

## ELECTROLAB, in collaboration with Simulations Plus, presents: The 2-Day GastroPlus™ Pharmaceutical Development Workshop



**October 26 - 27, 2017 in Mumbai, India**

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 in Mumbai, India on October 26 - 27.

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.

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.



**Attendance for this event is limited, so register today!**



**SimulationsPlus**

SCIENCE + SOFTWARE = SUCCESS

42505 10th Street West • Lancaster, CA 93534 • USA • phone: +1-661-723-7723

fax: +1-661-723-5524 • email: [info@simulations-plus.com](mailto:info@simulations-plus.com) • [www.simulations-plus.com](http://www.simulations-plus.com) • NASDAQ: SLP

## 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 should have a solid understanding of the interactions that exist among the various mechanistic phenomena affecting drug dissolution, absorption and pharmacokinetics (employing both compartmental PK and physiologically based pharmacokinetics - PBPK) and how they relate to the development of drug products, both in preclinical and clinical settings.

- Incorporating modeling & simulation to assist with Quality by Design (QbD) implementation
- Deconvoluting *in vivo* dissolution to help design *in vitro* experiments and generate mechanistic IVIVCs
- Assessing formulation strategies (e.g., micronization and nanoparticles) earlier in product development
- Identifying food effect, both positive and negative, on absorption
- Analyzing the impact of common ion effect on solubility & dissolution
- Running virtual bioequivalence studies to estimate sample sizes and achieve adequate power
- Screening for different salts and understanding the effect on precipitation kinetics
- Understanding optimization methods, objective function weighting, and constraints
- Properly using *in vitro* dissolution data to predict plasma concentration levels
- Designing controlled release products to reach therapeutic “windows” or target concentration profiles

## Course Instruction

Dr. Bolger joined Simulations Plus, Inc. as the first member and Director of Life Sciences in 1996. He programmed the first version of a software program called GastroPlus™ for simulation of mechanistic oral absorption and physiologically based pharmacokinetics in 1997. GastroPlus is currently used by all of the major pharmaceutical companies and many of the biotechnology and generic drug companies, and many of the drug regulatory agencies around the world. He currently works with a team of scientist /programmers at Simulations Plus in the development of software programs for estimation of biopharmaceutical properties and simulations of absorption and bioavailability. He was elected to the rank of Fellow of the American Association for the Advancement of Science in 1996. In 2017 he was appointed to the NIH Scientific Advisory Committee on Alternative Toxicological Methods.



**Mike Bolger, Ph.D.**



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## How will the workshop operate?

All presentation files and data sets needed to run case studies will be available in electronic format. All delegates will be responsible for bringing their own laptop. Electrolab will install GastroPlus on the delegates laptop prior to the workshop.

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

SESSION	TIME	TITLE
<b>DAY 1 : 26/10/2017</b>		
SESSION I	08.30 am R	egistration
	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
<b>DAY 2 : 27/10/2017</b>		
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: Mechanistic IVIVCs and virtual bioequivalence trials (integration with DDDPlus™ for dissolution specifications)
	3:00 pm	Applications: Formulation optimization to hit target PK profiles
	4:00 pm	TEA BREAK
SESSION VIII	4:15 pm	Applications: Food effect modeling
	6:00 pm	Adjourn



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## Where will this be held?



### **Mirage Hotel**

International Airport Approach Road  
Marol, Andheri (E), Mumbai - 400 059

Phone: +91-22-6672 1212/34

Email: [res@miragehotel.in](mailto:res@miragehotel.in)

[www.miragehotel.in](http://www.miragehotel.in)

Accommodation at concessional rates using  
promo code: **GASTROPLUS**

## Coordinator Contact Information

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# REGISTER NOW

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

## DELEGATE REGISTRATION

(to be filled and sent 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

### Accommodation at Concessional Rates

MIRAGE HOTEL

Tel : 91-22-6672 1212/34

Email : res@miragehotel.in

Use our code : **GastroPlus**

## 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, Off. 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 news@electrolabgroup.com.

## TERMS & CONDITIONS :

### Payment:

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

- All the online registrations can be done only till 10<sup>th</sup> Oct, 2017. For bookings thereafter, please contact the organisers 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 news@electrolabgroup.com no later than 10<sup>th</sup> Oct, 2017.
- 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 conference is cancelled, rescheduled or postponed due to a fortuitous event, Act of God, unforeseen occurrence or any other event that renders performance of this conference 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 reserved 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 news@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 :

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