

# DIA - ISPE Joint Conference on API – Advantage India

Building a Sustainable and Regulatory Compliant API Life Cycle

ID# 13653 | August 1-2, 2013  
Novotel Convention Center  
Hyderabad, India



## INTERNATIONAL SPEAKERS - US FDA

**Albinus D'sa**  
Deputy Country Director  
US FDA  
India

**Jason D. Rodriguez**  
Chemist  
US FDA

## PROGRAM CHAIRS

**Shashank Lulay**  
Consultant QA & RA

**Vijay Kshirsagar**  
Consultant  
TRAC Consulting  
Director, ISPE

## KEYNOTE SPEAKER

**Govind Rajan Narayanan**  
Managing Director  
Aurobindo Pharmaceuticals

**Kiran Kumar**  
President  
Inogen Laboratories Private Ltd  
(A GVK Bio Company)

## PROGRAM COMMITTEE

**R. Raghunandan**  
Pharma Consultant  
Vice Chair, ISPE India Affiliate

**Nandkumar Chodankar**  
Director  
ASolution Pharmaceutical Pvt. Ltd.

**Manikya Rao**  
Senior Director  
Dr. Reddy's Laboratories

**Rajiv Desai**  
President - Quality  
Dishman Pharmaceuticals and Chemicals Ltd.

**Kapil Bhargava**  
Former Deputy Drug Controller  
CDSCO

**Gopal Nair**  
Chairman  
ISPE India Affiliate

## India Office

A-303, Wellington Business Park I  
Andheri-Kurla Road, Marol, Andheri (East)  
Mumbai 400 059 India  
Www.diahome.org

## Worldwide Headquarters

800 Enterprise Road, Suite 200  
Horsham, PA 19044, USA

## PROGRAM CHAIRS



**Shashank Lulay**  
Consultant QA & RA



**Mr. Vijay Kshirsagar**  
Consultant  
TRAC Consulting  
Director, ISPE

## TOPICS

- Real-time release testing for the API
- Ideal contents of management review meetings for monitoring API performance
- Continuous process verification for legacy APIs
- Recent regulatory trends and risk management
- QbD for APIs: Challenges and Opportunities – a Road Map
- Surviving global regulatory inspections in today's environment
- Outsourcing of regulatory starting materials – changing regulatory expectations

## LEARNING OBJECTIVES

At the conclusion of this conference participants will be able to:

- Update themselves on current quality and regulatory issues
- Increase their competitiveness
- Equip themselves to file correctly and efficiently
- Understand the potential focus of regulators during their next inspection
- Understand and interpret the regulatory requirements in building the robust process technologies adhering to QbD, ICH Q11 etc.
- Instill the culture of built-in 'quality', reducing the rate of failures, re-calls, additional cost and time on investigations, documentation and CAPA

## WHO SHOULD ATTEND

Professionals involved in:

- Quality assurance
- Quality control
- Regulatory affairs
- Process development
- Technology transfer/commercialization sourcing
- Manufacturing

In collaboration with:



