REGISTRATION FORM

To be filled and sent to below mentioned address

Dr. / Mr. / Ms. _____

Designation: _____

Organization: _____ Department: _____

Address: _____

_____

Email: _____

Phone: _____ Mobile: _____

For online registration log on to **www.spds.in**

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.

☐ **For Bank transfer:**
To pay by Bank transfer, please send payments to :

*Beneficiary Name : Society for Pharmaceutical Dissolution Science
*Bank Name : Bank of India
*Account Number : 010 220 110000628
*IFSC Code : BKID0000102
*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

• **Professor Padma V. Devarajan**
HEAD,
Department of Pharmaceutical Science & Technology,
Institute of Chemical Technology
Email: pvdevarajan@gmail.com

PROGRAMME CO-ORDINATOR

• **Mr. S. D. Joag**
Society for Pharmaceutical Dissolution Science
Email: sdjoag@hotmail.com
M : 97696 67999

SERVICE DESK

• **Ms. Bhakti Saraf**
Society for Pharmaceutical Dissolution Science
Email: bhakti.saraf@spds.in
M : 84549 44110

UPCOMING COURSES

• **COURSE IV** [February 2016]
Automation in Dissolution Testing & Dissolution studies for novel drug delivery systems
Course Directors :
Samir Haddouchi, Managing Director, SPS Pharma Services, France &
Michelle Magnier, Product Manager & Application Specialist, SOTAX AG

• **COURSE V**
QbD in Dissolution Method Development: QTTP, Critical Method Attributes, Discriminatory Method. DOE's, Method Finalization
Course Director:
Mr. Vijay Kshirsagar, CEO & Director, TRAC Consulting, Mumbai

• **COURSE VI**
IVIVC, BIOWAIVERS AND CLINICAL APPLICATIONS OF IVIVC

COURSE PARTNER

sotax
Solutions for Pharmaceutical Testing

ACG

VENUE

SCITECH CENTRE
7, Prabhat Nagar, Jogeshwari (W), Mumbai - 102, Maharashtra
Tel.: 022-2678 0127

Society for Pharmaceutical Dissolution Science

announces

A Professional Development Certification Course Series

entitled

PHARMACEUTICAL DRUG DEVELOPMENT PROCESS
Role of Dissolution Testing

Course III

DISSOLUTION AND BIOAVAILABILITY : Fundamentals and Applications of IVIVC

Date : 19-20 October, 2015
Venue : Scitech Centre, Jogeshwari, Mumbai

Organized By

Society for Pharmaceutical Dissolution Science (SPDS)

Institute of Chemical Technology (ICT)

INTRODUCTION

This Professional Development Course Series on the role of Dissolution Testing in pharmaceutical drug development provides a comprehensive mass of critical information to the R&D (formulation and analytical), QC/QA, Regulatory Affairs and PK professionals concerning the intricacies associated with effective dissolution testing, from basics to advanced applications including correlating dissolution and bioavailability as well as biowaivers and clinical applications of IVIVC.

This Professional Advancement Course Series comprises four (4) short focused intensive courses structured as building blocks - from basics all the way to biowaivers and clinical applications. Each course is profuse with numerous examples and case studies as well as the instructor's vast experience(s) which provide a practical perspective of dissolution testing at various stages in drug development process to the participants. It is anticipated that the judicious combination of theoretical details and practical considerations employed by the instructor(s) will provide a consolidated and holistic understanding of the role of dissolution testing in pharmaceutical drug development process.

COURSE - III

DISSOLUTION AND BIOAVAILABILITY : Fundamentals and Applications of IVIVC

Dissolution testing, of course, is a regular quality control procedure in good manufacturing practice. Whether or not its numbers have been correlated with biological effectiveness, the standard dissolution test is a simple and, perhaps, an inexpensive indicator of the physicochemical consistency of the product. Dissolution data are also useful in the early stages of drug development and formulation. In the early stages of development, the researchers take steps to optimize drug and dosage form characteristics that will influence subsequent data concerning biological availability. In this sense, the dissolution test can be employed prospectively – while developing a formulation with appropriate drug release characteristics, and retrospectively – to assess whether a dosage form is releasing the drug at prescribed/predetermined rate and extent. The common principal assumption underlying these two uses of this test is that the dissolution test is able to adequately represent, if not predict, the biological performance, i.e., bioavailability, of the drug.

