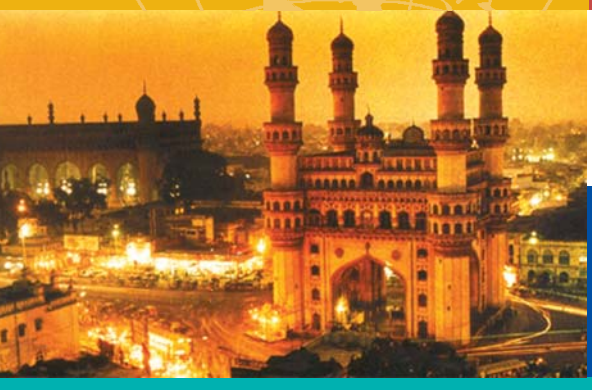

DIA Drug Information Association

EDQM Direction Européenne de la Qualité du Médicament & Soins de Santé

World Health Organization

International Conference

Quality of Active Pharmaceutical Ingredients

Tutorial Workshops: 5 September 2009
Conference: 6-7 September 2009

Hotel Taj Krishna, Hyderabad, INDIA

CONFERENCE OBJECTIVE

This conference is jointly sponsored by World Health Organization (WHO), The European Department of Quality Medicine (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

KEYNOTE SPEAKERS

S. Srinivasan
Chief Executive Officer and Managing Director
Matrix Laboratories Limited

Since January 2009, S. Srinivasan has served as Chief Executive Officer and Managing Director of Matrix, where he also served as Chief Operating Officer.

During his 15-year career at Matrix, Srinivasan has distinguished himself in a wide range of functional areas, including finance, sales and marketing, business development and strategic planning. He has contributed significantly to the company's growth. Mr. Srinivasan is a member of the Institute of Cost & Works Accountants of India.

J.M. Khanna, PhD
Executive Director–Science & Technology
Jubilant Organosys Ltd.

Dr. Jag Mohan Khanna is an internationally recognized research scientist who has done some novel work in the development of APIs, new chemical entities, new drug delivery systems, biotechnology and herbal drugs. He is also an expert in international drug regulatory affairs and intellectual property. Dr. Khanna has worked with various scientific research organizations in India and abroad during his more 39 year career. His last assignment was with Ranbaxy Laboratories, where he was President of R&D and Executive Director of the Board, as well as Chairman of Ranbaxy Pharmaceuticals Inc., USA. He has served as a member of Scientific Advisory Committee to Cabinet on Science & Technology for the Government of India.

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; and
- Outline the procedures for Certification of Suitability (COS).

WHO SHOULD ATTEND

- Government Regulators
- Regulatory Affairs Associates from Industry
- Chemistry Manufacturing and Controls
- Analytical Development Chemistry
- Formulation Development
- Technical Services, QA, QC

PROGRAM CHAIRPERSONS

SUSANNE KEITEL
EDQM

SMID MILAN
WHO

ORGANIZING COMMITTEE

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Sunayan Pharmaceuticals

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Mantena Laboratories Ltd

HEMANT SHARMA
Aurobindo Pharma Ltd.

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SATURDAY • SEPTEMBER 5

9.00 AM-1.00 PM HALF DAY TUTORIAL WORKSHOP I

WORKSHOP ON CEPS (CERTIFICATION PROCEDURES IN EUROPE)

S. Keitel
F. Benoit-Guyod
D. Byrne

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

THE EDQM INSPECTION PROGRAMME

HOW TO PREPARE A NEW APPLICATION – CONTENT OF THE DOSSIER – TOP DEFICIENCIES

REVISIONS OF CEPS AND HOW TO PREPARE AN APPLICATION FOR REVISION

1.00-5.00 PM HALF DAY TUTORIAL WORKSHOP II

WORKSHOP ON IMPORTANCE AND METHODS FOR MOVING FROM THE COMMON TECHNICAL DOCUMENT (CTD) TO THE ELECTRONIC COMMON TECHNICAL DOCUMENT (ECTD)

Shy Kumar
President
Datafarm Inc.

INTRODUCTION TO CTD AND E CTD

Background of ICH and CTD

Organization/Format of CTD

Advantages of CTD

AUTHORING TO COMPLY WITH CTD REQUIREMENTS

Using pre-defined templates

Granularity

PDF Publishing for Authors

INTRODUCTION TO ECTD

What is eCTD

Migration from paper-based CTD to eCTD

Components of eCTD

Managing life cycle

Benefits of eCTD

9.00 AM-1.00 PM HALF DAY TUTORIAL WORKSHOP III

WORKSHOP ON WHO PREQUALIFICATION PROGRAMME FOR PRIORITY MEDICINES

M. Smid
A. van Zyl
M. Mehmandoust

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 INGREDIENT AND FINAL PRODUCT QUALITY AND EVALUATION PROCESS

DEMONSTRATION OF BIOEQUIVALENCE

VARIATIONS TO PREQUALIFIED MEDICINES

SUNDAY • SEPTEMBER 6

8:00-9:00 AM REGISTRATION

9.00-9.30 AM INTRODUCTION – WHO, EDQM, DIA

9.30-10.15 AM KEYNOTE PRESENTATIONS
WHO/EDQM

STATE OF THE ART OF REGULATION OF ACTIVE PHARMACEUTICAL INGREDIENTS

CEO of Indian company with global vision and presence on global market

10.15-10.45 AM **TEA/COFFEE BREAK**

10.45 AM-1.15 PM SESSION 1

REGULATORY REQUIREMENTS WITH RELEVANCE FOR QUALITY OF API

MODERATOR:

