

ICDRA (REGULATORS ONLY)

PATIENTS ARE WAITING: HOW REGULATORS COLLECTIVELY MAKE A DIFFERENCE

PRESENT CHALLENGES AND OPPORTUNITIES – ROADMAP FOR THE FUTURE

DAY 2, 30 NOVEMBER 2016, WEDNESDAY		
09:00-10:30	<p>Workshop A: Similar biotherapeutic products Moderators: Enrica Alteri, EMA and Monica Eimunjeze, Nigeria Speakers:</p> <ul style="list-style-type: none"> – Biosimilars: how the EU experience can benefit regulators in other regions - John Borg, Malta – Role of regulators in technology transfer of similar biotherapeutic products - Nurma Hidayati, Indonesia – Biosimilars in African countries: challenges and opportunities - Hudu Mogtari, Ghana – How to get healthcare professionals and patients to accept biosimilars? - Parichard Chirachanakul, Thailand – Public standards for biosimilars - Susanne Keitel, EDQM <p>Discussion Participants:</p> <ul style="list-style-type: none"> – NMRA of Mexico (COFEPRIS) – All speakers 	<p>Workshop B: Regulating medical devices: how to take steps for successful implementation Moderator: Ms Gugu Mahlangu, Zimbabwe Speakers:</p> <ul style="list-style-type: none"> – WHO Global Model Regulatory framework for medical devices including IVDs - Agnes Kijo, Tanzania – The AHWP Playbook - Maura Linda Sitanggang, Indonesia – The new EU regulation for medical devices - Carlo Pettinelli, European Commission – Common rules of the regulating medical devices in the Eurasian Economic Union - Maria Churilova, Russian Federation
10:30-11:00	Coffee	
11:00-12:30	<p>Workshop C: Harmonization and work-sharing in Pharmacovigilance: what does this mean in practice Moderator: Christer Backman, Sweden Speakers:</p> <ul style="list-style-type: none"> – Managing risks: think globally, act locally - Enrica Alteri, EMA – Pharmacovigilance perspectives and developments within the AMRH Initiative – Fred Siyoi, Kenya – Adopt or adapt - What is the better solution for a LMIC? - Djamila Reis, Cape Verde – Pharmacovigilance, BMGF perspective – Raj Long, BMGF, BMGF 	<p>Workshop D: Blood products – old and new challenges Moderator: Jay Epstein, USA and Gugu Mahlangu, Zimbabwe Speakers:</p> <ul style="list-style-type: none"> – Regulation of blood and blood components as essential medicines - Christian Schärer, Switzerland – Implementation of new blood regulation in Ghana - Edwin Nkansah, Ghana – Regulation of antivenoms - James Southern, South Africa

12:30-13:30	Lunch
13:30-18:00	City tours