CONFERENCE OBJECTIVE
This conference is organized in cooperation with World Health Organization (WHO), The European Directorate for the Quality of Medicine & Health Care (EDQM) and Drug Information Association (DIA). The major focus of this conference will be on the current regulatory requirements for the quality of API, Compliance with GMP Standards from Global Regulatory Authorities Perspective. The conference will also focus on the current issues of Pharmacopoeial Monographs, as well as API Certification and WHO Prequalification requirements.

FEATURED TOPICS
• Regulatory requirements with relevance for quality of API Compliance of API manufacturers with current GMP Standards
• Current issues and challenges in the development of Pharmacopoeial Monograph
• API Certification and WHO Prequalification Program

LEARNING OBJECTIVES
At the conclusion of this meeting, participants should be able to:
• Describe the regulatory issues of API manufacturing and compliance
• Explain the current compliance issues of API
• Discuss the requirements of the API under the prequalification program Outline the procedures for Certification of Suitability (CEP)

WHO SHOULD ATTEND
► Government Regulators
► Regulatory Affairs Associates from Industry
► Chemistry Manufacturing and Controls
► Analytical Development Chemistry
► Formulation Development
► Technical Services, QA, QC
DAY 1 | FRIDAY, SEPTEMBER 17

9.00 AM-1.00 PM  HALF DAY TUTORIAL WORKSHOP I
WORKSHOP ON CEPs (CERTIFICATION PROCEDURES IN EUROPE)
Florence Benoit-Guyod
EDQM
Pascale Poukens-Renwart
EDQM

- GENERAL PRESENTATION OF THE CERTIFICATION PROCEDURE
- REGULATORY SYSTEM IN EUROPE
- THE PLACE OF CERTIFICATION AS A REGULATORY TOOL
- COMPARISON OF CEP AND ACTIVE SUBSTANCE MASTER FILE (ASMF)
- DESCRIPTION OF THE CEP PROCEDURE
- HOW TO PREPARE A NEW APPLICATION – CONTENT OF THE DOSSIER – CASE STUDIES
- REVISIONS OF CEPS AND HOW TO PREPARE AN APPLICATION FOR REVISION - CASE STUDIES
- HOW TO PREPARE FOR EDQM INSPECTION

1.30 AM-5.00 PM  HALF DAY TUTORIAL WORKSHOP II
WORKSHOP ON WHO PREQUALIFICATION PROGRAMME FOR PRIORITY MEDICINES
Deusdedit Mubangizi
WHO
Jurgen Schomakers
BfArM
Milan Smid
WHO

- WHO PREQUALIFICATION PROGRAMME
- PRINCIPLES, PREQUALIFICATION PROCEDURE UPDATE, LIFECYCLE OF PREQUALIFIED MEDICINE, INFORMATION OUTCOMES, PREQUALIFIED
- MEDICINES AND PRODUCTS OF PRIORITY NEEDS
- INSPECTIONS OF MANUFACTURERS AND CROs
- REQUIREMENTS ON DOCUMENTATION OF ACTIVE PHARMACEUTICAL INGREDIENT AND FINAL PRODUCT QUALITY AND EVALUATION PROCESS
- DEMONSTRATION OF BIOEQUIVALENCE
- VARIATIONS TO PREQUALIFIED MEDICINES

DAY 1 | SATURDAY, SEPTEMBER 18

Roundtable Discussion

8:45-9:30 AM  REGISTRATION

9.00-9.30 AM  INTRODUCTION TO THE PROGRAM
DIA
WHO
EDQM

9.30-11.00 AM  KEYNOTE PRESENTATION

11.00-11.30 AM  TEA/ COFFEE BREAK

11.30 AM -1.30 PM  SESSION 1
REGULATORY REQUIREMENTS WITH RELEVANCE FOR QUALITY OF API
Moderator

- REQUIREMENTS FOR THE QUALITY OF API FROM A EUROPEAN PERSPECTIVE
  Cornelia Nopitsch-Mai
  Federal Institute for Drugs and Medical Devices
  BfArM, Germany

- REQUIREMENTS FOR THE QUALITY OF API FROM AN INDIAN PERSPECTIVE
  Antony RajGomes
  Shasun Chemicals & Drugs Ltd

