

# US FDA-DIA-Pharmexcil Generic Drug Applications Workshop Series

April 30, May 2, May 4, May 7, 2012  
ID #12667-70



The primary focus of this workshop is to brief the small, medium and large scale pharmaceutical firms in India filing Abbreviated New Drug Applications (ANDAs) with the FDA. The workshop will address the on-going initiative of Quality by Design (QbD) that can be implemented in the pharmaceutical development of generic drug products. Having this understanding will help both generic applicants and the Agency in bringing quality generic products expeditiously to the market.

In identifying this need for common understanding within Indian pharmaceutical firms, U.S. FDA, DIA and Pharmexcil jointly present the Generic Drug Applications Workshop Series. This workshop will be conducted at four locations across India:

**April 30 | SciTech Centre, Mumbai**

**May 2 | Vivanta by Taj, Hyderabad**

**May 4 | Vivanta by Taj, Goa**

**May 7 | Lemon Tree, Chandigarh**

You are invited to participate in any one of these workshops and gain experience through a one-on-one interaction with two senior FDA staff members from the Office of Generic Drugs (OGD). They will share valuable information with participants on FDA's expectations for QbD, and how QbD will impact pharmaceutical development, ANDA submissions and future interaction with the U.S. FDA.

There will be an overview at the start of the workshop followed by three detailed sessions, during which participants will learn the meaning and expectations of terms used, such as "product design" and understanding and process design and understanding. In the afternoon session of the workshop, control strategies will be discussed.

At each one-day workshop, FDA staff from OGD will be available for a Q&A session in order to update applicants on recent issues, as requested.

These workshops are important to the FDA, DIA and Pharmexcil as they further our mission of disseminating important FDA regulatory information regarding drug application criteria to the industry.

#### India Office

DIA (India) Private Limited  
A-303, Wellington Business Park I  
Andheri-Kurla Road, Marol, Andheri (East)  
Mumbai - 400 059, India.

## PROGRAM

### KEY PRESENTERS

#### Dr. Lane Christensen

Science Staff, Office of Generic Drugs (OGD)  
FDA

#### Dr. Vilayat A. Sayeed

Division Director, Office of Generic Drugs (OGD)  
FDA

9:00 AM REGISTRATION

9:30 AM WELCOME ADDRESS

9:45 AM SESSION 1

**Quality by Design: Overview and Quality Target Product Profile**

11:15 AM TEA BREAK

11:30 AM SESSION 2

**Product Design and Understanding**

1:00 PM NETWORKING LUNCH

2:00 PM SESSION 3

**Process Design and Process Understanding**

3:30 PM TEA BREAK

3:45 PM SESSION 4

**Control Strategy, Risk Assessment, and Design of Experiments**

5:15 PM CONCLUDING REMARKS



**TRAVEL AND HOTEL**

Attendees should make airline reservations as early as possible to ensure availability. The following locations are holding a block of rooms at the reduced rate below until specified for the DIA event attendees. Room availability at this rate is guaranteed only until this date or until the block is filled.

**SCITECH CENTRE (AUDITORIUM ONLY)**

**Location:** Next to Unichem/Pfizer Office & Jogeshwari MTNL Office, Jogeshwari West, Mumbai - 400102; Phone: +91.22.3046.2832/33

**VIVANTA BY TAJ - BEGUMPET**

**Rate:** 6,000/- + taxes (inclusive of breakfast)  
**Location:** 1-10-147 & 148, Begumpet, Hyderabad, India- 500016  
**Contact Person:** Ms. Rajshree Thakur; Phone: +91.40.6725.2626

**VIVANTA BY TAJ - PANAJI**

**Rate:** 5,000/- + taxes (inclusive of breakfast)  
**Location:** Off D. B. Bhandokar Road Panaji, Goa - 403001  
**Contact Person:** Shaheen Tavares; Phone: +91.832.663.3636

**LEMON TREE HOTEL - CHANDIGARH**

**Rate:** 2,699/- + taxes (inclusive of breakfast + airport transfer)  
**Location:** Plot no. (3MW), Industrial Area, Phase I, Chandigarh - 160002  
**Contact Person:** Vinay Vashisht; Phone: +91.172.4423.2323

**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

**DELEGATE REGISTRATION: Rhean D'Souza**, Assistant Manager Marketing and Program Development, DIA (India) Private Limited  
 Cell: +91.98.2058.7798, Tel: +91.22.2859.4762  
 email: Rhean.Dsouza@diaindia.org

**CANCELLATION POLICY: On or before APRIL 23, 2012**

Cancellations must be in writing and received by April 23, 2012. Registrants who do not cancel in writing by that date and do not attend the event 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, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.

*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.*

**FULL MEETING CANCELLATION** Upon cancellation, the administrative fee that will be withheld from refund amount is Member/Nonmember Registration = INR 3,000 (**All refunds will be issued in the currency of original payment**)

**PLEASE CONSIDER THIS FORM AS AN INVOICE**

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**REGISTRATION FEES:** Registration fee includes refreshment breaks, luncheons, and conference material.

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.

	BASIC RATE	TAXES	TOTAL
Registration	5000	433	INR 5433

**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 within 5 working days.

**I will be attending the workshop at the following venue only ( ✓ )**

- April 30 | SciTech Centre, Mumbai                       May 4 | Vivanta by Taj, Goa
- May 2 | Vivanta by Taj, Hyderabad                       May 7 | Lemon Tree, Chandigarh

**Please check the applicable category:**

Academia    Government    Industry    CRO

**PLEASE PRINT ALL INFORMATION CLEARLY, IN CAPITAL LETTERS**

Degrees: \_\_\_\_\_  Dr.    Mr.    Ms.

Last Name (Family Name) \_\_\_\_\_

First Name \_\_\_\_\_

Job Title \_\_\_\_\_

Organisation \_\_\_\_\_

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:  
 Rhean D'Souza  
 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