

The GastroPlus™
PHARMACEUTICAL Development Workshop

Date : 27th - 28th Sept, 2018

Venue : Coral at Hotel Sahara Star

Opp Domestic Airport,
Mumbai, Maharashtra 400099

Time : 9:00 a.m. - 6:00 p.m.

"Utilized by all major regulatory agencies around the world"

30days
FREE TRIAL

#1
IVIVE
Program

GastroPlus™

PBPK modeling software from
discovery through development

PKPlus™

DDDPlus™

In vitro dissolution
testing software

Pharmacokinetic data analysis and
reporting for validated software purposes

Workshop conducted by
Grace Fraczkiwicz, Ph.D
(Team Leader, Simulation Studies)
&
Joyce Macwan, Ph.D
(Sr. Scientist, SimulationsPlus)



Insight you can't measure – the GastroPlus™
PBPK modeling & simulation package

What if it were possible to:

- Integrate the data which has been collected and, within the context of a virtual animal or human model, gain unique insights that improve your chances for success?
- Run simulations for different scenarios to avoid costly surprises?
- Utilize the outputs from these models to potentially waive expensive studies requested by regulatory agencies?

It's possible to do this and more
with the GastroPlus™ PBPK modeling platform

★ **For Delegates**

GastroPlus™
Training Outline

GastroPlus software training is best done in an environment where each person operates the program and takes an active part in running simulations along with the instructor. As much as possible, the training uses PowerPoint slides to introduce software features. Once a feature is discussed, trainees then use it on their individual computers to see how it works. We find this instruction method to be much more effective than starting with a lecture that explains the entire program and later having students operate the program.

The GastroPlus™ PHARMACEUTICAL Development Workshop

Date : 27th and 28th Sept, 2018

ELECTROLAB, in collaboration with Simulations Plus, the industry's leading provider of simulation and modeling software for drug discovery and development, will be hosting its "GastroPlus™ Pharmaceutical Development Workshop".

This 2-day hands-on course will provide an in-depth knowledge of the theories and application of state-of-the-art simulation and modeling software as it applies to problems facing pharmaceutical scientists dealing with drug product effects on dissolution, absorption and pharmacokinetics. Focus will be placed on applications of this technology as it relates to issues defined in the FDA's Critical Path Initiative. A combination of presentations and interactive examples, taken from actual industry experience, will illustrate how to recognize and deal with the multiple interacting phenomena that affect the dissolution, absorption and pharmacokinetics of particular drugs, dosing routes and dosage forms.

Who should attend?

This workshop is appropriate for scientists in pharmaceutical development who need an in-depth understanding of how formulation affects the highly interactive processes of dissolution, precipitation, gastrointestinal transit, absorption (passive and carrier-mediated), first-pass metabolism and pharmacokinetics. Although the course will use GastroPlus for all case studies, the guiding principles will be taught in a software-independent manner.

Class size is limited to encourage interaction with the course instructors and among delegates.

What will you learn?

Upon completion of this course you will have a thorough understanding of the interactions that exist among the various mechanistic phenomena affecting drug dissolution, absorption and pharmacokinetics and how they relate to the development of drug products both in preclinical and clinical settings.

You will gain experience in:

- ★ Assessing formulation strategies (e.g., micronization and nanoparticles) earlier in product development
- ★ Analyzing the impact of common ion effect on solubility & dissolution
- ★ Screening for different salts and understanding the effect on precipitation kinetics
- ★ Properly using in vitro dissolution data to predict plasma concentration levels
- ★ Deconvoluting in vivo dissolution to help design in vitro experiments and generate mechanistic IVIVCs
- ★ Estimating local concentration of drug following dermal and intramuscular administration
- ★ Running virtual bioequivalence studies to estimate sample sizes and achieve adequate power
- ★ Understanding optimization methods, objective function weighing and constraints
- ★ Designing controlled release products to reach therapeutic "windows" or target concentration profiles

The GastroPlus™ PHARMACEUTICAL Development Workshop

Date : 27th and 28th Sept, 2018

How will the workshop operate?

All presentation files and data sets needed to run case studies will be available in electronic format. All the delegates are requested to bring their own laptop. ELECTROLAB will install GastroPlus™ and DDDPlus™ on the delegates laptop prior to the workshop.

Breakfast, refreshment breaks and lunch will be provided each day.

Schedule at a Glance

SESSION	TIME	TITLE
DAY 1 : 27/09/2018		
SESSION I	09.00 am	Registration
	09.30 am	Welcome and an overview of the GastroPlus™ PBPK modeling platform
	09:45 am	Applications: QSAR/PBPK modeling integration – defining inputs through chemical structures and in silico F% simulations in animals and humans
	11:00 pm	TEA BREAK
SESSION II	11:30 am	Applications: Mechanistic dissolution modeling (aqueous solubility vs. pH, biorelevant solubility, preformulation assessment, particle size distributions)
	1:00 pm	LUNCH BREAK
SESSION III	2:00 pm	Applications: Mechanistic dissolution & precipitation modeling (Z-factor options, precipitation kinetic features)
	4:00 pm	TEA BREAK
SESSION IV	4:15 pm	Applications: Mechanistic oral absorption modeling (the ACAT™ model, ASFs, paracellular absorption)
	6:00 pm	Adjourn
	7:00 pm	Networking : Dinner and Cocktails
SESSION	TIME	TITLE
DAY 2 : 28/09/2018		
SESSION V	09.30 am	Applications: Systemic PK modeling considerations (PKPlus™ Module)
	10:30 am	Applications: Mechanistic IVIVCs and virtual bioequivalence trials
	11:00 pm	TEA BREAK
SESSION VI	11:15 am	Applications: Mechanistic IVIVCs and virtual bioequivalence trials (integration with DDDPlus™ for dissolution specifications)
	1:00 pm	LUNCH BREAK
SESSION VII	2:00 pm	Applications: Formulation optimization to hit target PK profiles
	3:00 pm	Applications: Additional dosage routes: Mechanistic dermal absorption models and IM models
	4:00 pm	TEA BREAK
SESSION VIII	4:15 pm	Applications: Incorporating mechanistic modeling and simulation to assist with formulation development and regulatory evaluations
	6:00 pm	Adjourn