1.30-2.30 PM  SESSION 2
COMPLIANCE OF API MANUFACTURERS WITH GMP STANDARDS
Moderator

- WHO GMP AND INSPECTIONS OF API MANUFACTURERS
  Deusdedit Mubangizi
  WHO

- EU GMP REQUIREMENTS AND INSPECTIONS OF API MANUFACTURERS ORGANIZED BY EMEA
  Olivier Gross

3.50-4.15 PM  TEA/COFFEE BREAK

4.15-5.00 PM  API INSPECTIONS – THE EDQM EXPERIENCE
Moderator

- FDA GMP REQUIREMENTS AND INSPECTIONS OF API MANUFACTURERS
  MurliDhara Gavini

ROUNDTABLE DISCUSSION
DAY 3 | SUNDAY, SEPTEMBER 19

9:00 AM-1:00 PM SESSION 3
CURRENT ISSUES & CHALLENGES IN THE DEVELOPMENT OF PHARMACOPOEIAL MONOGRAPHS
EUROPEAN PHARMACOPIEIA
Pascale Poukens-Renwart
EDQM
INTERNATIONAL PHARMACOPIEIA
Caroline Mendy
WHO

10:30-11:00 AM TEA/COFFEE BREAK
CURRENT ISSUES AND CHALLENGES IN THE DEVELOPMENT OF INDIAN PHARMACOPOEIAL MONOGRAPH
SOME NEW CHALLENGES IN THE IMPURITIES ARENA
E Sreedhar
Dr. Reddys
ROUNDTABLE DISCUSSION

1:00-2.30 PM LUNCH

2.30-5.15 PM SESSION 4
API CERTIFICATION AND WHO PREQUALIFICATION
Moderator
EDQM CERTIFICATION SCHEME
Pascale Poukens-Renwart
EDQM
WHO Prequalification and API Requirements
Jurgen Schomakers
BfArM

3.50-4.15 PM TEA/COFFEE BREAK

4.15-5.00 PM
DMF PROCEDURES AND COMMUNICATION BETWEEN API MANUFACTURERS, FPP MANUFACTURERS AND REGULATORY
Cornelia Nopitsch-Mai
Federal Institute of Drugs and Medical Devices
BfArM, Germany
ROUNDTABLE DISCUSSION

5:00 PM CLOSING REMARKS
CONFERENCE ADJOURNED

5th Annual Conference on Drug Discovery and Clinical Development: Meeting the Challenges of Next Generation R&D — Enhancing Efficiency, Effectiveness and Innovation
October 23-26, 2010    Tutorials: October 23, 2010**
Hotel The Lalit Ashok, Bangalore, India

Program Co-Chairs

Balasubramanian Sankaranarayanan
Practice Director Cognizant, India

Krathish Bopanna
President & Executive Director Semler Research Center

Larisa Nagra Singh
Senior Director Clinical Operation, ICON

Conference Topics:
• Drug Discovery
• Regulatory Affairs
• Early / Pre-Clinical Development
• Clinical Operations
• Quality Assurance and Compliance
• Biologics and Vaccines
• Pharmacovigilance and Drug Safety
• Clinical Data Management, Biostatistics, and Medical Writing
• Central Lab Management
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**MEETING CONTACTS**
Fahd Khan, Manager Marketing & Program Development, DIA (India) Private Limited; Cell: +91-9223267327, Fax: +91-22-28594762, Email: Fahd.Khan@dialindia.org
Pallavi Gokhale, Marketing Assistant, DIA (India) Private Limited; Cell: +91-9819138650; Fax: +91-22-28594762; Email: Pallavi.Gokhale@dialindia.org

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Cancellations must be in writing and be received by August 17, 2010. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. If the event is cancelled, the organizers are not responsible for any airfare, hotel or other costs incurred by registrants.

Upon cancellation, the administrative fee that will be withheld from refund amount is:

- **FULL MEETING CANCELLATION (All refunds will be issued in the currency of original payment):**
  - Member/Nonmember Registration = INR 3,000
  - Student Registration = INR 500

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Meeting I.D. # 10658 – September 18-19, 2010 – Hotel Holiday Inn, Mumbai, INDIA

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**TUTORIALS**
Industry, Academia, and Students

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