

Division of  
Biochemical  
Sciences



# Seminar

## BioPune Series

NCL  
Innovations



CII - Biotechnology Resource Center,  
NCL Innovation Park, Pune

BioPune Seminar Series Talk # 2

on

## “Globalization of Drug Development Operations: Evolution & Opportunities”

by

**Dr. Chitra Lele,**  
PhD, Chief Scientific Officer,  
Sciformix Corporation

on

**Thursday, 30 August 2012**  
at 4pm-5pm in the  
Training Room,  
Venture Center  
NCL Innovation Park,  
Dr. Homi Bhabha Road,  
Pune – 411008

Tea shall be served at 3.45pm at the venue.  
This is a free event but registration is required:

<http://biopune.eventbrite.com>

**Dr. Chitra Lele**



PhD, Chief Scientific Officer,  
Sciformix Corporation

**Abstract:**

Taking a page out of the globalization and off-shoring of software development, global pharmaceutical companies started planning support of their drug development operations from offshore locations about 15 years back. India featured prominently in the plans.

This presentation will provide an overview of the type of activities and processes that have been supported from offshore locations, how they have evolved, the domain expertise and skills required to perform these and how the required capability has been built in India. We will also look at how this trend has led to creation of an entire segment of the off-shoring industry in India, which business models have emerged, how entrepreneurs have responded to the opportunity and how the current trends are likely to shape the future of this industry. We will also briefly review the relevance of this development to the pharmaceutical industry in India.

**About the speaker:**

Currently Chief Scientific Officer of Sciformix Corporation, a KPO that focuses on Safety and Risk Management, Biostatistics, Pharmacovigilance; Scientific writing & Regulatory Affairs; member of the founding team; Prior to Sciformix, was Executive Director, Development Operations India, Pfizer Global R&D; During 9+ years at Pfizer, was responsible for establishing the first offshore Clinical Data Management centre in India, and then growing it to a size of over 400, including captive and contract resources; Prior to Pfizer, worked as a biostatistician in Medical schools in the US, and as a faculty member in US & in India.

Other significant professional activities:

- (1) Instrumental in setting up Academy for Clinical Excellence (ACE) at the Bombay College of Pharmacy (BCP), a governing council member and a course developer and faculty member.
- (2) Founding member of the Indian Association for Statistics in Clinical Trials
- (3) Visiting faculty member at University of Pune and at IIT Bombay for several years, involved in teaching and research activities
- (4) Instrumental in creating awareness about applications of statistics in clinical trials in India and in developing M.Sc courses on this topic
- (5) As a pioneer in setting up offshore statistics and data management operations in India to support global clinical trials, was responsible for advising several global pharma cos and CROs who set up similar units in India and thus contributed significantly to the establishment and development of this profession in India
- (6) Associate member of the Society of Actuaries, USA