

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,
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Institute of Chemical Technology
Email: pvdevarajan@gmail.com

PROGRAMME CO-ORDINATOR

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UPCOMING COURSES

- 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 Director:
Dr. Umesh Banakar,
Professor and President,
Banakar Consulting Services,

COURSE PARTNER

sotax
Solutions for Pharmaceutical Testing



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 IV

Automation in Dissolution Testing & Dissolution Studies for Novel Drug Delivery Systems

Date : 21-22 March, 2016 (Monday-Tuesday)
Venue : Scitech Centre, Jogeshwari, Mumbai



Society for Pharmaceutical
Dissolution Science
(SPDS)

Organized By



Institute of
Chemical Technology
(ICT)



INTRODUCTION

Automation in Dissolution Testing

"Automation has been extensively used for decades in global Pharmaceutical Research laboratories. While drug screening and drug delivery are obviously associated with robotics, dissolution testing is still mainly using the manual technique as a reference in regulation documents. However the recently revised USP chapter 1092 starts now to reveal the importance of dissolution automation. Since the 70's, the SOTAX AG has considered the automation of dissolution testing as one of the main vectors to improve the daily efficiency for their customers from R&D and QC pharmaceutical laboratories. Such a statement can be correlated by hundreds of installations of fully automated dissolution systems which have proven the efficiency of this vision.

The purpose of this course on dissolution automation done by one of the Dissolution Experts from SOTAX AG, Switzerland is to help the attendees defining what level of automation they may require. Through a step by step evaluation of the attendees complete dissolution process (dosage forms, method, workload, and analytical requirements) the limiting steps will appear and the various solutions to eliminate them will then be discussed. Method transfer possible deviations will be discussed as the existing possibilities to minimize their impact. Multiple examples of semi-automation and fully automation will be presented during the training, including videos. As automation enhances efficiency and therefore impact the laboratory workload positively, the final part of this training will be used to show examples of ROI calculation on dissolution automation. We do hope that this training on dissolution automation will help its attendees moving forward on the way to a more consistent and efficient dissolution testing process."

The flow through cell (USP4): Principles and advantages

Although the flow through cell was invented already 40 years ago, its use is getting more and more frequent. This change is related to the limitations of the conventional paddle and basket methods and using USP4 can help addressing some of these drawbacks.

New types of formulations and drug delivery technologies call for a new approach to in-vitro drug release testing. Formulations such as ER,SR, combination products, injectable suspensions, nanoparticles, microspheres and other parenteral formulations as well as medical devices such as drug eluting stents, contact lenses etc can be challenging. The flow through technique is able to fulfill the requirements of such complex formulations. Its flexibility and ability to characterize the release properties of a wide variety of formulations make it a powerful tool for pharmaceutical development. This workshop will discuss current and new applications related to the USP Apparatus 4.

SCHEDULE

DAY 1

Automation in Dissolution testing

- Registration 09.30 hrs
- Welcome Address 10.00 hrs
- The role of Dissolution testing and its associated requirements 10.15 hrs
- Dissolution workflow and automation levels 10.45 hrs.
- **Tea Break** 11.15 hrs
- Regulation vs automation 11.45 hrs
- Is Automation Method and Product dependent? 12.10 hrs
- The 3 key achievements / benefits of dissolution automation 12.30 hrs
- **Lunch** 13.15 hrs
- Method comparison and transfer 14.15 hrs
- Implementing automation: mainly a financial decision? 14.45 hrs
- Q & A session 15.15 hrs
- User experience with Automation 15.45 hrs

DAY 2

Flow through cell dissolution (USP4)

- Fundamentals of dissolution: history, theory 10.00 hrs
- USP4 : principles and parameters, method development 10.30 hrs
- **Tea Break** 11.00 hrs
- Use of USP4 for API characterization 11.30 hrs
- Use of USP4 for generics developments 12.00 hrs
- Q & A 12.30 hrs
- **Lunch** 13.00 hrs
- Use of USP4 for non-conventional dosage forms 14.00 hrs
- Q & A session 15.00 hrs
- User experience with USP4 15.30 hrs

ABOUT THE COURSE DIRECTORS



Michel Magnier

Product Manager & Application Specialist in Dissolution Testing, SOTAX Business Unit Europe & Asia-Pacific

After completing a Master degree in Biochemistry/Organic Chemistry at the University of Paris XI Orsay, Michel Magnier started to work on scientific instrumentation at Fisher Scientific Group as Product Manager France for seven years developing different product lines including UV-Vis spectrophotometry and climatic chambers. End of 1999, Michel Magnier joined the SOTAX Group to specialize in the pharmaceutical testing market covering this specific field for SOTAX France. After six successful years, Michel Magnier moved to SOTAX AG headquarters in Switzerland. Since 2005, he has held different positions in Marketing, Business Development as well as Product Management. Michel Magnier is now Product Manager & Application Specialist in Dissolution Testing for SOTAX Business Unit Europe & Asia-Pacific



Samir Haddouchi

Managing Director
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Prior to joining SPS Pharma Services in 2005, Samir spent more than 10 years in the pharmaceutical industry. As a chemist, he started working on the analytical development of agrochemical compounds at Sandoz Agro in the region of Basel (Switzerland). During the Novartis merger, he moved to Orléans (France) in 1998 to join the analytical group in the technical development department where he became responsible for dissolution. In 2005, he resigned from Novartis to create SPS Pharma Services in Clermont Ferrand which is the first and only CRO specialized in Dissolution and Release Testing. Since then, Samir manages SPS facility and is in charge of projects management. In April 2013, SPS Pharma Services moved to a new larger facility in Orleans (France) in order to ensure better efficiency and provide a broader range of services to its clients, including cGMP routine testing. Fields of interest and expertise: analytical development (HPLC), in vitro dissolution and release testing (all techniques from USP1 to USP7), in vitro-in vivo correlations (IVIVC), formulation development, laboratory automation. Samir is regularly invited as speaker in international conferences as well as expert for various organizations (scientific societies and Health Authorities).

WHO SHOULD ATTEND

- Scientists from R&D, QA & QC responsible for Automation & Dissolution testing of NDDS
- Project Heads responsible for Automation of Labs
- Managers/ Analysts and Chemists
- Students, PhD Scholars and Faculty from Pharmacy Colleges
- Regulators