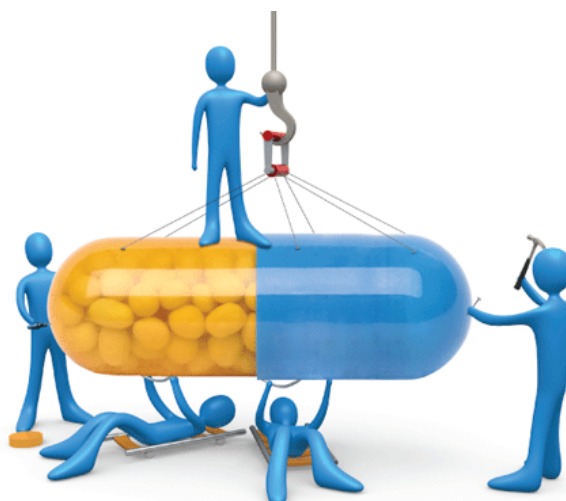




A NATIONAL CONFERENCE ON
Quality by Design: An Essential Requirement
in Pharmaceutical Industry

16th - 17th March, 2013

Organized by
Gujarat Technological University



Supported by
Parul Institute of Pharmacy,
Parul Institute of Pharmacy & Research
&
Leicester School of Pharmacy, DeMontfort University, UK

● **Venue** ●

Parul Campus

Auditorium, Central Administrative Building,

P. O. Limda, Ta. Waghodia, Dist. Vadodara

Ph. : 02668-260232, Telefax : 02668-260201

Email : parulpharmacyevents@gmail.com, Web : www.parul.ac.in/event.html

ABOUT GTU

GTU started its functioning in July 2008 with affiliation of 50 Degree Engineering colleges, 69 Degree Pharmacy colleges, 59 Diploma Engineering colleges and 17 Diploma Pharmacy colleges. Approximately around 52000 students were enrolled as the first batch of the university & today the university has more than 4 lacs students enrolled. GTU has bagged many awards like ICT Enabled University Award and Manthan Award for e-learning in the year 2009; GESIA Award and Digital Learning and Best Interface between Academia and Industry at the World Education Summit Award in the year 2011. To Promote Industry –Academia Relations and to enhance the quality of research work that is really useful to Industry, GTU has established 25 Innovation Sankuls under the guidelines of Honorable VC Dr. Akshai Aggarwal.

ABOUT THE HOST INSTITUTES

Parul Institute of Pharmacy & Parul Institute of Pharmacy & Research, Vadodara are leading institutions in Gujarat, contributing in the field of Pharmacy education & Research since 2004. The Institutes started PG courses in 2008 & are currently providing M. Pharm. in Pharmaceutics, Pharmaceutical Technology, Quality Assurance, Quality Assurance Techniques, Pharmacology & Pharmaceutical Chemistry. Aim of these Institutes is to train students with high degree of professional skills, special sensitivity to ethical and moral concerns, comprehensive knowledge in pharmacy and health care sectors. These Institutes have filed 4 Patent Applications in the field of drug discovery & formulation development in 2011 & 5 Patent Applications in 2012. The Institutes are run by Parul Trust, established as registered Trust in 1990 by Dr. Jayesh Patel, a man of great vision and acumen. The trust has gone much ahead in achieving its goals and strives to ensure the right to “education, health and employment” to the most underprivileged strata of society.

ABOUT THE LEICESTER SCHOOL OF PHARMACY

The Leicester School of Pharmacy has been teaching students in Pharmaceutical Sciences for over 100 years, producing some of the leading textbooks in the field and having strong history of research. In recent years they have been developing both teaching and research programmes encompassing the new approach “Pharmaceutical Quality by Design”. They have been working in collaboration with the range of International Pharma companies on these developments and are delighted to collaborate with Parul Institute in presenting this important workshop

Organizing Committee

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Dr. Akshai Aggarwal

Hon. Vice Chancellor

Gujarat Technological University
Ahmedabad

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Dean, Faculty of Pharmacy, GTU

