REGISTRATION FORM

To be filled and sent to below mentioned address

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Designation: _____

Organization: _____ Department: _____

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For online registration log on to
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REGISTRATION FEES PER COURSE :

• Industry Professionals	8000 INR + ST as applicable
• Academia	4000 INR + ST as applicable
• For Group Booking	• 3 & above : 10% Discount (same company) • 5 & above : 20% Discount (same company)

PAYMENT DETAILS :

☐ **By Cheque/DD No.**_____amount _____INR made payable to **Society for Pharmaceutical Dissolution Science** and send to : 601, Eco House, Vishweshwar Nagar, Goregaon (E), Mumbai - 400063 • Tel.: 91-22-42950191/92

☐ **Online Payment :** We accept Visa, Master Card, Diners club, American Express and Maestro cards. To pay by credit card, please visit www.spds.in and click on Delegate Registration icon. You will be redirected for payments to our payment portal, Event Avenue for secure payments. You will receive a payment confirmation from payment portal after making the payment.

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*Beneficiary Name: Society for Pharmaceutical Dissolution Science
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*Branch : IGIDR Branch, Goregaon (E), Mumbai.

Please mail the copy of delegates name and the course registered for along with the bank transfer details to the service desk

PROGRAMME CHAIR

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UPCOMING COURSE

• **COURSE VI**
IVIVC, BIOWAIVERS AND CLINICAL APPLICATIONS OF IVIVC
Course Director:
Dr. Umesh Banakar,
Professor and President,
Banakar Consulting Services, USA.

COURSE PARTNER

sotax
Solutions for Pharmaceutical Testing

VENUE

BOMBAY COLLEGE OF PHARMACY
Kalina, Santacruz (E), Mumbai - 400 098. India
Tel.: 91-22-2667 0871

Society for Pharmaceutical Dissolution Science
announces
A Professional Development Certification Course Series
entitled

PHARMACEUTICAL DRUG DEVELOPMENT PROCESS
Role of Dissolution Testing

Course V

QbD in Dissolution Method Development : QTTP, Critical Method Attributes, Discriminatory Method. DOE's, Method Finalization

04-05, July, 2016 (Monday-Tuesday)
Bombay College of Pharmacy, Kalina, Mumbai

Organized By

Society for Pharmaceutical Dissolution Science (SPDS)

Bombay College of Pharmacy (BCP)

INTRODUCTION

Conventional application of QbD by and large is to product development. Dissolution testing is very critical and this program is intended to show how QbD can be applied to have a robust discriminatory method which in turn will result into an efficacious product which is most likely to pass bio-equivalence testing.

QbD has the potential to allow more flexible regulatory approach based on understanding, and optimisation of design of a product and its manufacturing process In vitro dissolution testing is a key tool for this purpose and the present bioequivalence guidelines and biopharmaceutical classification system (BCS) provides a platform for regulatory applications of in vitro dissolution as a marker for consistency in clinical outcomes.

However, the application of these concepts might need to be further developed in the context of QbD to take advantage of the higher level of understanding that is implied and displayed in regulatory documentation utilising QbD concepts. Aspects that should be considered include identification of rate limiting steps in the absorption process that can be linked to pharmacokinetic variables and used for prediction of bioavailability variables, in vivo relevance of in vitro dissolution test conditions and performance/interpretation of specific bioavailability studies on critical formulation/process variables.

Current reliance on OGD or pharmacological method may not hold good for your product. Why aspect of it shall be discussed in this training program

SCHEDULE

DAY 1

Introduction
- Why QbD?
- Historical Background
- Advantages to the customer & company

Current Regulatory Scenario
- Regulatory Observations
- End Quality Vs Built in Quality
- Current regulatory expectations on QbD implementation

Understanding ICH Q8 & ICH Q11
- Contents
- Steps described
- Role of PAT

Development of Discriminatory Dissolution Method
- Limitations of Using OGD Method
- Limitations of using Pharmacopeial method
- Developing tailor made method
- Use of Innovator samples

Investigation of OOS & OOT trend result obtained in Dissolution testing
- Investigation tools & Techniques·
- Product problem, method problem or testing problem?·
- Applying CAPA involving QbD principles ?

