



Industry and Regulatory Perspectives on CMC Compliance

April 12, 2009 Tutorial
April 13-14, 2009 Conference

Cidade de Goa, Vainguinim Beach, Goa, INDIA

PROGRAM CHAIRPERSON

Dr. Nandkumar Chodankar
Chief Mentor and Executive Director
Shasun Chemicals and Drugs (India)
Chair, DIA Advisory Council of India (ACI)

PROGRAM COORDINATOR

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General Manager, Government Affairs and
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GlaxoSmithKline

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Former Deputy Director
Food and Drug Administration, Goa

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President Formulations
Watson Pharmaceuticals

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Find Solutions to the Challenges Facing CMC and Supply Chain Management Professionals.

The rapid development and constantly changing Chemistry, Manufacturing and Controls (CMC) environment of biopharmaceutical products and their manufacturing process technologies, coupled with ongoing changes in compliance regulations, has made it imperative for companies to have an effective strategy to achieve CMC compliance.

FEATURED TOPICS

- ▶ Challenges to CMC and Manufacturing
- ▶ Challenges in Meeting Compliance Requirements
- ▶ Supply Chain Management Opportunities and Challenges
- ▶ Panel Discussion and Case Studies

LEARNING OBJECTIVES

At the conclusion of this meeting, participants should be able to:

- Enhance the challenges of CMC and Manufacturing.
- Understand the global regulatory compliance requirements.
- Improve the understanding and issues surrounding to supply chain.

WHO SHOULD ATTEND

This program will benefit:

- Regulatory and CMC Professionals
- Analytical Development Chemists
- Formulation Development
- Technical Services Professionals
- CMC Project Professionals
- Supply Chain Management Companies

VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!

DIA, Unit No.6, Gayatri Commercial Complex, Behind Mittal Industrial Estate, Andheri Kurla Road, Andheri (E), Mumbai 400 059.

SUNDAY • APRIL 12

08.00-09.00 REGISTRATION

09.00-13.00 TUTORIAL

MOVING FROM CTD TO eCTD

- Overview of CTD to eCTD
- Global Perspectives and Overview of CTD to eCTD [JP/ EU/ US/ CA/ AU]
- Agency readiness and preparing for eCTD

TUTORIAL INSTRUCTORS:

Mr. Michael Schultz
LORENZ Archiv-Systeme GmbH
Germany

Mr. Sultan Ghani
Director, DIA India
Former Director, Health Canada

MONDAY • APRIL 13

08.00-9.30 REGISTRATION AND CONTINENTAL BREAKFAST

9.30-10.30 DIA WELCOME AND OPENING CEREMONY

9.30-9.35 LIGHTING OF THE LAMP

9.35-9.45 WELCOME ADDRESS AND INTRODUCTION

Dr. Nandkumar Chodankar
Chief Mentor and Executive Director
Shasun Chemicals and Drugs (India)
Chair, DIA Advisory Council of India (ACI)

9.45-10.15 KEYNOTE SPEAKER:

CHALLENGES OF PHARMACEUTICAL INDUSTRY IN INDIA
DR. PRAKASH A. MODY
Chairman and Managing Director
Unichem Laboratories

10.15-10.30 CHIEF GUEST SPEAKER:

Shri Vishwajit Rane
Honorable Health Minister
Government of Goa

10.30-10.35 VOTE OF THANKS

Mr. S S Sardessai
Former Deputy Director
Food & Drug Administration, Goa

10.35-11.00 TEA/COFFEE BREAK

11.00-11.30

INVITED ADDRESS: GLOBAL REGULATORY CHALLENGES OF TODAY AND TOMORROW
Dr. Emmanuelle Voisin
Chief Executive Officer
Voisin Consulting



11.30-13.00 SESSION 1:

CMC CHALLENGES TO CMC AND MANUFACTURING

SESSION MODERATOR:

Chi-wan Chen, PhD
Executive Director
Global Regulatory CMC
Pfizer, Inc

11.30-12.00 REMARKS FROM THE MODERATOR

12.00-12.45

MOVING INDUSTRY TOWARDS QUALITY BY DESIGN (QbD)
Rakhi B. Shah, PhD
Pharmacologist/Staff Fellow
Division of Product Quality Research
Office of Testing and Research
Food and Drug Administration (FDA)

12.45-13.00 QUESTIONS AND ANSWERS

13.00-14.00 NETWORKING LUNCHEON

14.00-17.00 SESSION 2:

CHALLENGES TO CMC AND MANUFACTURING

SESSION MODERATOR:

Mr. Sultan Ghani
Director, DIA India
Former Director, Bureau of Pharmaceutical Sciences (BPS)
Health Canada

14.00-14.45

PRODUCT DEVELOPMENT REQUIREMENTS FOR WHO PREQUALIFICATION
Mr. Sultan Ghani
Director, DIA India
Former Director, Bureau of Pharmaceutical Sciences (BPS)
Health Canada

14.45-15.30

DOCUMENTATION: WHAT – WHY – HOW
Dr. Nandkumar Chodankar
Chief Mentor and Executive Director
Shasun Chemicals and Drugs (India)
Chair, DIA Advisory Council of India (ACI)

15.30-16.00 TEA/COFFEE BREAK

16.00-16.45

CHANGING IMPURITY PROFILE

Vijay Vitthal

Vice President, Research and Development
Megafine Chemicals

16.45-17.00 QUESTIONS AND ANSWERS

TUESDAY • APRIL 14

9.30-12.30 SESSION 3:

SUPPLY CHAIN MANAGEMENT

SESSION MODERATOR:

