

Pharma Edge Centre  
(I) Pvt. Ltd.

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**SOTAX**  
Solutions for Pharmaceutical Testing

Announces Three day  
workshop on

***in vitro-in vivo*  
correlation (IVIVC),  
Biowaivers & Statistical  
aspects of Bioequivalence  
in Drug Product  
Development**

On 27<sup>th</sup>, 28<sup>th</sup> & 29<sup>th</sup> Jan 2012

At  
Mumbai

Do not miss this unique opportunity to fulfill your desire to evaluate yourself *in vivo* drug profile from dissolution results using Excel

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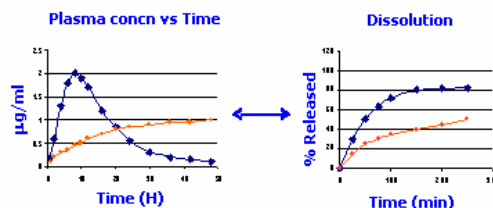
### Objective of present workshop

Objective of present workshop is to address one of the most important topics in drug product development & bioequivalence and that is **IVIVC**.

During formulation development, formulation optimization may require altering formulation composition, manufacturing, equipment and batch sizes. Normally, these types of changes require bioavailability studies to be performed to ensure that the "new" formulation displayed statistically similar *in-vivo* behavior as the "previously developed and accepted" formulation. This requirement can delay the marketing of the new formulation and add time and cost to the process.

*In vitro-in vivo* correlation (IVIVC) has been defined by the Food and Drug Administration (FDA) as "a predictive mathematical model describing the relationship between an *in-vitro* property of a dosage form and an *in-vivo* response".

In view of this, the *in-vitro* property, drug dissolution can be used to predict the *in-vivo* plasma drug concentration profile



A good correlation is a tool for predicting *in vivo* results based on *in vitro* data.

The main purpose of carrying out an IVIVC is to utilize *in vitro* dissolution profiles as a surrogate for *in vivo* bioequivalence and to support bio-waivers.

IVIVC also allows optimization of a particular formulation which may require fewest possible pilot studies in man. The knowledge obtained from IVIVC can be used to fix dissolution acceptance criteria.

IVIVC will reduce the number of bioequivalence studies required for approval as well as during scale-up and post-approval changes.

Hands on examples worked out by participants will provide confidence to use IVIVC regularly

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India is emerging as a major player in developing generic drug products. Understanding of IVIVC will help the F & D to develop better formulations in a minimum possible time.

IVIVC plays an important role in product development in that it:

- Serves as a surrogate of *in vivo* and assists in supporting bio-waivers
- Supports and validates the use of dissolution methods and specifications
- Assists in quality control during manufacturing and selecting appropriate formulations
- Additional advantage of an IVIVC is to assist in validating or setting dissolution specifications.

The present workshop will address IVIVC basics, correlation levels, A, B, C etc., bio-waivers based on IVIVC, other details and examples to make the participants fully conversant to the technique of working out IVIVC correlation.

### Biostatistics

The workshop will also cover statistical aspects of BA/BE studies. Introduction to basic concepts of biostatistics with examples followed by the most important biostatistical concepts such as **sample size calculation** will be discussed in details. Participants will be calculating sample size using excel during the workshop. Biostatistical aspects for **two way crossover** design will be covered in detail including examples. In view of several **highly variable drugs'** bioequivalence studies being carried out in various CROs, all minute aspects of statistical issues to cover **Reference scaling** will be discussed in detail. The presentations are designed using simple examples to make sure each and every participant, a biostatistician or a non-statistician will understand the basics. The examples will be worked out by the participants themselves to get rid of fear of evaluating statistical parameters in a biostudy.

### This workshop is useful for

- Principal investigators, Pharmacologists & senior bio-analysts working in Bioequivalence CROs
- Biostatisticians working on BA/BE studies in CROs as well as in Pharma R&D canterers
- All those involved in generic formulation development (F&D) for ANDA and other submissions
- M. Pharm students looking forward to career in F&D and BA/BE
- Any other person related to BA/BE interested to learn IVIVC

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## Workshop topics

- Introduction to the three days course
- Biopharmaceutical approach: BCS, API and other metrics
- In Vitro methods to access permeability and dissolution: apparatus, media Permeability and in vivo data
- Establishment of in vivo studies, calculation of Pharmacokinetics and dissolution parameters
- How to access pharmacokinetic parameters and in vivo dissolution/absorption curves : Deconvolution, Wagner- Nelson, PK parameters, Limits and use

### Introduction to In Vitro-In Vivo correlation

- Backgrounds of correlations
- When IVIVC could be established
- Correlation levels: A,B,C multiple level C, implications
- IVIVC in practice
- Simulation of In Vivo data based on IVIVC
- Limitation of IVIVC
- IVIVC in comparison to IVIVR
- Examples and applications of IVIVC

### Application to

- NCE development
- Non classical route of administration and formulation
- Generic development

### Biostatistics

- Basic concepts of biostatistics
- Sample size calculation
- Statistical aspects of two way crossover study
- Statistical aspects of Reference scaling
- Examples of above for participants

Detailed schedule will be provided later

Participants are requested to bring laptops. Examples will be worked out by the participants. Participants will actually construct plots of in vitro profile from an in vivo data using excel or vice versa. This will help the participants understand the basics of IVIV correlations in detail and they will be confident to use the same in their day to day F & D activities

### At this workshop you will:

- Understand basic concepts of IVIVC
- Understand the applicable equations used
- Understand how to establish correlation
- Use the data appropriately for correlation
- Carry out correlation in excel from sample data
- Work out examples

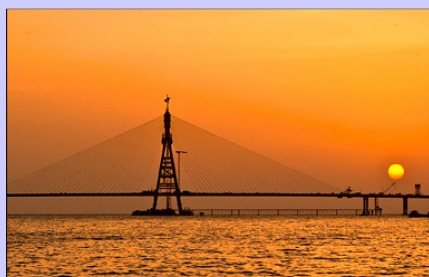
## Registration:

The registration\* fee for participation in the workshop is Rs. 8500.00 (plus service tax) for Indian participants and US \$ 500 for all others.

The workshop registration fee includes breakfast, tea, lunch & snacks. The fee also covers the cost involved in providing workshop material.

Payment may be made through DD or multi-city cheque payable to "Pharma Edge Centre (I) Pvt. Ltd." payable at Mumbai.

Kindly write your name, Organization, Mobile number & e mail ID on the back and send the DD to address given below.



**Mumbai 27<sup>th</sup>, 28<sup>th</sup> & 29<sup>th</sup> Jan 2012**

Kindly bring your laptops with you to the workshop. You will be working out examples of in vivo in vitro correlation yourself

\* There is a no refund policy for cancellations; however, if you cannot attend the workshop, you may make a substitution/name change at any time. Substitutions must be from the same company or organization

Venue details will be communicated to the participants

## Speakers:



**J-M. Cardot**  
Faculté de Pharmacie  
Laboratoire de Biopharmacie  
Univ.Clermont, 28 Place H. Dunant, BP 38  
63001 Clermont-Ferrand FRANCE



**Helmut Schütz**  
BEBAC - Consultancy Services for  
Bioequivalence and Bioavailability Studies  
Neubaugasse 36/11, 1070 Vienna, Austria



**Vinay P. Shedbalkar**  
Pharma Edge Centre (I) Pvt. Ltd.  
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