Workshop on Quality by Design

A detailed workshop on ‘Building Blocks of QbD’,
First time in India

Mumbai, India
5th – 8th July 2012

“If you can’t describe what you are doing as a process, you don’t know what you’re doing.”

W. Edwards Deming

The implementation of Quality by Design approach for New Drug Applications (NDAs) requires a good understanding of statistical, analytical and risk assessment methods. Also, from January 2013, the U.S. Food and Drug Administration (FDA) expects generic drug manufacturers to implement Quality by Design (QbD) into their Abbreviated New Drug Applications

**Course trainers**

Mr. Ranjit Barshikar
Ranjit Barshikar is a Quality-cGMP consultant with 42 years experience in Pharmaceutical Industry, especially in Quality Management, R&D and Regulatory. His expertise include PAT, QbD, Risk Management, GxP, Due Diligence, Quality Management, Prepare the Organization for US FDA / EU & other Regulatory Inspections, Monitor Quality of Outsourcing products etc. He was nominated as an IPA expert for new ICH Expert working Group on CTD QOS and has served as member of IPA, IDMA, ISPE, Gujarat council of Bio-Technology etc.

Dr. Khandavilli Gopala Krishna
Dr. Gopala has over 17 years professional experience in leading projects on Quality by Design, process improvements, yield and productivity improvements using Six Sigma and Lean tools. He has extensive application knowledge of Design of Experiments and is highly proficient in statistical analysis using Minitab. Dr. Krishna is currently leading the operational excellence initiative for the Indian operations of a leading multinational pharmaceutical company.

Mr. Vijay Dhonde
Vijay has more than 17 years of experience helping clients worldwide, in a diverse range of sectors, to successfully implement Strategy, Management and Operational Improvements projects. Deep expertise in the Design of Experiment, helping many companies to build & design robust processes that will achieve optimum process performance and imbibe quality in their products & processes.

**Key benefits & learning outcomes**
- Understand QbD approach for drug development
- Establish Quality Target Product Profile and identify Critical Quality Attributes
- Design robust processes and assess key & critical process parameters
- Construct a design space for drug development using design of experiments
- Assess risk and apply risk control methods
- Apply Process Analytical Techniques (PAT) for continuous improvement

**SSA’s training differentiates itself in the following ways**
- Combination of educational presentation and case studies, productive in-session assignments and participants collaboration to provide actionable learning
- SSA’s indigenous chalk & talk methodology of teaching
- Use of handy feature-rich software for graphical and statistical analysis
- Hard copies of presentation materials and tools
- Free trial version of advanced statistical software like Minitab® and @Risk

**Testimonials from previous events**

“Excellent, the training program was very interesting and we learnt new things related to Design of Experiment. DOE topics were explained in an excellent manner and need more training sessions like this”

- Lupin Pharma

“New concept of DOE very well understood. It explains scientific way of desiring. Explained various concepts. Overall program was excellent”

- USV Pharma

“Really enjoyed the interaction. Mr Vijay has great presence and good breadth of knowledge”

- ACG

Software Partners

Learning starts at
Introduction to Quality by Design

- QbD in the context of the ICH guidelines for pharmaceutical manufacturing industry in the 21st century
- QbD implementation ICH Guidelines
- Real-time release

ICH Guidelines

- Brief overview of ICH Q8, ICH Q9, ICH Q10 and ICH Q11
- Risk-based, modern pharmaceutical manufacturing

Basic Statistics

- Mean, Median, Mode
- Variation and Standard Deviation
- Descriptive statistics
- Normal distribution, central limit theorem
- Measurement System Analysis
- Hypothesis Testing
- ANOVA

QbD Methodology

- The evolution of process understanding
- Constructing the Quality Target Product Profile (QTPP)
- Identification of Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs)
- Process parameters ranking methods

Creating the Design space

- Design space concepts and relevance of design space
- Screening the Experimental Space
- Identification of Key and Critical Process Parameters
- Creating a factorial design
- Analyzing a factorial design
- Response surface methodology, process optimization
- Using DoE to define a design space
- Process validation in the QbD paradigm

Risk Assessment

- Risk estimates
- Process risk quantification using Monte Carlo simulation
- Risk assessment using FMEA
- Control Plan

Scaling up

- Scale-up theory; scaling-up by scaling-down
- Process understanding for effective technology transfer
- Advantages and challenges of continuous chemical processing

Process Analytical Technology (PAT)

- PAT principles
- Levels of PAT implementation
- Control strategies
- Real time release

Why you can’t miss this Workshop?

