

AGENDA WORKSHOP ANMDM- ARPIM - APMGR
14.06.2013
Sala Platinum, Hotel Howard Johnson

8:30 – Welcome Coffee

9:00 – 9:15

Cuvant de deschidere – Dr. Marius Savu - Presedintele ANMDM
Alocutiuni – Laurentiu Mihai – Director Executiv APMGR
Dan Zaharescu – Director Executiv ARPIM

9:15 – 10:30

*Impuritati in substanta activa: ghiduri si implementari; impuritati in substante active noi:
Ghidul CPMP/ICH/2737/99-ICH Q3A (R2)*
Studiu de caz: corelatia profil impuritati-proces de sinteza/stabilitate
Ing. Chim. Sp. Tatiana Cojocariu, Dr. Farm. Constantin Popescu

1. a. *Impactul calitatii medicamentelor asupra rezultatelor clinice*
– Prof. Atholl Johnston - BSc, BA, MSc, PhD, CSci, FBPharmacolS, FRCPath
The London School of Medicine and Dentistry, Queen Mary University of London
Director of Analytical Services International Ltd

1. b. *Gestionarea valorii medicamentelor de-a lungul ciclului lor de viata*
Pierre Anhoury, MD, MPH, Clin. Oncology
Managing Director, Life Sciences, Accenture

10:30 – 11:00

Deficiente frecvent intalnite in evaluarea calitatii medicamentelor de sinteza
Dr. Farm. Carmen Purdel, Ing. Chim. Marina Popescu

11:00 – 11:30 – Pauza de cafea

11:30 – 12:30

Deficiente frecvent intalnite in evaluarea medicamentelor biologice
Biol. pr. Mirela Tavakol, Biol. pr. Madalina Doru
3.a. *Biosimilarele – cerinte calitative si standarde – Biosimilarele – Pioneering the Future!*
Steffen Wagner, CEO Sandoz Romania

12:30 – 13:00

Impactul Regulamentului pediatric asupra dezvoltarii medicamentelor pediatrice
Farm. pr. Nela Vilceanu, Dr. Dana Gabriela Marin

13:00 – 13:45

Serviciul de farmacovigilenta si managementul riscului - Scurta trecere in revista a activitatii
Dr. Daniela Pomponiu
5.a. *Impactul noii legislatii in domeniul farmacovigilentei in UE din perspectiva
producatorilor de generice*
Victoria Bodea, MD, PhD, Head Pharmacovigilance Europe, EU QPPV Ranbaxy

13:45 – 14:15

Schimbari majore in Regulamentul privind variatiile. Gestionarea variatiilor de catre ANMDM

Dr. Simona Badoi, Farm. pr. Nadia Grigoras

14:15 – 14:45 Concluzii si incheierea lucrarilor