As of date, in vitro dissolution tests seem to be the most reliable predictors of in vivo availability. Although official test have great practical value, the fact that there is still a need for test more directly related to bioavailability has been recognized. While the bioavailability of drug substances and drug products in humans can provide a confirmatory evidence of a potential relationship between dissolution and physiological availability, it is often impractical to perform extensive and expensive human testing.

This 2-day course is designed to present the means to assess and develop method of correlating in vitro and in vivo performance parameters. These parameters will permit effective means to predict physiological availability (bioavailability). While the theoretical details of in vitro-in vivo correlation (IVIVC) are presented during the didactic sections, hands-on handling of data is provided during the workshop session. In so doing, the participants will become conversant with the intricacies associated while correlating dissolution and bioavailability data thus providing means to understand concepts behind IVIVC as well as the mechanics involved therein.

SCHEDULE

DAY 1

• Registration	09:30 Hrs.
• Welcome address	10:00 Hrs.
• Fundamentals of Correlation	10:15 Hrs.
• **Tea / Snacks**	**11:00** Hrs.
• Dissolution And Bioavailability	11:30 Hrs.
• **Lunch**	**13.00** Hrs.
• Dissolution Testing & Data Analyses	14:00 Hrs.
• **Tea Break**	**15.00** Hrs.
• Demonstration of Dissolution Test Apparatus	15:30 Hrs.

DAY 2

• Bioavailability Assessment & Data Analyses	09:30 Hrs.
• **Tea / Snacks**	**10:30** Hrs.
• Basics of *In Vitro/in Vivo* Correlation (IVIVC)	11:00 Hrs.
• Dissolution and Bioavailability (IVIVC) : Part I	11:45 Hrs.
• Dissolution and Bioavailability (IVIVC) : Part II	12:00 Hrs.
• **Lunch**	**12.45** Hrs.
• Dissolution and Bioavailability (IVIVC) : Part III	14:00 Hrs.
• **Tea Break**	**15:00** Hrs.
• Applications of IVIVC In Drug Development	15:30 Hrs.
• Summary and Concluding Remarks Review of a "complete" Case Study Presentation	16:15 Hrs.
• Concluding Remarks	17:00 Hrs.
• Q & A	17.15 Hrs.

The course will be conducted by Dr. Umesh Banakar

ABOUT THE COURSE DIRECTOR

Umesh V. Banakar, Ph.D.
Professor and President,
Banakar Consulting Services,
Carmel, IN 46032 USA
(umeshbanakar@juno.com)

Dr. Umesh V. Banakar is on the International Scientific Advisory Board of several pharmaceutical corporations worldwide. Of date, he has successfully completed several Pharmaceutical Product Development Technology Transfer through education assignments sponsored by the UN/IESC and other pharmaceutical corporations worldwide. Additionally, he has served as **testifying/non-testifying expert in patent litigations** in the disciplines of pharmaceutical formulations/technology, clinical investigations and dissolution testing. Furthermore, he has planned and executed the development, both *in vitro* and clinical, of **several NDAs and ANDAs (both IR and MR products)**. He is the Founding **Chairperson of 2 International CROs**. Thus far, he has **successfully executed almost 400 clinical investigations (Phase I, II and III including BE)** for submission to regulatory agencies worldwide. Additionally, he is the founding Board Member and Principal Scientific Adviser of **Society for Pharmaceutical Dissolution Science [SPDS]**.

He has authored over 100 publications, over 100 published abstracts and presentations, numerous specialized workshop manuals, several chapters and monographs, over 45 expert book reviews and 5 guest editorials. The texts that he has authored include: **Pharmaceutical Dissolution Testing, Drug Development Process: Increasing efficiency and cost effectiveness**, among others. He is the co-author of an electronic text**: Basic Pharmacokinetics**. He is on the roster of experts with WHO, United Nations – TOKTEN program and International Executive Service Corps (IESC). He is listed in Who's Who in Biotechnology, Who's Who Among Asian Americans, and American Men and Women of Science.

WHO SHOULD ATTEND

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