



DILIsym[®]

2-Day Introductory Course

September 21-22, 2021

Who should attend?

This is a beginner's course for clinicians, pharmaceutical/biotechnology scientists, and engineers in the areas of toxicology, clinical pharmacology, pharmacovigilance, DMPK and ADME looking to learn more about liver injury - prior experience with DILIsym is not required.

The course will use DILIsym X (DSX), the newest and most advanced release of DILIsym, but many of the guiding principles will be taught in a software-independent manner. Class size is limited to encourage interaction with the course instructors and among attendees. Virtual networking among industry, government, and academic scientists is part of the experience!

What will you learn?

You will understand the following important aspects of liver safety investigation:

- concepts accepted by regulators related to drug-induced liver injury (DILI) monitoring and detection
- primary mechanisms, (e.g., mitochondrial dysfunction, ROS, bile acids, and lipotox) often involved in DILI events
- *in vitro* assay design and execution for DILI-related mechanisms
- pharmacokinetics, including prediction of liver concentrations using GastroPlus[®] and how this impacts DILI predictions (*note that a separate GastroPlus workshop is recommended for detailed PBPK training*)

You will gain basic experience with:

- translating *in vitro* data into DILIsym parameter values, including the use of automated optimization
- simulating expected DILI outcomes for humans, rats, mice, and dogs
- utilizing simulated populations (SimPops[®]) to predict infrequent events in a diverse patient population

How will the workshop operate?

This workshop will be entirely virtual. Attendees will be responsible for acquiring/using their own computers to log on. The workshop will start at 8:30 AM ET both days and conclude at 5 PM ET. Mid-morning and mid-afternoon breaks will be taken, and a break will be taken for lunch from Noon ET to 1 PM ET. All attendees will follow the same track. Log-in information will be sent out to all registered attendees in advance of the course, along with course materials.

Day 1 – 'DILIsym Introduction,' including DILI and QST overview, software overview, introduction to mechanisms included in DILIsym and associated assays, and interaction of DILI mechanisms. SimPops and optimization may also be covered if time allows.

Day 2 – 'Focus on Application of DILIsym to Evaluate Compounds,' including workflow, SimPops, how to use Specified Data to input PK information from GastroPlus, step-by-step parameter derivation examples, and a live, hands-on compound example exercise. Optimization may also be covered if time allows.



"DILIsym is helping to address major DILI events for drug developers & regulators. It has been recently licensed to the USFDA."

Paul B. Watkins, M.D.
Director of UNC Institute for Drug Safety Sciences



Register online! www.simulations-plus.com/workshops

DILIsym Services

SP+ A SIMULATIONS PLUS COMPANY

REGISTRATION FORM

Attendance is limited • Please register by September 13, 2021

Please fill in this form and return to Brett Howell (bhowell@DILIsym.com);
To register by phone, please call Brett at +1-704-202-1455

The DILIsym 2-Day QST Virtual Workshop September 21-22, 2021

DILI-sim member and/or DILIsym license holder from industry
Academic or government
Non-members and non-license holders from industry

Title: Professor Dr. Mr. Mrs. Miss Ms.

First name:

Last name: Company:

Position: Department:

Address:

Telephone: Email:

Purchase Order No. (if applicable):

FREE - DILI-sim member and/or DILIsym license holder from industry
FREE - Academic or government
\$600 - Non-members and non-license holders from industry

Cost for the workshop includes all workshop materials.

Method of payment (Please check one)

- Payment by check (you will be invoiced upon receipt of your completed registration form)
- Payment online (you will be redirected to the payment portal when registering online at www.simulations-plus.com/workshops)

Terms and Conditions

Cancellation Policy: Cancellations made prior to September 13, 2021, will be eligible for an 80% refund. Refunds for cancellations will be honored up to 45 days after the date of payment for credit card transactions. Substitutions are allowed up to 10 days before the event.

Payment Terms: Following completion and return of the registration form, the total fee must be paid within 30 days of receipt of invoice. All fees must be paid in full prior to the start of the workshop.