

REGISTRATION

Send an e-mail to macabreraster@gmail.com to receive full information about the course.

SPEAKERS

Gordon L. Amidon

Professor. Ann Arbor University. Michigan

Marival Bermejo

Professor. Miguel Hernandez University. Spain

Miguel Angel Cabrera

Professor. Universidad de Las Villas. Santa Clara. Cuba

Arik Dahan

Assoc. Professor. Ben-Gurion University. Israel

Isabel González-Álvarez

Assoc Professor. Miguel Hernandez University. Spain

Peter Langguth

Professor. University of Mainz. TBC

Salomon Stavchansky

Professor. University of Texas. TBC

ORGANIZING COMMITTEE

Miguel Angel Cabrera Perez

Isabel Gonzalez-Alvarez

Marival Bermejo

Gordon L. Amidon

Sponsors :

Center of Genetic Engineering and Biotechnology

Cuban Society of Pharmacology

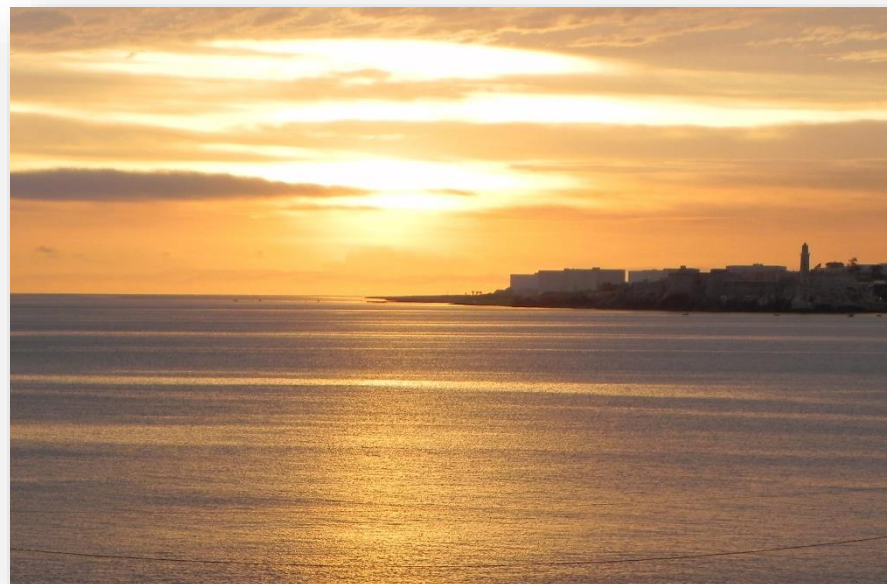
Drug Delivery Foundation



WORKSHOP ON BCS DRUG EVALUATION AND BIOEQUIVALENCE

12th - 14th September 2016, La Habana, Cuba

This course will offer a scientific program focused in BCS application, in order to attract scientists working in drug development and medicines evaluation. Lectures and hands on BCS, methods for estimating and evaluating drug intestinal absorption, dissolution test and IVIVC. Attendants should have their own laptops with Microsoft Office or Open Office. Lectures will be in Spanish and English. No simultaneous translation provided.



La Habana, Cuba September 2016

DAY 1		Session I: BCS concepts	
09:00-09:15		OPENING CEREMONY	
09:15-10:00	Cuban Universities role in Biopharmaceutical optimization		<i>Miguel Angel Cabrera</i>
10:00 - 10:45	Scientific bases of BCS and <i>In vitro</i> Bioequivalence		<i>Gordon Amidon</i>
10:45 - 11:30	Current Regulatory BE Biowaiver Standards: FDA and EMA		<i>Peter Langguth</i>
11:30 – 12:00		COFFEE BREAK	
12:00 – 12:45	Provisional BCS classification of WHO essential medicines		<i>Marival Bermejo</i>
12:45 – 13:30	Statistical design and Evaluation of Bioequivalence Studies - Average Bioequivalence		<i>Salomon Stavchansky</i>
13:30 – 14:15	Approaches of Therapeutic equivalence in Cuba		<i>Celeste Sanchez</i>
14:15 – 15:00	Regulatory approaches for BE globally		<i>Marival Bermejo</i>
09:15-10:00	Intestinal Segmental Dependent Absorption and BE Standards		<i>Arik Dahan</i>
10:00 - 10:45	Scientific and Regulatory Considerations of Biosimilars: A Global Perspective		<i>Salomon Stavchansky</i>
10:45-11.30	The solubility-permeability interplay. Supersaturation and absorption		<i>Arik Dahan</i>

DAY 2		Session II: BCS parameters	
11:30 – 12:00		COFFEE BREAK	
12:00 – 12:45	Bicarbonate buffer		<i>Gordon Amidon</i>
12:45 – 13:30	Challenges and Opportunities of Drug Excipient Interactions		<i>Salomon Stavchansky</i>
13:30 – 14:15	BCS Class II Biowaivers and In Vitro—In Vivo Relationships		<i>Peter Langguth</i>
14:15 – 15:00	Refined Classification of BCS		<i>Gordon Amidon</i>

DAY 3		Session III: Hands on parameters calculation	
09:30 -10:15	<i>In vitro in vivo</i> correlation		<i>Isabel González/ Marival Bermejo</i>
10:15 - 11:00	Dimensionless number estimation and BCS classification		<i>Gordon Amidon</i>
11:00 - 12:00	In silico methods for predicting permeability and solubility. In silico provisional BCS classification		<i>Miguel Angel Cabrera</i>
12:00 – 12:30		COFFEE BREAK	
12:30 – 13:00	In vitro dissolution tests: kinetic models and profile comparisons. F2 calculation		<i>Isabel González</i>
13:00 – 14:00	In vitro and in situ methods for permeability estimation		<i>Isabel González</i>