**All attendees will receive a Certificate of Attendance at the conclusion of the event**

## DAY 1 | THURSDAY, AUGUST 1, 2013

9.15-9:45 am Opening Ceremony

**Kaushik Desai**  
Director  
DIA India

**Gopal Nair**  
Chairman, ISPE

9.45-10.00 am INAUGURAL ADDRESS

**V. G. Somani**  
Joint Drugs Controller (I)  
CDSCO

10.00-10.30 am Keynote address I

**Govind Rajan Narayanan**  
Managing Director  
Aurobindo Pharmaceuticals

10.30-11.00 am Keynote address II

**Kiran Kumar**  
President  
Inogen Laboratories Private Ltd  
(A GVK Bio Company)

11.00-11.30 am TEA BREAK

11.30 am-12.30 pm Session 1

11.30 am-12.00 pm

**Changing Regulatory Expectations**  
Current expectations of global regulators for APIs

**Albinus D'sa**  
Deputy Country Director  
US FDA India Office

12.00-12.30 pm

**Indian Scenario**  
Current expectations of Indian regulators for APIs

**Kodanda Ram**  
Regulatory Expert  
Andhra Pradesh

12.30-1.30 pm NETWORKING LUNCH

1.30-3.00 pm SESSION 2

1.30-2.15 pm

**ICH Q7 - Interpretations Made Easy**  
Interpretations of different and important sections of Q7

**Nandkumar Chodankar**  
Director  
ASolution Pharmaceutical Pvt. Ltd.

2.15-3.00 pm

**ICH Q11-Challenges in Implementation**

**Rajiv Desai**  
President - Quality  
Dishman Pharmaceuticals and Chemicals Ltd.

3.00-3.30 pm Tea Break

3.30-5.00 pm SESSION 3

3.30-4.15 pm

**Cleaning Validation - Conventional Process**  
Discussions on the existing philosophy of Cleaning Validation

**Satya Balaji**  
Associate Director  
Dr. Reddy's Laboratories

4.15-5.00 pm

**Antony Raj Gomes**  
Senior Vice President - Quality  
Mylan Pharmaceuticals

5.00 pm DAY END

## JOIN A COMMUNITY!

*Joining a Community is easy, convenient,  
and free as part of your DIA membership.*

DIA Communities allow members to exchange information, explore industry hot topics, and build a professional network through a discipline-specific, global or regional Community. Network and share information and ideas through state-of-the-art online media and forums.

Go to [www.diahome.org/Community](http://www.diahome.org/Community)  
to join the Community of your choice

To become a DIA member, go to  
[www.diahome.org/membership](http://www.diahome.org/membership).



## Day 2 | FRIDAY, August 2, 2013

9.30-10.15 am SESSION 4

**Discussion on the New EU Guidelines on Setting Health-based Exposure Limits****Ganesh Prasad**  
Consultant

10.15-11.00 am SESSION 5

**API Monograph Development****Surendra Nath (Invited)**  
Senior Vice President  
USP

11.00-11.30 am TEA

11.30 am-12.00 pm SESSION 6

**Process Validation New Concepts**  
FDA Guidance 2011 on PV**Sunil Singhai**  
Vice President, Tech. Transfer  
Dr. Reddy's Laboratories

12.00-1.00 pm SESSION 7

12.00-12.30 pm

**Cold Chain Management for APIs**  
Good distribution practices for APIs needing cold chain**A. J. Reddy**  
Vice President - Supply Chain  
Mylan Pharmaceuticals

12.30-1.00 pm

**Ravi Mathur**  
Senior Director and Head Logistics  
Dr. Reddy's Laboratories

1.00-1.45 pm NETWORKING LUNCH

1.45-3.00 pm SESSION 8

**Rapid Screening Methods****Jason D. Rodriguez**  
Chemist  
US FDA

3.00-3.30 pm TEA BREAK

3.30-4.30 pm SESSION 9

3.30-4.00 pm

**Quality Risk Assessment in API Manufacturing**  
ICH Q9 based discussion on APIs**Vijay Kshirsagar**  
Consultant  
TRAC Consulting  
Director, ISPE**Preparing for Regulatory Challenges**

4.00-4.30 pm

**Manikya Rao**  
Senior Director  
Dr. Reddy's Laboratories

4.30-5.00 pm Q &amp; A



## ISPE has something for you!

ISPE, the International Society for Pharmaceutical Engineering, is the world's largest not-for-profit association dedicated to preparing technical professionals to lead global change and innovation in pharmaceutical manufacturing sciences and technology.

### By becoming an ISPE Member, you:

- Join 20,000 Members and industry professionals serving all areas of the pharmaceutical manufacturing industry
- Enhance your skills
- Build your career
- Interact with top minds in 90 countries worldwide Whether you are new to the industry or a seasoned professional, ISPE is your Society of choice!

### KNOWLEDGE

ISPE provides you with the tools, resources and technical knowledge you need to do your job successfully.

### COMMUNITY

As an ISPE Member, you become part of a unique community through which you can connect and collaborate with industry leaders, regulators and academics from around the globe.

### PROFESSION

ISPE membership provides you with a valuable network to help you succeed and achieve your professional goals.

