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**
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  Department of Pharmaceutical Science & Technology,
  Institute of Chemical Technology
  Email: pvdevarajan@gmail.com

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UPCOMING COURSES

- **COURSE II [24-25 August, 2015]**
  BIOEFFICACY CENTERED DISSOLUTION METHOD DEVELOPMENT: Applications and Analyses
- **COURSE III [19-20 October, 2015]**
  DISSOLUTION AND BIOAVAILABILITY: Fundamentals and Applications of IVIVC
- **COURSE IV [21-22 December, 2015]**
  IVIVC, BIOWAIVERS AND CLINICAL APPLICATIONS OF IVIVC
- **COURSE V**
  QbD in Dissolution Method Development: QTTP, Critical Method Attributes, Discriminatory Method. DOE's, Method Finalization

COURSE PARTNER

sotax
Solutions for Pharmaceutical Testing

VENUE

INSTITUTE OF CHEMICAL TECHNOLOGY
N. P. Marg, Matunga, Mumbai - 400 019
Tel.: 022-33612254

Society for Pharmaceutical Dissolution Science

announces

A Professional Development Certification Course Series

entitled

PHARMACEUTICAL DRUG DEVELOPMENT PROCESS
Role of Dissolution Testing

Course I

PHARMACEUTICAL DISSOLUTION TESTING:
Fundamentals and Advanced Applications

Date : 22-23 June, 2015
Venue : ICT, Matunga,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 - 1

PHARMACEUTICAL DISSOLUTION TESTING: Fundamentals and Advanced Applications

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 product development 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 a result, the FIRST STEP, a comprehensive understanding of the in vitro dissolution test and its performance (data) is essential - fundamentals of the test, its characterization and its advanced applications in drug development. In particular, the objective(s) and the utility of this data change depending on the stage of drug development and so do the requirements associated with the objective(s). Often, in vitro dissolution performance of a product defines the quality of the product, thus, warranting the necessity of its appropriate characterization while exploring its full potential in drug development.

This 2-day course will present the fundamentals of the science behind the dissolution test, the details of the test and the characterization of the dissolution performance at various stages of drug development. Additionally, the importance of 'dissolution performance' in the context of regulatory considerations, intellectual property perspective and defining the quality aspects of the drug product will be discussed.

SCHEDULE

DAY 1

• Registration	09:30 Hrs.
• Welcome address	10:00 Hrs.
• Introduction, Objectives and Scope	10:15 Hrs.
• **Tea / Snacks**	**11:00 Hrs.**
• Science Behind Dissolution Test - Drug Development Perspective	11:30 Hrs.
• Intrinsic versus Apparent Dissolution Testing	12.30 Hrs.
• **Lunch**	**13.15 Hrs.**
• Compendial Methods and Non-compendial Modifications	14:15 Hrs.
• **Tea Break**	**15.15 Hrs.**
• Dissolution Performance - Characterization of Dissolution Performance	15.45 Hrs.

DAY 2

• Dissolution Test Equipment Demonstration - I	09:30 Hrs.
• **Tea and Snacks**	**10:30 Hrs.**
• Intro to Biorelevant Dissolution Method Development	11:00 Hrs.
• Regulatory Perspective: Part 1 - Relevance of f2 equation	12:00 Hrs.
• **Lunch**	**13.00 Hrs.**
• Dissolution Test Equipment Demonstration - II	14:00 Hrs.
• Regulatory Perspective: Part 2 – Biowaivers	15:00 Hrs.
• **Tea Break**	**15:45 Hrs.**
• Intellectual Property (IP) Considerations	16:15 Hrs.
• Summary and Concluding Remarks, Q & A	17:00 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