Dr. Vinay Nayak

President Formulations
Watson Pharmaceuticals India

9.30-10.15 REMARKS FROM MODERATOR

10.15-11.00

SUPPLY CHAIN MANAGEMENT – OUTSOURCING OPPORTUNITY AND CHALLENGES

Chi-wan Chen, PhD

Executive Director, Global Regulatory CMC
Pfizer, Inc

11.00-11.30 TEA/COFFEE BREAK

11.30-12.15

SUPPLY CHAIN CHALLENGES

Rajesh Sharma

Manager, Life Sciences and Pharmaceuticals
TNT

12.15-12.30 QUESTIONS AND ANSWERS

12.30-13.30 NETWORKING LUNCH

13.30-17.00: SESSION 4:

CHALLENGES IN MEETING COMPLIANCE REQUIREMENT

SESSION MODERATOR

Dr. Nandkumar Chodankar

Chief Mentor and Executive Director
Shasun Chemicals and Drugs (India)
Chair, DIA Advisory Council of India (ACI)

13.30-14.15

FDA Speaker Invited

14.15-15.00

QUALITY AUDITING; SHARPENING ONSITE AUDITING SKILLS

V Siva Kumar

GMP Specialist and Quality Auditor- USP

15.00-15.30

TEA BREAK

15.30-16.15

REGULATORY COMPLIANCE AND CMC CHALLENGES OF HERBALS

Archana Shekher

Project Director and General Manager
Voisin Consulting

16.15-17.00

QUESTIONS & ANSWERS AND CLOSING REMARKS

17:00

CONFERENCE AJOURNED



Member Early-bird Rate —
Register by April 15 & Save INR 1,000



DIA 2nd Indian Annual Regulatory Conference
Access to Medicines:
Regulatory and Public Health Interface

Tutorials: May 3, 2009 | Conference: May 4-5, 2009
Hyatt Regency Hotel, Mumbai, INDIA

CONFERENCE AND TABLETOP EXHIBITS INFORMATION:

Leena Amanna, Phone +91-22-6765-3227
email: Leena.Amanna@diaindia.org

VISIT WWW.DIAHOME.ORG FOR A COMPLETE SCHEDULE OF EVENTS!

DIA

Unit No.6, Gayatri Commercial Complex
Behind Mittal Industrial Estate

Andheri Kurla Road, Andheri (E), Mumbai 400 059.

Worldwide Regulatory and Public Health Agencies Come Together to Discuss Ways of Making Medicines More Accessible.

This conference will convene international regulatory, industry, academia, and researchers to discuss the issues related to the access of medicines and their impact on public health.

TRAVEL AND HOTEL

The most convenient airport is Dabolim (GOI-Dabolim) - Approximate driving time is 40 minutes and distance is 28 kms (17 miles) from the resort. Attendees should make airline reservations as early as possible to ensure availability.

Nearest Railway Station: Karmali Railway Station (Old Goa) - Approximate driving time is 25 minutes & distance is 14 kms (9 miles) from the resort.

The Cidade de Goa Hotel is holding a block of rooms at the reduced rate until April 7, 2009, for the meeting attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

Please contact The Cidade de Goa Hotel by telephone at +Tel: +91-832-2454545, Fax: +91-832-2454541/42 and mention the DIA India meeting. The hotel is located at Vainguinim Beach, Goa 403004, India.

MEETING CONTACT AND EXHIBITS INFORMATION

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Vinisha Bhavsar, DIA (India) Private Limited; Phone: +91-22-6765-3226; Fax: +91-22-2859-4543; Email: dia.diaindia@gmail.com

▶ **DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.**

CANCELLATION POLICY: On or before APRIL 6, 2009

Cancellations must be in writing and be received by April 6, 2009. 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):

Standard = INR 3,000 • Academia/Government = INR 2,000 • Tutorial = INR 1,000 • Student = INR 500

PLEASE CONSIDER THIS FORM AN INVOICE**Industry and Regulatory Perspectives on CMC Compliance**

Meeting I.D. # 09955 – April 12-14, 2009, Cidade de Goa, Vainguinim Beach, Goa, INDIA

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

Registration Fees	Register online at www.diahome.org or check payment and submission method below.	
Be a DIA Member	INR 1,600	<input type="checkbox"/>
▶ Standard Member Rate	INR 7,000	<input type="checkbox"/>
Total	INR 8,600	<input type="checkbox"/>
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▶ Academia/Government	INR 5,000	<input type="checkbox"/>
▶ Student*	INR 2,500	<input type="checkbox"/>
*A limited number of student registrations are available. A student is an undergraduate/graduate who can document enrollment in an accredited, degree granting, academic program. Student registration is by fax or mail ONLY. Please send completed registration form, copy of student identification, and payment.		
▶ Tutorial Fees-April 12, 2009	INR 5,000	<input type="checkbox"/>
Exhibits: To receive information on Banner or Table Top display, please check the appropriate box: Please send me information on <input type="checkbox"/> Banner Display <input type="checkbox"/> Table Top Display		
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<input type="checkbox"/> DEMAND DRAFT/CHEQUE Completed form, along with draft/cheque made payable to DIA (India) Private Limited , should be sent to: Leena Amanna , Operations Manager, DIA (India) Private Limited, No. 6, Behind Mittal Industrial Estate, Gayatri Commercial Complex, Andheri Kurla Road, Andheri-east, Mumbai 400059 India, Phone: +91-22-6765-3227		

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Job Title _____ Affiliation (Company) _____

Address (Please write your address in the format required for delivery to your country.) _____

City _____ State _____ Zip _____ Country _____

Telephone Number _____ Fax Number _____

email (Required for confirmation)

IF FAXING OR MAILING THIS FORM, PLEASE PROVIDE A COPY OF REGISTRANT'S BUSINESS CARD.