### So, why become a Member?

- ISPE includes a membership rich with diversity and offering a broad representation of all pharmaceutical professionals.
- We work to keep our membership informed of the latest technological and regulatory trends occurring in the pharmaceutical marketplace.
- We are committed to the advancement of the educational and technical efficiency of our Members through forums for the exchange of ideas and practical experience.

Join ISPE and start realizing the benefits of membership today!

**TRAVEL AND HOTEL**

Attendees should make airline reservations as early as possible to ensure availability.  
Nearest Airport: Rajiv Gandhi International Airport

**Contact Details:** Hyderabad International Convention Centre, Novotel and HICC Complex (Near Hitec City), P.O. Bag 1101, Cyberabad Post Office, Hyderabad, Andhra Pradesh, India

**Hotel Sales Manager:** Radhika Mitra, Director of Sales - Meetings and Events (Asia Pacific); Tel: +91.99664 03281; Fax: +91.406613.4322; email: rmitra@hicc.com

**MEETING CONTACTS**

**MEETING MANAGER:** Manoj Trivedi, Senior Manager Marketing and Program Development, DIA (India) Private Limited  
Cell: +91.98.1977.7493, Tel: +91.22.6765.3226

email: Manoj.Trivedi@diaindia.org

**Drug Information Association**

A-303, Wellington Business Park 1 | Andheri-Kurla Road, Marol Andheri East, Mumbai 400059

► **CANCELLATION POLICY: On or before JULY 25, 2013**

Cancellations must be in writing and received by July 25, 2013. Registrants who do not cancel in writing by that date and do not attend the event will be responsible for 75% of the registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations.

**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.**

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):**  
DIA will deduct administrative charges for the following categories:  
Member/Nonmember Registration = 3,000 INR and Student Registration = 2,000 INR

**PLEASE CONSIDER THIS FORM AS AN INVOICE**

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**Building a Sustainable and Regulatory Compliant API Life Cycle**  
**Meeting I.D. # 13653 | August 1-2, 2013 | Novotel Convention Center, Hyderabad**

**REGISTRATION FEES** *Registration fee includes refreshment breaks, and will be accepted by mail/courier.*

*Join DIA now to qualify to save on future events and to receive all the benefits of membership.  
To see all the benefits of DIA membership, visit [www.diahome.org](http://www.diahome.org) and click on Membership.*

	NONMEMBER			MEMBER		
	BASIC RATE (INR)	Service Tax 12.36%	TOTAL (INR)	BASIC RATE (INR)	Service Tax 12.36%	TOTAL (INR)
<b>Industry</b>	9000	1113	10113	8000	989	8989
<b>Academia</b>	6000	742	6742	6000	742	6742
<b>Student</b>	4000	495	4495	3500	433	3933

**Register 10 from your company and receive the 11th FREE! Contact our group discount representative for details or call +91.98.2058.7798**

**\*A limited number of student registrations are available.**

A student is an undergraduate/graduate who can document enrollment in a Signature accredited, degree granting, academic program. Please send completed registration form, copy of student identification, and payment.

**REGISTRATION TERMS AND CONDITIONS:** Registration form should be duly filled, signed by the authorized person.

You are requested to email the duly filled and signed Registration Form first and then courier/mail it along with registration fees on or before 5 working days before the event.

**Please check the applicable category:**

Academia  Government  Industry  Student

Non-Member  DIA/ISPE Member : Customer ID No.: \_\_\_\_\_

**Please Print All Information Clearly**

Degrees:  Dr.  Mr.  Ms.

Last Name (Family Name)

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 State Country

Telephone Number Fax Number Mobile Number

email (Required for confirmation) **Signatory**

Payment contact person's Full Name Telephone Number Email

Total Amount Due Organisation PAN no.

**PAYMENT INFORMATION**

Completed form along, with draft/ cheque made payable to DIA (India) Private Limited should be sent to:

**Bhavesh Vora**

**Sr. Executive Accounts**, DIA (India) Private Limited  
Cell: +91.982.097.2630, Tel: +91.22.6523.0676  
email: Bhavesh.Vora@diaindia.org