

# Introductory Course

October 6<sup>th</sup>, 2022

## 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 kidney injury - prior experience with RENAsym is not required.

The course will use RENAsym v1A, the first iteration of RENAsym, 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 kidney safety investigation:

- · concepts related to acute kidney injury (AKI) monitoring and detection
- primary mechanisms, (e.g., mitochondrial dysfunction, oxidative stress or ROS, and crystal nephropathy) often involved in drug-induced AKI events
- in vitro assay design and execution for AKI-related mechanisms
- pharmacokinetics, including prediction of renal concentrations using GastroPlus<sup>®</sup> and how this impacts AKI predictions (note that a separate GastroPlus workshop is recommended for detailed PBPK training)

#### You will gain basic experience with:

- · translating in vitro data into RENAsym parameter values
- simulating expected AKI outcomes for humans and rats
- 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 9 AM ET and conclude at 4:30 PM ET. Mid-morning and mid-afternoon breaks will be taken, and a break will be taken for lunch from approximately 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.

**Agenda by Topic** – 'RENAsym Introduction,' including AKI and QST overview, software overview, introduction to mechanisms included in RENAsym and associated assays, interaction of AKI mechanisms, virtual populations (SimPops), and compound evaluation workflow including how to use Specified Data to input PK information from GastroPlus.

### Attendance is limited Please register by September 29<sup>th</sup>, 2022

FREE - RENAsym member and/or RENAsym license holder from industry
FREE - Academic or government
\$300 - Non-members and non-license holders from industry
Cost for the workshop includes all workshop materials.

Terms and Conditions

Cancellation Policy: Cancellations made prior to September 29<sup>th</sup>, 2022, 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.



