GLOBAL SUMMIT ON REGULATORY SCIENCE GSRS2017

Emerging Technologies For Food and Drug Safety

Hosted by:

Global Coalition for Regulatory Science Research (GCRSR)

and

Brazilian Health Regulatory Agency (ANVISA)

Brasilia, DF BRAZIL

September 18-20, 2017

Venue:
Parque Cidade (Park City) Convention Center
Brasilia and Brazil

Global Coalition for Regulatory Science Research

ANVISA
Agência Nacional de Vigilância Sanitária

GLOBAL SUMMIT ON REGULATORY SCIENCE GSRS2017

Emerging Technologies for Food and Drug Safety

Program at Glance

	Day 1 Mon, September 18th	Day 2 Tue, September 19th	Day 3 Wed, September 20th
Morning Session	Registration and Poster Setup 8:00 – 4:00 pm Welcome and Introduction 8:30 - 8:40 am **Session 1:** **Global Regulatory Landscape** 8:40 – 12:00pm **Page 2**	**Session 3:** **Emerging Fields and Methodologies** 8:30 – 12:00pm **Page 4**	**Session 5:** **Science-Based Regulatory Practice** Panel Discussion 8:30 – 10:05am **Session 6:** **GSRS/GCRSR: today and tomorrow** 10:30 - 12:00pm Adjournment **Page 6-7**
Afternoon Session	**Session 2:** **Drug and Food Safety** 1:00 – 4:00pm Poster session 4:00 pm – 6:00 pm Presentation time 4:00 – 5:00 pm **Page 3**	**Session 4:** **Standards and Reproducibility** 1:00 – 4:30pm Poster session 4:30 pm – 6:00 pm Presentation time 4:30 – 5:00 pm **Page 5**	

Day 1 Morning Session	
Monday, September 18, 2017	
8:00am – 4:00pm	**Registration and Poster Setup**
8:30am – 8:40am	**Welcome and Introduction** **William Slikker, Jr., Ph.D.,** Director, National Center for Toxicological Research, US Food and Drug Administration , USA

8:40 am – 12:00pm	**Session 1: Global Regulatory Landscape** Session Co-Chairs: **William Slikker, Jr., Ph.D.,** Director, National Center for Toxicological Research, US Food and Drug Administration, USA **Matías Gómez, PharmD,** Director , Office of Monitoring and Risk Management of the National Institute of Drugs of ANMAT, Argentina
8:40am – 8:45am	**Session introduction**
8:45am – 9:15am	**Regulatory perspective in Brazil for food and drug safety** **Jarbas Barbosa da Silva Júnior, Ph.D.,** Director-President, National Health Regulatory Agency (ANVISA), Brazil
9:15am – 9:45am	**Evolving role of pharmacovigilance** **Hans-Georg Eichler, M.D., M.Sc.,** Senior Medical Officer, European Medicines Agency (EMU), EU
9:45am – 10:15am	**Food safety and regulation by European Food Safety Authority (EFSA)** **Hubert Deluyker , Ph.D.,** Scientific Adviser, European Food Safety Authority (EFSA), EU
10:15am – 10:45am	**Regulatory science and emerging technologies in Sub Sahara Africa** **Orish Ebere Orisakwe, Ph.D.,** Toxicology Unit, Department of Experimental Pharmacology, University of Port Harcourt, Nigeria
10:45am – 11:00am	**Break (15 Minutes)**
11:00am – 11:30am	**Regulatory science in Japan** **Haruhiro Okuda, Ph.D.,** Deputy Director-General, National Institute of Health Sciences (NIHS), the Ministry of Health, Labor, and Welfare (MHLW), Japan
11:30am – 12:00am	**Setting and challenges of Good Regulatory Practice (GRP) in Argentina** **Matías Gómez, PharmD,** Director , Office of Monitoring and Risk Management of the National Institute of Drugs of ANMAT, Argentina
12:00pm – 1:00pm	**Lunch**

