Workshop

Advances in scientific-regulatory issues in drug development and authorization processes

MD Pharmacon Pharmaceutical Services Ltd (*www.mdpharmacon.com)* organizes a one-day (May 29, 2015) workshop on '*Advances in scientific-regulatory issues in drug development and authorization processes'*. The program is focusing on the scientific basis for the regulatory standards which have undergone rapid and significant changes since the beginning of this century up to the most recent changes in the regulatory framework adopted by Agencies. Overall, the workshop will focus on current 'hot topics' of regulatory science as outlined in the attached program.

Workshop Summary

This one-day workshop is intended for Academics/students or scientists working in Academia, pharmaceutical industries and companies, regulatory agencies, and contract research organizations. The attendees of this workshop may have or not a scientific background on the issues discussed in this workshop.

This workshop will begin with a short overview of the current regulatory status in the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). A special emphasis will be made on biowaivers in conjunction with concepts of the Biopharmaceutics Classification System (BCS) and more recent developments of the Biopharmaceutics Drug Disposition Classification System (BDDCS). New innovation trends in dissolution will also be discussed.

Further to the above, the workshop will also unveil specific quality and formulation-related issues including non-traditional use of excipients, primary packaging interaction studies and paediatric formulation development.

This course will also focus on some special types of products such as modified release as well as topical drugs with emphasis on the establishment of Bioequivalence and therapeutic equivalence. Also, since biosimilar products are a future wave of drug development, the relevant current or upcoming regulatory guidelines for biosimilars will be discussed.

The workshop will proceed with presentation of the modeling approaches for the biopharmaceutic classification of drugs and the biowaiver status. Special emphasis will be placed on the use of modeling & simulation methods in bioequivalence. This session will cover the theoretical and the regulatory aspects as well as examples of modeling and simulation applications.

Finally, the workshop will end up with a round table discussion where participants will have the opportunity to address specific questions to the speakers.

Workshop on Advances in scientific-regulatory issues in drug development and authorization processes

Organized by MD Pharmacon Pharmaceutical Services Ltd

Aegli Zappiou, Athens,

May 29, 2015

Scientific Program

Time	Speaker / Event	Topic
9.00	Chrysa Daousani *MD Pharmacon Pharmaceutical Services, Athens, Greece*	Introduction: The drug regulatory setting
9.30	Vinod Shah *International Pharmaceutical Federation (FIP)*	Dissolution, BCS and biowaivers
10.00	Gordon Amidon *College of Pharmacy, University of Michigan, USA*	CO_2/Bicarbonate: The magic buffer
10:30	Leslie Benet *Schools of Pharmacy and Medicine , University of California, USA*	The utilization of BDDCS principles by the regulatory agencies (Video presentation)
11.00	**Coffee break**	
11.30	Panos Constantinides *Biopharmaceutical & Drug Delivery Consulting, LLC Gurnee, IL (USA)*	Non-traditional Uses of excipients in oral drug products : Applications and development considerations
12.00	Nikos Megkoulas *QualiMetrix SA, Analytical laboratories - Quality control, Athens, Greece*	Primary packaging interaction studies: Current trends on regulatory and GMP requirements
12.30	Chrysa Daousani *MD Pharmacon Pharmaceutical Services, Athens, Greece*	Paediatric formulations: Current challenges in development and assessment
13.00	**Lunch**	
14.00	*Laszlo* Endrenyi *Emeritus Professor, University of Toronto, Canada*	Do the current regulatory bioequivalence requirements adequately reflect the therapeutic equivalence of modified-release drug products?
14.30	Vinod Shah *International Pharmaceutical Federation (FIP)*	Topical drugs: Regulatory requirements for therapeutic interchangeability
15:00	Panos Macheras *Emeritus Professor, National & Kapodistrian University of Athens, Greece*	Biosimilars
15.30	**Coffee break**	
16.00	Panos Macheras *Emeritus Professor, National & Kapodistrian University of Athens, Greece*	Modeling approaches supporting biowaiver applications
16.30	Vangelis Karalis *Faculty of Pharmacy, National & Kapodistrian University of Athens, Greece*	Modeling approaches in bioequivalence - regulatory related issues
17.00	**Round Table Discussion**	
18:00	**End of Workshop**	