DAY 2

QbD Process Step 1: Setting DTPP (Dissolution Target Product Profile)
- Prior Knowledge Management (Literature Survey)
- Understand DTPP
- Setting DTPP for your product

QbD Process Step 2 : Setting CPA's QA's (Critical Quality Attributes)
- Knowledge base forgeneric product
- Linking material attributes to CQA's
- Linking CPP's (critical process parameters) to Dissolution

QbD Process Step 3 : Initial Risk Assessment
- Risk Management principles as per ICH Q9
- FMEA : A good predictive risk management tool
- Risk related to product characterisation & development

QbD Process Step 4 : Design of Experiments
- Univariate & multivariate experiments by type of dissolution instrument, media,RPN, pH etc.
- Data feeding
- Output Data Analysis

QbD Process Step 5 : Design Space Determination
- Analysis of the output
- Arrive at the design space
- Changes in the design space

QbD Process Step 6: Dissolution Control Strategy & Life Cycle Management
- Definition
- Risk based approach
- Understand product & process
- Continuous Process & Method Verification
- Corrective & Preventive Actions (CAPA)

ABOUT THE COURSE DIRECTOR

Mr. Vijay Kshirsagar,
CEO & Director,
TRAC Consulting, Mumbai

Mr. Vijay Kshirsagar is an accomplished Quality, Regulatory & Analytical professional with 39+ years of rich experience of working for highly reputed Indian & Multinational Pharmaceutical firms. Till end April 2013, he worked for Unichem for about 7 years as Executive Vice President responsible for Corporate Quality, Regulatory, Analytical Research, Bioanalytical services & Pkg Development based in Mumbai. Prior to Unichem he worked for Ranbaxy, Sun Pharma , Lupin, IPCA, German Remedies & Tata Pharma in various capacities including senior positions like Director-Quality , GM-Quality etc handling both Pharma & API operations.. He has successfully represented his company in US and UK courts regarding IP related matters (Para IV filings).

In May 2013, he has formed his own Pharma Consultancy called TRAC offering specialized services globally, for cGMP Training, Regulatory Filings, Auditing & Compliance Services.. His clients include reputed pharma companies based in India, US, Europe, China, Turkey, Jordon, Bangladesh, Malaysia & Oman. He continues to be associated with Unichem, as Advisor on Quality & Regulatory matters. As a consultant he has helped 3 companies in India & outside to get their first time US FDA approval & also offering effective remediation services to some of the companies going through regulatory issues. Vijay has led from front for successful completion of several regulatory inspections by US FDA, MHRA, EDQM, ANVISA, WHO, TGA etc. both for Drug Products & API's. He has been instrumental in driving the filings of dossiers & DMF's for various regulated & semi-regulated markets. He has been a frequent trainer in India & abroad having spoken on wide range of topics including cGMP/GLP/PQS/ Validations/Regulatory Aspects/ QbD/Data Integrity/Quality Metrics/Investigations/Technical writing & Auditing.

He is currently working on the board of Directors of ISPE-India. He is also the President of 'Society for Pharmaceutical Dissolution Science'. IDMA has conferred upon him an 'Outstanding Analyst Award 2011' for his contribution towards pharmaceutical analysis. Guideline written by him on CAPA is published by IDMA. He has also published articles on cGMP related topics like OOS, QbD & cGMP in reputed journals/books. His chapter on 'OOS Investigations' is a reference material being a part of the book for Pharmacy students. In 2015, he has been specially awarded by Unites States Pharmacopeia, India for his contribution to USP's Stakeholders Forum. He is M.Sc. by Research in Organoanalytical Chemistry from Mumbai University. He has a good Microbiological background too having done his graduation with Microbiology as a principle subject.

WHO SHOULD ATTEND

- Junior Level Analysts / Chemists
- Scientists from R&D, QA & QC
- Students, PhD Scholars and Faculty from Pharmacy Colleges
- Regulatory