Day 1 Afternoon Session

Monday, September 18, 2017

1:00pm – 4:00pm	**Session 2: Drug and Food Safety** Session Co-Chairs: **Danitza Passamai Rojas Buvinich, Ph.D.,** National Health Regulatory Agency (ANVISA), Brazil **Kaoruko Tachibana,** Food Safety Commission of Japan, Japan
1:00pm – 1:05pm	**Session introduction**
1:05pm – 1:35pm	**Leveraging a Wealth of Data and New Technologies to Align Regulatory Agencies and the Pharmaceutical Industry toward Reducing Toxicity Associated Drug Development Costs, Timelines and Attrition: 1) Reducing 2 yr Rodent Carcinogenicity Testing, and 2) Deploying Novel Models to Improve Liver Safety Prediction** **Frank Sistare, Ph.D.,** Scientific Associate Vice President, Safety Assessment and Laboratory Animal Resources, Merck and Co., Inc., USA
1:35pm – 2:05pm	**Baseline practices for the application of bioinformatic analyses of genomic data supporting regulatory food safety – a proposal from GCRSR Bioinformatics technical working group** **Gary Van Domselaar, Ph.D.,** Chief, Bioinformatics, National Microbiology Laboratory, Public Health Agency of Canada, Canada
2:05pm – 2:30pm	**Break (25 Minutes)**
2:30pm – 3:00pm	**The EFSA FoodEx2 food classification system and its application in food safety risk assessment** **Davide Arcella, Ph.D.,** Scientific Assistance Directorate, Evidence Management Unit at the European Food Safety Authority (EFSA), EU
3:00pm – 3:30pm	**The challenges of regulating Dietary Supplement: novel foods and nutritional/health claims** **Thalita Antony de Souza Lima,** National Health Regulatory Agency (ANVISA), Brazil
3:30pm – 4:00pm	**Panel Discussion**
4:00pm - 6:00pm	**Poster Session** **Presenter needs to stand by their poster between 4:00pm - 5:00pm**

Day 2 Morning Session

Tuesday, September 19, 2017

8:30am – 12:00pm	**Session 3: Emerging Fields and Methodologies** Session Co-Chairs: **Maurice Whelan, Ph.D.,** Professor, Head, Chemical Safety and Alternative Methods, European Commission's Joint Research Centre (JRC), EU **Tara Barton-Maclaren, Ph.D.,** Manager, Risk Assessment Division Existing Substances Risk Assessment Bureau, Health Canada, Canada
8:30am – 8:35am	**Session introduction**
8:35am – 9:05am	**The integration of emerging data and novel methodologies to support risk assessment under Canada's Chemicals Management Plan** **Tara Barton-Maclaren, Ph.D.,** Manager, Risk Assessment Division Existing Substances Risk Assessment Bureau, Health Canada, Canada
9:05am – 9:35am	**A*STAR Singapore: Innovating alongside regulators for global impact** **Kenneth Lee, Ph.D.,** Senior Director, Agency for Science, Technology & Research (A*STAR), Singapore **Lit-Hsin Loo, Ph.D.,** Assistant Professor, Bioinformatics Institute, Agency of Science, Technology of Research (A*STAR), Singapore
9:35am – 10:05am	**The use of in silico methods for chemical hazard assessment** **Qasim Chaudhry, Ph.D.,** Professor of Food Safety and Innovation University of Chester, United Kingdom
10:05am – 10:30am	**Break (25 Minutes)**
10:30am – 11:00am	**Use of stem cells to assess chemical and drug safety: 3D culture, microphysiological systems and modeling** **William Slikker, Jr., Ph.D.,** Director, National Center for Toxicological Research, US Food and Drug Administration, USA
11:00am – 11:30am	**Incorporating novel methods into integrated approaches to testing and assessment of chemicals** **Maurice Whelan, Ph.D.,** Professor, Head, Chemical Safety and Alternative Methods, European Commission's Joint Research Centre (JRC), EU
11:30am – 12:00pm	**Panel Discussion**
12:00pm – 1:00pm	**Lunch**