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CAMRx Pharmacy Development

Group

Leicestershire, UK

Mr. R.R. Shah

Managing Director,

Mercury Laboratories Ltd.,

Baroda

Chief Coordinator

Dr. Sulekha Bhadra

Professor,

Parul Institute of Pharmacy

Confirmed Speakers

■ **Dr. Walkiria Schlindwein**

De Montfort University, UK

■ **Dr. Joanne Broadhead**

De Montfort University, UK

■ **Dr. Rajesh K.S**

Principal, Parul Institute of
Pharmacy, Vadodara

■ **Dr. Deepak Gondaliya**

Manager, FDD, Sun Pharma,
Vadodara

■ **Dr. Ravi Naidu**

Astra Zeneca, Bangalore

■ **Mr. Mark Anderson**

Principal, Stat-Ease, USA

■ **Mr. Amit Sonawane**

Systech India, Mumbai

■ **Dr. Sabyasachi Goswami**

Umetrics, Singapore

■ **Mr. Jayesh Parmar**

Manager, Formulation
Techniques, Colorcon

Workshop Overview

DAY 1

Registration	09:30-10:00 AM
Inaugural Function	10:00-10:30 AM
Plenary session	10:30-11:30 AM
'Origin of QbD & its introduction in Pharmaceutical industries'	
Tea Break	11:30-12:00 AM

Session 1: QbD approaches to Product Development and Manufacture	12:00- 01:00 PM
ICH guidelines Q8, Q9, Q10, Q11 FDA Process validation	
Lunch	01:00-02:00 PM
Session 2: QbD for Generic drugs	02:00-03:30 PM
Regulatory & Industrial challenges in implementing QbD Demystifying QbD from Regulator's perspective	
Session 3: Design and analysis in Product & Process development	03:30-04:30 PM
Exploration of Observational data Screening application for Tablet Excipients	

DAY 2

Breakfast	09:30-10:00 AM
Session 4: QbD in Processes	10:00- 11:00 AM
QbD & PAT – an Analysis of current situation PAT instrumentation for continuous manufacturing	
Tea Break	11:00-11:30 AM
Session 5: QbD in Practice	11:30- 12:30 PM
QbD for Sterile Products	
Lunch	12.30- 01.30 PM

Session 6: Case studies	01:30- 03:00 PM
QbD approach across multiple process steps Development and Manufacture of API	
Session 7: Statistical software	03:00- 04:00 PM
Advances in QbD/ DOE What to look for in a Statistical software	
Valedictory:	04:00-04:30 PM

● Poster competition

Papers on research projects highlighting use of Design of Experiments or Quality by Design are invited for Poster Presentation. The abstracts can be submitted online at parulpharmacyevents@gmail.com or a hard copy along with CD to the Scientific Committee. Last date of submission of Abstracts is 05th March 2013.

● Guidelines

- Poster should be of size 1m x 1m
- Presenting author should be present at the venue to present the poster

Scientific Committee

Dr. B.K. Shridhar
Dr. Prafulla Sabale

Registration Committee

Mrs. Archana Navale
Mr. Parag Patel

Stage Committee

Ms. Shweta Gupta
Mrs. Bijal Prajapati
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Name	:		
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Address	:		
Mobile	:		Email:
Participant Category:			
		<input type="checkbox"/> Industry	<input type="checkbox"/> Academic
		<input type="checkbox"/> Research Scholar / Student	
DD Amount	:		
DD No.	:		
Drawn Bank	:		
Date	:		
		Sign (applicant)	Sponsoring authority/Principal
		Date :	
		Place :	

● Poster Presentation ●

1st Prize Rs. 3000/-

2nd Prize Rs. 1500/-

Type of delegate	Fees (Rs.)
Industry	3000
Academic	750
Research Scholars / Students	500

Please forward the duly filled registration form along with D.D. in favour of "Parul Pharmacy events" Payable at Vadodara to mailing address:

To,
The Registration Committee,
Parul Institute of Pharmacy
P.O. Limda, Ta. Waghodia, Vadodara-391760.
Tel: 02668-260232, 09427847294
Email: parulpharmacyevents@gmail.com

Salient features

- FREE trial CD of Design Expert software will be given to registered users at the event.
- Mr. Mark Anderson, Principal at Stat-Ease, USA will demonstrate 'How to perform DOE for QbD using Design Expert software' through Webinar session.
- Best posters will be awarded with cash prize and a certificate
- Case Studies from Astra for QbD
- The selected papers will be published in special edition in a journal of repute.
- Conference proceedings will be published for referencing in research papers by the participants and other researchers