- First time in India, an in-depth and structured workshop on QbD
- Expert trainers with hands-on experience in real life application of QbD
- Hands-on Experience using statistical software like Minitab® and @Risk
- Open interaction with experts who are clued into rules and regulations of FDA
- Learning through Case Study

Who Should Attend

- Analytical chemists
- R&D chemists and chemical engineers
- Process chemists & engineers, and formulators
- Validation engineers
- Quality assurance/compliance/control scientists
- cGMP compliance scientists
- Regulatory affairs personnel

About Software Partners

Minitab® 16: Minitab 16 is the leading statistical software for analyzing data in quality and process improvement projects, and in statistics education. It contains the statistical methodical need to make firm decision. It produces vivid graphs that help you prepare for and interpret analysis and is simple to learn and use. Minitab is the complete package for quality improvement. You can easily access statistical tools you need at every step of your project including a comprehensive collection of general statistics such as descriptive statistics, t-tests, normality tests and much more

@Risk: @RISK is the world's most widely used risk analysis tool. Avoid risk by using Monte Carlo simulation to show possible outcomes in your Microsoft Excel spreadsheet. @RISK is used to analyze risk and uncertainty in a wide variety of industries. From the financial to the scientific, anyone who faces uncertainty in their quantitative analyses can benefit from @RISK. It is used to identify, measure, and root out the causes of variability in your production and service processes and designs.

In-house training solutions:

If you have a number of participants with similar training needs, then you may wish to consider having an In-House Training solution delivered locally on-site. Course can be tailored to specific requirements.

Please contact Sarfaraz Hussain on +91 98700 64786 or email sarfarazh@ssa-solutions.com to discuss further possibilities

Register Now
Tel: +91-22-25685494 | 25652448
Email: sarfarazh@ssa-solutions.com

SSA reserves the right to change the venue of, or speakers at the training course should circumstances require. © SSA Business Solutions
Registration Form
Please complete this form and send it to

SARFARAZ HUSSAIN
Email: sarfarazh@ssa-solutions.com

Name: __________________________________________________
Position: ________________________________________________
Email: __________________________________________________
Name: __________________________________________________
Position: ________________________________________________
Email: __________________________________________________
Name: __________________________________________________
Position: ________________________________________________
Email: __________________________________________________
Organization: ____________________________________________
Address: ________________________________________________
City/ Town: ______________________________________________
Pin code: ____________________ State: ______________________
Tel: ___________________________/ ________________________
Nature of Business: _______________________________________

Payment Details
Fee payable (incl. serv tax): Rs. _________________________ Cheque Demand Draft No.: ________________
Dated (DD/MM/YY): _____ / _____ / ______ drawn in the name of “SSA BUSINESS SOLUTIONS (P) LTD.”, payable at Mumbai
How did you come to know about SSA: ___________________________________________ (Google/ Friend/ Email/ Phone/ Seminar/ Ad/ Other)

Register Now
Tel: +91-22-25685494 | 25652448
Email: sarfarazh@ssa-solutions.com

Date: 5th – 8th July 2012
Venue: Mumbai, India

SSA Business Solutions
725/ 726, Corporate Centre, Nirmal Lifestyle,
LBS Marg, Mulund (W), Mumbai – 400 080
www.ssa-solutions.com

Hotel Accommodation
Accommodation is not included in the training fee. If you are unable to reserve an accommodation, please contact us and we can provide you a list of hotel properties generally located near the training venue.

Fees:
☒ Professional training fee @
  Book before 15th June, pay only Rs. 36,000 + 12.3% tax
  Book after 15th June, pay Rs. 40,000 + 12.3% tax
☒ Group Discounts
  Bring one or more delegate to this workshop and get a 5% savings off the regular price
Course fees includes course binders, lunch, refreshments & service charge

Discount (if any): ________________________ Payment terms: ________________________
Signature & stamp of nominating authority: __________________________ UID: ________________________