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 APIs and compliance with GMP standards from Global Regulatory Authorities’ perspective. The conference will also focus on the current issues of Pharmacopoeial Monographs, as well as EDQM API Certification and WHO Prequalification requirements.

FEATURED TOPICS

• Regulatory requirements with relevance for quality of APIs
  ▪ 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 WHO Prequalification Programme
• 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 | WEDNESDAY, SEPTEMBER 14**

**08.00-09.00 AM**
REGISTRATION

**09.00-09.30 AM**
INTRODUCTION

**09.30-10.15 AM**
KEYNOTE PRESENTATION

**10.15-10.40 AM**
TEA/COFFEE BREAK

**10.40-13.10 AM**
SESSION 1

*Regulatory Requirements with Relevance for Quality of APIs*

**Mike Morris**
IMB, CHMP/CVP Quality Working Party

10.00-11.20
EU Requirements for the Quality of APIs – Latest Developments

**Mike Morris**
IMB, CHMP/CVP Quality Working Party

11.20-12.00
Requirements for the Quality of APIs from an FDA Perspective

**DIA**

12.00-12.40
Requirements for the Quality of APIs from an Indian Perspective

**DIA**

12.40-13.00
ROUNDTABLE DISCUSSION

**13.00-14.15 AM**
LUNCH

**14.15-17.30 AM**
SESSION 2

*Compliance of API Manufacturers with GMP Standards*

14.15-14.55
WHO Prequalification Programme and Inspections of API Manufacturers

**Deusdedit Mubangizi**
WHO

14.55-15.30
EU GMP Requirements and Inspections of API Manufacturers Organized by EDQM

**Thomas Hecker**
EDQM

15.30-16.05
FDA-EMA-TGA Joint GMP Inspection Programme

**Olivier Gross**
EMA

16.05-16.30
TEA/COFFEE BREAK

16.30-17.10
FDA Inspections Organized in India

**DIA**

**17.10**
END OF DAY 1

**DAY 2 | THURSDAY, SEPTEMBER 15**

**09.00-13.00 AM**
SESSION 3

*Current Issues and Challenges in The Development of Pharmacopoeial Monographs*

09.00-09.45
European Pharmacopoeia

**Pascale Poukens-Renwart**
EDQM

09.45-10.30
International Pharmacopoeia

**Herbert Schmidt**
WHO

10.30-11.00
TEA/COFFEE BREAK

11.00-11.45
Indian Pharmacopoeia: An Update

**Dr K. N. Singh**

11.45-12.30
API Stability Testing and Impurities Testing

**Sultan Ghani**
Former Director Health Canada

12.30-13.15
Toxicological Qualification of Impurities

**Claus Olejniczak (tbc)**

Round Table Discussion

**13.15-14.30 AM**
LUNCH

**14.30-17.30 AM**
SESSION 4

*API Certification and WHO Prequalification*

14.30-15.10
EDQM Certification Scheme

**Pascale Poukens-Renwart**
EDQM

15.10-15.50
WHO Prequalification of APIs

**Antony Fake**
WHO

15.50-16.15
TEA/COFFEE BREAK

16.15-16.55
PANEL DISCUSSION

Challenges and Opportunities of WHO Prequalification and EDQM Certification of Suitability on API Industry

16.55-17.30
ROUNDTABLE DISCUSSION

17.30
WORKSHOP ADJOURNED
### EDQM Tutorial

<table>
<thead>
<tr>
<th>Time</th>
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<td>09.00-9.30</td>
<td>The EDQM Certification of Suitability to the European Pharmacopoeia Monograph Procedure — Place and Role in the European Regulatory System</td>
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<td>09.30-10.30</td>
<td>Overview of the Procedure</td>
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<td>10.30-10.50</td>
<td>Coffee Break</td>
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<td>10.50-11.20</td>
<td>Revisions of CEPS</td>
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<td>11.20-12.15</td>
<td>Case Studies</td>
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<td>12.15-13.00</td>
<td>EDQM Inspection Programme — How to Prepare for an Inspection</td>
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### WHO Prequalification Programme Tutorial

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<td>9.00-9.30</td>
<td>WHO Prequalification of Medicines Programme</td>
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<td>9.30-10.20</td>
<td>Inspections of Manufacturers</td>
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<tr>
<td>10.40-11.30</td>
<td>Requirements on Documentation of Active Ingredient and Finished Product Quality, Evaluation Process</td>
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<td>11.30-11.50</td>
<td>Demonstration of Bioequivalence</td>
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<td>11.50-13.00</td>
<td>Prequalification of Active Pharmaceutical Ingredients</td>
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13.00 Post-Conference Workshops Adjourned
TRAVEL AND HOTEL
Attendees should make airline reservations as early as possible to ensure availability.
The closest airport to this hotel is Hyderabad Airport.
Single / Double INR 6500 + Taxes
Hotel The Park is located at 22, Raj Bhavan Road, Hyderabad, 500082 INDIA.
Phone: +91-9335558857, Fax: +91-402333010
Contact Person: R. Vivek Anand, Email: vivek.anand@theparkhotels.com

MEETING CONTACTS
MEETING MANAGER: Manoj Trivedi, Senior Manager Marketing and Program Development, DIA (India) Private Limited; Cell: +91-981977493, Fax: +91-22-2859-4762, Email: Manoj.Trivedi@diaindia.org
EXHIBITS: Manoj Trivedi or Syed Vaqar, Assistant Manager Marketing and Program Development; Email: vaqar.syed@diaindia.org, +91-22-28594762
REGISTRATION: Pallavi Gokhale, Assistant Manager – Program Development & Operations, DIA (India) Private Limited; Cell: +91-9004682564, Fax: +91-22-2859-4762; Email: Pallavi.Gokhale@diaindia.org or Shailendra Singh. Marketing and Promotion Executive; Email: shailendra.singh@diaindia.org, +91-22-922367327

PLEASE CONSIDER THIS FORM AN INVOICE
Quality of Active Pharmaceutical Ingredients
Meeting I.D. # 11658 – September 14-16, 2011 – Hotel The Park, Hyderabad, INDIA

REGISTRATION FEES
Registration fee includes refreshment breaks, luncheons, and will be accepted by mail or fax.

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TUTORIAL FEES*

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*Post-Conference Workshops will be included in the conference attendance fees.

EXHIBITS: Manoj Trivedi or Syed Vaqar, Assistant Manager Marketing and Program Development; Email: vaqar.syed@diaindia.org, +91-22-28594762

Mail or fax this form to +91-22-28594762.

PAYMENT INFORMATION

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Completed form, along with draft/cheque made payable to DIA (India) Private Limited should be sent to:
DIA (India) Private Limited, A-303, Wellington Business Park I Andheri-Kurla Road, Marol, Andheri (East), Mumbai 400 059 India
Phone: +91-22-6765-3226 Fax: +91-22-28594762

Important Notes:

Please send completed registration form, copy of student identification, and payment.

Important Notes:
A student is an undergraduate/graduate who can document enrollment in a Signature accredited, degree granting, academic program. Student registration is by fax or mail only.
A limited number of student registrations are available.

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First Name [ ] M.I.

Job Title

Affiliation (Company)

Address (Please write your address in the format required for delivery to your country): [ ] Business Address [ ] Home Address

Postal Code [ ] City [ ] Country

Telephone Number [ ] Fax Number [ ] Mobile Number

email (Required for confirmation)

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