PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INIDA
(Set up by Ministry of Commerce & Industry, Govt. of India)

DRAFT PROGRAMME

SUBJECT: WORKSHOP ON GLOBAL PHARMACEUTICAL OPERATIONS
DATE: 29 November 2016 09:00 - 21:30
VENUE: Shangri-La's Hotel, 19 Ashoka Road, Connaught Place, New Delhi

9:00 - 9:30 Registration

9:30 - 9:40 Welcome and introduction

9:40 - 10:40 Inaugural Session: Setting the Scene - Globalisation and the interplay of Trust, Regulation and Business

With a panel composed of:

- **Mr. Tomasz Kozlowski,** EU Ambassador to India
- **Joint** Secretary, Department of Pharmaceutical
- **Mr. Madan Mohan Reddy Chairman / Mr. Dinesh Dua, Vice Chairman, Pharmaceuticals Export Promotion Council of India**
- **Dr. Adrian van den Hoven,** Director General Medicines For Europe

10:40 - 11:00 Networking Break

11:00 - 12:45 Session 1: Towards a universally acceptable quality culture - challenges and opportunities

Session Chair : **Dr. Daara B. Patel,** Secretary-General IDMA (Indian Drug Manufacturers Association)

- India, the Quality Medicines Pharmacy of the World - India Perspective.
  Senior official from Department of Commerce
- Quality of Medicines in a Globalized World - The European Union Perspective
  European Union Delegation to India
- Ensuring Global Supply Chain Security: The EMA perspective on Quality culture.
  Mr. Brendan Cuddy, Head of Manufacturing and Quality Compliance, EMA
- India the Quality Pharmacy of the World - challenges and opportunities
  Dr. Haribabu Bodepudi, Global Head OSD, Mylan
- **Q&A session** with session speakers

12:45 – 13:45 Networking Lunch

13:45 - 15:30 Session 2: Strengthening Good Clinical Practices Oversight - Current practices and future prospects

Session chair : Dr. Y.K Gupta, Professor & Head- Department of Pharmacology, AIIMS

- The Medicines For Europe perspective
  Dr. Barbara Müller, Sandoz **and Dr. Gerald Beuerle, TEVA**
- The Indian CRO perspective
  Apurva Shah, Veeda
- The EMA perspective
  Dr. Anabela Marcal, Head of Compliance and Inspections, EMA
- The Indian regulator perspective
  Senior official from Drug Controller General of India, CDSCO
- **Q&A session** with session speakers and Indian CRO representatives

15:30 – 16:00 Networking Break

16:00 – 17:45 Session 3: Strengthening Good Manufacturing Practices Oversight – Current practices and future prospects

Session Chair : Mr. Paul Fleming BGMA

- The Medicines For Europe perspective
  Ms. Mechthild Sander, AET
- The Indian Manufacturer perspective
  Dr. Purandare, Global QA head Cipla.
- The EMA perspective
  Dr. Anabela Marcal, Head of Compliance and Inspections, EMA
- **The Indian Perspective**
  Senior official from Ministry of Health
- **Q&A session** with session speakers and Indian Manufacturer representatives.

17:45 – 18:00 Closing address

18:00 – 19:30 Reception and walking dinner.

19:30 -21:30 Networking event