Day 2 Afternoon Session

Tuesday, September 19, 2017

1:00pm – 4:30pm	**Session 4: Standards and Reproducibility** Session Co-Chairs: **Weida Tong, Ph.D.,** Director, Division of Bioinformatics and Biostatistics, National Center for Toxicological Research, US Food and Drug Administration, USA **Martha Hugas, Ph.D.,** Head of Biological Hazards and Contaminants Unit, European Food Safety Authority (EFSA), EU
1:00pm – 1:05pm	**Session introduction**
1:05pm – 1:35pm	**Reproducible Toxicogenomics for Regulatory Decision-Making** **Weida Tong, Ph.D.,** Director, Division of Bioinformatics and Biostatistics, National Center for Toxicological Research, US Food and Drug Administration, USA
1:35pm – 2:05pm	**Standards in precision medicine – A China's perspective** **Leming Shi, Ph.D.,** Professor and Director, Center for Pharmacogenomics School of Life Sciences and Shanghai Cancer Center, Fudan University, Shanghai, China
2:05pm – 2:35pm	**Towards reproducible in silico practice via OpenTox** **Barry Hardy, Ph.D.,** Managing Director, Douglas Connect GmbH Technology Park Basel, Basel, Switzerland
2:35pm – 3:00pm	**Break (25 Minutes)**
3:00pm – 3:30pm	**Reproducibility considerations for nanotechnology products for regulatory review** **Anil Patri, Ph.D.,** Director, Division of Nano toxicology, National Center for Toxicological Research, US Food and Drug Administration, USA
3:30pm – 4:00pm	**Medical Dictionary for Regulatory Activities (MedDRA)** **Anna Zhao-Wong, M.D., Ph.D.,** Deputy Director, MedDRA MSSO, USA
4:00pm – 4:30pm	**Panel Discussion**

4:30pm - 6:00pm	**Poster Session** **Presenter needs to stand by their poster between 4:30pm - 5:00pm**

Day 3 Morning Session

Wednesday, September 20, 2017

8:30am – 10:00am	**Session 5: Science-Based Regulatory Practice** Session Co-Chairs: **Steve Ostroff, Ph.D.,** Deputy Commissioner, US Food and Drug Administration, USA **Primal Silva, Ph.D.,** Acting Vice President, Canadian Food Inspection Agency, Canada
8:30am – 8:35am	**Session introduction: questions to panelists**
8:35am – 10:05am	**Panelist:** **Jarbas Barbosa da Silva Júnior, Ph.D.,** Director-President, National Health Regulatory Agency (ANVISA), Brazil **Orish Ebere Orisakwe, Ph.D.,** Toxicology Unit, Department of Experimental Pharmacology, University of Port Harcourt, Nigeria **Matías Gómez, PharmD,** Director , Office of Monitoring and Risk Management of the National Institute of Drugs of ANMAT, Argentina **Martha Hugas, Ph.D.,** Head of Biological Hazards and Contaminants Unit, European Food Safety Authority (EFSA), EU **Frank Sistare, Ph.D.,** Scientific Associate Vice President, Safety Assessment and Laboratory Animal Resources, Merck and Co., Inc., USA
10:05am – 10:30am	**Break (25 Minutes)**

10:30am – 12:00pm	**Session 6: GSRS/GCRSR: today and tomorrow** Session Co-Chairs: **Steve Ostroff, Ph.D.,** Deputy Commissioner, US Food and Drug Administration, USA **Primal Silva, Ph.D**., Acting Vice President, Canadian Food Inspection Agency, Canada
10:30am – 10:40am	**GSRS/GCRSR – The past, present and future** **William Slikker, Jr., Ph.D.,** Director, National Center for Toxicological Research, US Food and Drug Administration, USA
10:40am – 10:50am	**FDA's Office of International Program (OIP) and GSRS/GCRSR** **Carl Sciacchitano, Ph.D.,** Senior Advisor, Office of International Program (OIP) , US Food and Drug Administration, USA
10:50am – 11:00am	**Regulatory science in China and its contribution to GSRS/GCRSR** **Li Bo, Ph.D.,** Director, National Institutes for Food and Drug Control (NIFDC), China Food and Drug Administration (CFDA), China

11:00am – 11:10 am	**An update of the GCRSR Nanotechnology Working group** **Anil Patri, Ph.D.,** Director, Division of Nano toxicology, National Center for Toxicological Research, US Food and Drug Administration, USA
11:10am – 11:20am	**An update from the GCRSR Bioinformatics Technical Working group** **Weida Tong, Ph.D.,** Director, Division of Bioinformatics and Biostatistics, National Center for Toxicological Research, US Food and Drug Administration, USA
11:20am – 11:30am	**GCRSR Cross-Training Working group** **Primal Silva, Ph.D.,** Acting Vice President, Canadian Food Inspection Agency, Canada
11:30pm –	**Closing Remarks and Adjournment** **Steve Ostroff, Ph.D.,** Deputy Commissioner, US Food and Drug Administration, USA