



# DRUG DEVELOPMENT WITH FOCUS ON NON-CLINICAL STUDIES IN THE CENTER OF INNOVATION AND PRE-CLINICAL STUDIES (CIEnP)

20-24 August 2018, CIEnP, Florianópolis, SC

**Target audience:** Professionals who develop activities in areas related to the development of medicines / vaccines in the public sphere, pharmaceutical industries and academia.

FREE REGISTRATION: [inscricao@ciemp.org.br](mailto:inscricao@ciemp.org.br)

**Necessary requirements:** Please send your short CV (1 page) by e-mail and a letter of interest.

**COURSE VENUE:** Centro de Inovação e Ensaios Pré-Clínicos – CIEnP. Av Luiz Boteiux Piazza, 1302, Cachoeira do Bom Jesus, Sapiens Parque, Florianópolis - SC.  
[www.ciemp.org.br](http://www.ciemp.org.br)

## FINAL PROGRAM

### DAY 1: 20/08/2018 - MONDAY

**João Batista Calixto, PhD (CIEnP)**

*Scenario of non-clinical drug development in Brazil: Reality and Perspectives*

**João Batista Calixto, PhD (CIEnP)**

*Reproducibility, traceability and reliability in non-clinical research*

**Jarbas Siqueira, PhD (CIEnP)**

*Understanding Good Laboratory Practice (GLP) applied to pre-clinical studies*

**Eliezer Barreiro, PhD (UFRJ)**

*Drug Discovery: identification of lead compounds*

### DAY 2: 21/08/2018 - TUESDAY

**Rodrigo Marcon, PhD (CIEnP)**

*Efficacy (proof of principle) studies in non-clinical drug development*

**Raquel Schwanke, PhD (CIEnP)**

*ADME assays in nonclinical drug development*

**Melina Heller, PhD (CIEnP)**

*Development and validation of analytical methods applied to Pharmacokinetics*

**Melina Heller, PhD (CIEnP)**

*Identification, quantification, stability of constituents of plant extracts for the development of herbal medicines*

### DAY 3: 22/08/2018 - WEDNESDAY

**Raquel Schwanke, PhD (CIEnP)**

*Pharmacokinetics and Toxicokinetics*

**Cristina Freitas, PhD (CIEnP)**

*Genotoxicity and mutagenicity assays required for nonclinical drug development*

**Allisson Bento, PhD (CIEnP)**

*General toxicity studies*

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*Carcinogenicity and reproductive toxicology studies*

### DAY 4: 23/08/2018 - THURSDAY

**Edinéia Andrade, PhD (CIEnP)**

*Safety pharmacology studies*

**John Foster, PhD (ToxPath Sciences Ltd, UK)**

*Principle Consultant Pathologist. He worked for AstraZeneca Pharmaceuticals as a Senior Principal Pathologist and Deputy Director of Pathology.*

**Pathology in Toxicology Studies**

**Ernie Harpur, PhD (Newcastle University, UK)** President of the British Toxicology Society, Chair of the Board of Trustees and Executive Committee of ILSI HESI and a member of the ILSI Board of Trustees.

**Risk assessment in drug development**

**David Jones, PhD** Expert Pharmacotoxicologist within the Licensing Division of the Medicines and Healthcare products Regulatory Agency (MHRA), UK. European Union representative in the ICH revision of the M3 Guideline and on the ICH S10 Guideline.

**Regulatory aspects of nonclinical studies to support clinical development**

### DAY 5: 24/08/2018 - FRIDAY

**João Batista Calixto, PhD (CIEnP)**

*Investigational New Drug (IND) and dose transposition between species*  
**João Massud, PhD (Senior Consultant in Drug Development, Professor of Pharmaceutical Medicine)**  
*General aspects of clinical research: A view from industry*

**João Batista Calixto, PhD (CIEnP)**

*Regulatory aspects: non-clinical studies to supporting clinical trials (FDA Toxicological/Pharmacological Review analyses)*

THE COURSE IS LIMITED TO 50 ATTENDENTS

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