org/training/in-house/course-listing.html

Mike Anisfeld is prepared to tailor courses to local needs with a duration of 5 to 20 days.

The best local organizers would be the local pharmaceutical industry associations, and/or/with Ministries of Health, because these courses would also be ideal to train government GMP inspectors.

Mike Anisfeld does not expect to be paid for his time, but expects the local organizers to cover his travel (prepaid ticket) and living expenses at a business class hotel,
ex-Chicago, USA.

Obligations on receiving party:

Organization
Local organization of everything relating to the course with a minimum of 25 participants per course

Whoever takes over the organization, a combination of participants from industry and regulatory agencies is preferred.

Financial obligation
All organizational expenses and return air ticket (full fare economy) out of Chicago and local accommodation for Mr Anisfeld to be covered either by the organizer (local manufacturers association or Ministry of Health) or through course registration fees.

Anybody interested in the offer should initially contact

Agathe Wehrli
Pharmabridge coordinator
wehrlia@bluewin.ch

GMP training carried out under Pharmabridge so far:

Sri Lanka:
2005: 14-16 June: 1x2 +2x1 days with 54,43 and 43 participants respectively

Nigeria:
2005:
12-13 December: How to perform GMP Inspection (20 inspectors: 10 from NAFDAC, 10 from Pharmacy Council of Nigeria)
14-15 December: Current Trends and Expectations in GMP with 33 participants from industry

2006:
4-5 December: Validation, Water systems attended by 13 participants from Pharmacists Council of Nigeria
5-7 December: Validation, Water systems attended by 34 participants from industry (from 16 companies)

2007:
11-12 June (day 1: Good documentation. practices (41 participants); day 2:Managing a QC Lab in a GMP Way (38 participants). Most participants attended both days

Mongolia:
2007: 5 days (including visits to manufacturers) with 50 to 65 participants from Ministry of Health

Ghana:
2007, 07-11 May: 5 days on 5 GMP topics; 60 participants from regulatory body and industry

7th May, 2007	International (EU & USA) GMPs for cosmetics and drug manufacturers
8th May, 2007	Managing QC laboratories in a GMP compliant manner
9th May, 2007	Good documentation practices
10th May, 2007	Fundamentals and essentials of validation
11th May, 2007	Fundamentals and essentials of pharmaceutical water systems

2008, 19-23 May: 5 days on 5 GMP topics; 61 participants from regulatory body and industry

19th May 2008	Passing an FDA Inspection: A - Z
20th May 2008	Design and Engineering of GMP Compliant Pharmaceutical Manufacturing Facilities
21st May 2008	Performing Effective GMP Inspections: Strategies and Tactics
22nd May 2008	GMPs For Executive Management
22nd May 2008	Effective Investigations and Corrective Actions (CAPA) Proper Investigation Of Quality Events
23rd May 2008	Effective Investigations and Corrective Actions (CAPA) Proper Investigation Of Quality Events

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