SCIENTIFIC AND REGULATORY ISSUES IN DRUG DEVELOPMENT AND BIOEQUIVALENCE
(ivivc, bcs, bddcs, biowaiver, paediatric, statistics, modeling and simulation)

MD Pharmacon Pharmaceutical Services Ltd (www.mdpharmacon.com) and the Portuguese Society for Pharmaceutical Sciences organize a one-day (Lisbon, June 6, 2016) international symposium covering different aspects pertinent to bioequivalence, including modelling and regulatory tools.

The speakers have been thoroughly chosen as top scientists in their fields and will convey state of the art information on each of the subjects.

The subjects addressed by the speakers are of utmost importance to those working in the biopharmaceutics of innovator as well as generic drug development and applications

Workshop summary

This one-day symposium is intended for Academics/students or scientists working in Academia, pharmaceutical industries, regulatory agencies, and contract research organizations. The symposium will begin with an overview of the contribution of the Biopharmaceutics Drug Disposition Classification System (BDDCS) to the recent development of Pharmaceutical Sciences and will proceed with an account of the role of In vitro/in vivo correlations (IVIVC) in predicting in vivo behavior of drug delivery systems and thus avoiding unnecessary human clinical studies. These are dealt with in practical terms concerning the statistical planning and data treatment of bioequivalence BE studies.

Proceeding with a practical approach, case studies in generic drug product development will cover a range of situations that the generic industry faces in planning new generic drug products.

Dissolution studies are essential in generic drug product development and may provide the basis of strength biowaivers, which is an essential aspect in avoiding unnecessary human clinical studies. The establishing of similarity between dissolution profiles, especially when the conditions for the f2 metric are not followed, is still under debate and the issue of the different alternative metrics available will be covered.

The Biopharmaceutics Classification System (BCS) is not only a useful tool for obtaining waivers for *in-vivo* bioequivalence studies but also for decision making in the discovery and early development of new drugs. The presentation will focus on factors like dose strength, kinetic solubility, dual classification, and non binary BCS considerations emerged since the inception of BCS in 1995.

The need for development of appropriate oral paediatric dosage forms to optimize clinical care, with easy to swallow and palatable formulations in appropriate dosage increments, is overwhelming and the European Regulation on medicinal products in children (in force since 2007) is a large stimulation for a proper evaluation of medicinal products in children and the availability of formulations adapted to age. However, development of medicinal products in children is more difficult, takes longer and is more costly than in adults. The presentation will focus on current challenges in scientific and regulatory aspects of paediatric drug development and evaluation, covering areas such as pharmaceutical development and excipients, BCS evolutions, extrapolation concepts and regulatory framework.

The current modelling work on drug dissolution and release relies on the diffusion layer model of dissolution and the empirical use of power law or the Weibull function, respectively. The (bio)relevance of the reaction limited model of dissolution and the time dependent character of drug dissolution or release along with their biopharmaceutical aspects will be presented.

SPCF
Sociedade Portuguesa de Ciências Farmacêuticas

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Programme

TIME	SPEAKER	TOPIC
08:45	**José Morais** Faculdade de Farmácia, Univ. Lisboa Portugal	Welcome; introduction
09:00	**Leslie Benet** University of California, St. Francisco, USA	Historical Development of BDDCS: The Observations, The Predictions, Understanding the Scientific Basis and The Extensions
09:40	**Peter Langguth** University of Mainz, Germany	In vitro/in vivo correlations: The basis of forecasting dosage form bioperformance
10:20	**coffee break**	
11:00	**Helmut Schütz** BEBAC - Consultancy Services for Bioequivalence and Bioavailability Studies, Austria	Statistical planning and evaluation of bioequivalence studies
11:40	**Nuno Silva** Faculdade de Farmácia, Univ. Lisboa Portugal	Case studies in generic drug product development
12:20	**lunch break**	
14:00	**Paulo Paixão** Faculdade de Farmácia, Univ. Lisboa Portugal	Strength biowaivers: Dissolution profiles similarity metrics
14:40	**Panos Macheras** National and Kapodistrian Univ. of Athens, Greece	BCS: Then and now
15:20	**coffee break**	
15:40	**Chrysa Daousani** National and Kapodistrian Univ. of Athens, Greece MD Pharmacon Pharmaceutical Services	Paediatric formulations: Current challenges in development and assessment
16:20	**Panos Macheras** National and Kapodistrian Univ. of Athens, Greece	Drug Dissolution and Release: Current and future modeling and biopharmaceutical aspects

The Symposium venue is the Faculty of Pharmacy, University of Lisbon, on June 6th, 2016

Registration-Fees

Early bird registration (up to May 15TH 2016):

- Industry: 400 €
- Academia-Government: 300 €
- Student: 100 €

Late bird registration (up to May 27th 2016):

- Industry: 450 €
- Academia- Government 350 €
- Student: 150 €