



**Uka Tarsadia University**  
Sponsored



**Six Days Workshop**  
on  
**Applications of QbD in Pharmaceutical Research**



**Date:** 14<sup>th</sup> Nov to 19<sup>th</sup> Nov 2016

**Organized by**  
**Maliba Pharmacy College, Bardoli, Gujarat**

**Participants:**  
M.Pharm

**Co-ordinators:**  
Ms. Hetal Patel  
Mr. Praful Dedhiya

**Time:**  
9:00 AM to 3:30 PM

**Venue:**  
IBM Lab; Class EG-117  
Maliba Pharmacy College

**Course objectives:****By attending this workshop, participants will be able to**

- understand the concept of Quality by Design (QbD)
- learn applications of various statistical designs for dosage form development and method development in pharmaceutical research
- understand fundamentals of various screening and RSM designs
- perform regression analysis by microsoft excel
- perform various screening and RSM designs manually and/or by using software (Design Expert)

**Teaching methodology:** The workshop will be conducted through lectures and hands on training on MS-office Excel and Design-Expert® (Trial version).

**Certification:** All the participants will be evaluated through assignments and written tests. Certificate will be awarded to those who qualified.

**Attendance:** Attendance is compulsory for all sessions.

**Course sessions:** Total twelve sessions will be conducted.

<b>Day 1: 17<sup>th</sup> Oct 2016 Monday</b>	Session 1: Introduction of QbD, Steps of QbD, Selection of factors and levels, Factorial Design, Manual calculation for effect of 2 factors on response by $2^2$ factorial design  Session 2: Practice of QTPP and CQA writing for various research projects selected from literature, Hands on training for $2^2$ Factorial design using various case studies
<b>Day 2: 18<sup>th</sup> Oct 2016 Tuesday</b>	Session 1: Analytical QbD (ATP, CQA and CPP), Hypothesis testing, Z test, One way ANOVA, Level of significance  Session 2: Problems of Z test and One way ANOVA
<b>Day 3: 19<sup>th</sup> Oct 2016 Wednesday</b>	Session 1: Theory of Regression analysis and Polynomial equations, Demonstration of Regression analysis in microsoft excel  Session 2: Practice of Regression analysis in microsoft excel using various case studies
<b>Day 4: 20<sup>th</sup> Oct 2016</b>	Session 1: Theory of Plackett Burman Design and

<b>Thursday</b>	<p>Fractional factorial design, Demonstration of Plackett Burman Design and Fractional factorial design in Design Expert software</p> <p>Session 2: Hands on training for Plackett Burman Design and Fractional factorial design in Design Expert software using various case studies</p>
<b>Day 5: 21<sup>st</sup> Oct 2016 Friday</b>	<p>Session 1: Theory of Box Behnken Design, Demonstration of Box Behnken Design in Design Expert software</p> <p>Session 2: Hands on training for Box Behnken Design in Design Expert software using various case studies</p>
<b>Day 6: 22<sup>nd</sup> Oct 2016 Saturday</b>	<p>Session 1: Theory of Central Composite Design, Demonstration of Central Composite Design in Design Expert software</p> <p>Session 2: Hands on training for Central Composite Design using Design Expert software using various case studies</p>