REGISTER NOW

Send the below registration details along with cheque/DD to ELECTROLAB registered office at Mumbai.

DELEGATE REGISTRATION

(to be filled and to below mentioned address)

Title: _____ Full Name: _____

Designation: _____ Department: _____

Organization: _____ Address: _____

Email: _____ Phone: _____ Mobile: _____

REGISTRATION FEES : _____

Industry Professionals : 40000 INR + 18% GST

Students/Academia/
Research Scholars : 20000 INR + 18% GST

PAYMENT DETAILS : _____

For Bank transfer:

To pay by Bank transfer, please send payments to :

*Beneficiary Name: ELECTROLAB (INDIA) PVT LIMITED

*Bank Name : DBS BANK LIMITED

*Account Number : 811210089238

*IFSC Code : DBSSOIN0811

*Branch : FORT HOUSE 221, Dr. D.N.ROAD, FORT,
MUMBAI - 400 001

By Cheque/DD No. _____ amount _____ INR made payable

To ELECTROLAB (INDIA) PVT LIMITED

Head Office : 401, Tirupati Udyog, I. B. Patel road,

Opp. Western Express highway, Goregaon (East),

Mumbai - 400 063, India.

Please mail the copy of delegates name and the course registered for along with the bank transfer details to the service desk at marketing@electrolabgroup.com

TERMS AND CONDITIONS : _____

Payment:

All payments must be made in full before the workshop date.

- All the online registrations can be done only till 15th Sept, 2018. For bookings thereafter, please contact the organizers at 91 - 22 - 4161 3122/113
- Workshop fees include entrance to the workshop sessions, refreshments as per onsite schedule and the workshop papers. Please note that accommodation and travel are not included in the workshop fee.
- Fees are subject to applicable GST as per government rules and regulations.

Cancellation and Substitutions:

- Once booked, cancellation of delegate cannot be made, however a substitution can be made at any time. Please email details of the substitute delegate to marketing@electrolabgroup.com before 15th Sept, 2018.
- In the event that ELECTROLAB cancels an event for any reason, you will receive a credit note for 100% of the workshop fee paid.
- In the event that ELECTROLAB postpones an event for any reason and the delegate is unable or unwilling to attend on the rescheduled date, you will receive a credit note for 100% of the workshop fee paid.
- Credit notes can be used towards another ELECTROLAB event to be mutually agreed with ELECTROLAB which must occur within one year from the date of postponement.
- Except as specified above, no credits will be issued for other forms of cancellation.

- ELECTROLAB is not responsible for any loss or damage as a result of a substitution, alteration or cancellation/postponement of an event. ELECTROLAB shall assume no liability whatsoever in the event this workshop is cancelled, rescheduled or postponed due to a fortuitous event, Act of God, unforeseen occurrence or any other event that renders performance of this workshop impracticable, illegal or impossible. For purposes of this clause, a fortuitous event shall include, but not be limited to: war, fire, labour strike, extreme weather or other emergency.

Programme Changes:

- Please note that speakers and topics were confirmed at the time of publishing however, it may be necessary due to unforeseen circumstances to alter the content, timing, speakers or venue. ELECTROLAB reserve the right to alter or modify the advertised speakers and/or topics if necessary
- Any substitutions or alterations will be updated.

Your Details:

- By entering your details in the fields above, you agree to allow ELECTROLAB and companies associated with the event to contact you (by post, telephone, sms, email or fax) regarding other related products or services.
- If at any time you do not wish to receive anything from ELECTROLAB or carefully selected 3rd parties, please write to marketing@electrolabgroup.com.
- Students are required to produce the Student Identity card at the time of registration while collecting their badges.

This contract is subject to Mumbai Jurisdiction law

SERVICE DESK : _____

1. Co-ordinator

Contact: Rachana Shetty

Tel : +91 - 22 - 4161 3113

Mobile : +91 9167930377

Email : marketing@electrolabgroup.com

2. Co-ordinator

Contact : Padmanabh Mukhedkar

Tel : +91 - 22 - 4041 3129

Mobile : +91 9619435868

Email : padmanabh.mukhedkar@electrolabgroup.com

Head Office : 401, Tirupati Udyog, I. B. Patel road, Off. Western Express highway, Goregaon (East), Mumbai - 400 063, India.

Factory : EL 23/24, T. T. C., Electronic Zone, M. I. D. C, Mahape, Navi Mumbai - 400 710, India.