REQUIREMENTS FOR THE QUALITY OF API FROM A EUROPEAN PERSPECTIVE SPEAKER
Dr. Jean-Luis Robert
Chair of CHMP/CVMP Quality Working Party
EMEA

REQUIREMENTS FOR THE QUALITY OF API FROM AN FDA PERSPECTIVE
Vilayat A. Sayeed, PhD
Director, Division of Chemistry III
OPS, OBD, CDER, FDA

Requirements for the Quality of API from an Indian Perspective
Nandkumar Chodankar
Chair
pACI

Roundtable Discussion

1.15-2.30 PM **LUNCH**

2.30-5.30 PM SESSION 2

Compliance of API Manufacturers with GMP Standards

Moderator:

WHO GMP and Inspections of API Manufacturers
Andrew van Zyl
WHO

EU GMP Requirements and Inspections of API Manufacturers Organized by EMEA
Dr. Olivier Gross
EMEA

API Inspections – The EDQM Experience
Dr. Florence Benoit-Guyod
EDQM

3.50-4.15 **TEA/COFFEE BREAK**

FDA GMP Requirements and Inspections of API Manufacturers Organized by FDA
Speaker (US FDA)

Roundtable Discussion

MONDAY • SEPTEMBER 7

9.00-1:00 SESSION 3

Current Issues & Challenges in the Development of Pharmacopoeial Monographs

European Pharmacopoeia
Dr. Susanne Keitel
EDQM

International Pharmacopoeia
Ms. Carolin Mendy
WHO

10.30-11.00 **TEA/COFEE BREAK**

Current Issues and Challeges in the Development of Indian Pharmacopieal Monograph
G.N. Singh
Director & Goverment Analyst
Central Indian Pharmacopiea Monograph

Some New Challenges in the Impurities Arena
Dr. Susanne Keitel
EDQM

Roundtable Discussion

1.00-2.30 PM **LUNCH**

2.30-5.30 PM SESSION 4

API Certification and WHO Prequalification

Moderator:

EDQM Certification Scheme
Dr. Pascale Poukens-Renwart
EDQM

WHO API Prequalification
Maryam Mehmandoust
WHO

3.50-4.15 PM **TEA/COFFEE BREAK**

DMF Procedures and Communication between API Manufacturers, FPP Manufacturers and Regulatory Authorities
Dr. Jean-Louis Robert
Chair CHMP/CVMP Quality Working Party
EMEA

Roundtable Discussion

4:15 PM CLOSING REMARKS
Nandkumar Chodankar
Chair
pACI

4.30 PM CONFERENCE ADJOURNED

TRAVEL AND HOTEL The Capital of Andhra Pradesh, Hyderabad is an integral part of the famous twin-city pair of Hyderabad and Secunderabad, which was situated on the opposite banks of the Hussain Sagar Lake. It is easily accessible from most other cities by air, rail, and road. The most convenient airport is Rajiv Gandhi International Airport – Approximate driving time is 1 Hour and distance is 30 Km from the hotel. Attendees should make airline reservations as soon as possible to ensure availability. From Hyderabad railway station the Hotel is located 10 Km.

Taj Krishna is holding a block of rooms at reduced rate until August, 2009. Room availability at this rate is guaranteed only until the block is filled.

Contact Information:
Taj Krishna, Hyderabad, Road No. 1, Banjara Hills, Hyderabad – 500034, India
Contact No. +91- 40 – 66662323, Fax No. +91- 04 – 66661313
Email: Krishna.hyderabad@tajhotel.com

MEETING CONTACT AND EXHIBITS INFORMATION

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Vinisha Bhavsar, DIA (India) Private Limited; Phone: +91-22-6765-3226; Fax: +91-22-2859-4762; Email: dia.diaindia@gmail.com

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Quality of Active Pharmaceutical Ingredients

Meeting I.D. # 09958 – September 5-7, 2009 – Hotel Taj Krishna, Hyderabad, INDIA

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Student*	INR 2,000 ❑	INR 2,000	INR 800	INR 2,800 ❑	INR 2,800 ❑
Tutorial Fees – Saturday, September 5					
9:00 AM-1:00 PM TUTORIAL WORKSHOP I	INR 3,000 ❑	9:00 AM-1:00 PM TUTORIAL WORKSHOP I		INR 3,000 ❑	9:00 AM-1:00 PM TUTORIAL WORKSHOP I INR 3,000 ❑
1:00-5:00 PM TUTORIAL WORKSHOP II	INR 3,000 ❑	1:00-5:00 PM TUTORIAL WORKSHOP II		INR 3,000 ❑	1:00-5:00 PM TUTORIAL WORKSHOP II INR 3,000 ❑
9:00 AM-1:00 PM TUTORIAL WORKSHOP III	INR 3,000 ❑	9:00 AM-1:00 PM TUTORIAL WORKSHOP III		INR 3,000 ❑	9:00 AM-1:00 PM TUTORIAL WORKSHOP III INR 3,000 ❑
TOTAL AMOUNT DUE	_____	**TOTAL AMOUNT DUE**		_____	**TOTAL AMOUNT DUE** _____

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