

# Conference on Technological Advances in Meeting Regulatory Challenges

ID# 13663 | April 25, 2013

Mumbai Exhibition Center | Goregaon (East), Mumbai



## PROGRAM CHAIR

### G. G. Gurudatta

CEO, Estima Pharma Solutions LLP  
Bangalore

## PROGRAM COMMITTEE

### Shirish Dabhade

Assistant Commissioner  
FDA, Maharashtra State

### Kaushik Desai

Director, DIA India

### A. M. Rao

President, Quality, Aurobindo Pharma  
Hyderabad

### Nandkumar Chodankar

Executive Director, Excel Industries

### Ashis Banerjee

Gansons

### Sandeep Shah

Erweka India

## KEYNOTE SPEAKER



### Albinus D'sa

Deputy Country Director  
US FDA, India

## GUEST OF HONOUR



### V. G. Somani

Deputy Drug Controller  
CDSCO, India

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CEO, Estima Pharma Solutions LLP  
Bangalore

## PROGRAM HIGHLIGHTS

- Understanding of the technological advancements in facility design
- Lean validation concepts — a new trend
- Ensuring automation in meeting global regulatory challenges
- In-depth view of qualification and validation of facilities, equipment, and utilities

## LEARNING OBJECTIVES

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

- Understand the type of technological advancements available in the current scenario
- Get insight into lean validation concepts in performing the qualifications
- Gather update on automation challenges
- Assess regulatory overview of qualification and validations
- Get an oversight of design considerations for new facilities

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

*To know more about  
the program please  
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24 25 26 April 2013

## India Office

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Horsham, PA 19044, USA

## PROGRAM SCHEDULE

9.00-9.30 AM REGISTRATION

9.30-9.45 AM WELCOME/INTRODUCTION

9.45-10.30 AM KEYNOTE/GUEST OF HONOUR

KEYNOTE

**Albinus D'sa**

Deputy Country Director  
US FDA India

GUEST OF HONOUR

**V. G. Somani**

Deputy Drug Controller CDSCO, India

10.30-11.00 AM SESSION 1

### Technological Challenges in Meeting Global Regulatory Guidelines

**Reddy B. Sreenivasa**

Vice President Operations, Shasun Pharmaceuticals Ltd.

11.00-11.30 AM TEA/COFFEE BREAK

11.30 AM-12.00 PM SESSION 2

### Regulatory Views on Qualification/Validation

**A. M. Rao**

President, Quality, Aurobindo Pharma  
Hyderabad

12.00-12.30 PM SESSION 3

### Lean Validation Concepts: ASTM E 2500

**S. C. Singhai**

Vice President, Tech Transfer  
Dr. Reddy's Labs

12.30-1.00 PM SESSION 4

### ICH Q8/Q9/Q10: Strategy for Successful Implementation

**B. G. Kini**

Technical Director  
Bristol Laboratories, UK

1.00-2.00 PM NETWORKING LUNCH/VISIT TO EXHIBITION

2.00-2.30 PM SESSION 5

### Approach to GAMP V Guidelines: Case Studies

**V. Mehta**

Director  
Epitome Technologies

2.30-3.00 PM SESSION 6

### Regulatory Outcomes: Equipment/Instruments

**G. G. Gurudatta**

CEO  
Estima Pharma Solutions LLP  
Bangalore

3.00-3.30 PM TEA/COFFEE BREAK

3.30-4.00 PM SESSION 7

### Design Considerations of New Pharma Facilities

**Ravi Saxena**

Managing Director  
cGMP Pharma 'n' Plans Private Limited

4.00-4.30 PM SESSION 8

### Containment Technology: Design Challenges

**Seshachalam**

Vice President, Quality  
Shilpa Medicare

4.30-5.15 PM PANEL DISCUSSION

### Technological Advances in Meeting Regulatory Challenges

**All Speakers**

**TRAVEL AND HOTEL**

Attendees should make airline reservations as early as possible to ensure availability.  
Nearest Airport: Mumbai.

**Contact Details:** Goregaon (East), Mumbai - 400063, Maharashtra, India.  
Phone: +91-22-66450123  
Website: [http://www.pharmapropack.com/OnlineRegistration\\_Pharma.aspx](http://www.pharmapropack.com/OnlineRegistration_Pharma.aspx)

**MEETING CONTACTS**

**MEETING MANAGER: Manoj Trivedi**, Senior Manager  
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**Drug Information Association**  
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**Conference on Technological Advances in Meeting Regulatory Challenges**  
**Meeting I.D. # 13663 | April 25, 2013 | Mumbai Exhibition Center | Goregaon (East), Mumbai**

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