



# Workshop: Genomics in Cancer Risk Assessment

August 27-28, 2009 San Servolo, Venice, Italy



## Parallel Satellite Workshop:

10th International Conference on Environmental Mutagens (ICEM) Aug 20-25 2009 Firenze  
VII World Congress on Alternatives & Animal Use in the Life Sciences Aug 30 -Sept 3, 2009 Rome

## Organizing committee:

Jiri Aubrecht, Pfizer/HESI Genomics Committee  
Raffaella Corvi, European Centre for the Validation of Alternative Methods (EC ECVAM), JRC  
Bernward Garthoff, Bayer CropScience  
Jos Kleinjans, Maastricht University/carcinoGENOMICS  
Anneloes Melman, Maastricht University/carcinoGENOMICS  
Raegan O'Loone, Health and Environmental Sciences Institute (HESI)  
Richard S. Paules, NIEHS/HESI Genomics Committee  
Rene Reijnders, Maastricht University/carcinoGENOMICS

## Program

Thursday, August 27, 2009

- 9:00 am **Welcome and Introduction**  
**Richard S. Paules**, NIEHS, NIH, US
- 9:15 - 9:45 am **Keynote Address I**  
**Elizabeth Mansfield**, US FDA  
*Genomics at the US Food and Drug Administration (FDA)*
- 9:45 - 10:00 am **Break**
- 10:00 - 12:10 am **Session I. Current Approaches in Cancer Risk Assessment for Drugs and Chemicals; Session Chair - Bernward Garthoff**  
**Jan-Willem van der Laan**, EMEA/RIVM, National Institute of Public Health & Environment, The Netherlands  
*Carcinogenic Risk Assessment of Human Pharmaceuticals: A European Regulatory Perspective*  
**Wim de Coen**, European Chemicals Agency, Helsinki  
*REACH Regulation: Overview and Application of Integrated Testing Strategies*  
**Kate Guyton**, US Environmental Protection Agency  
*Consideration of Multiple Mechanisms of Carcinogenesis in Human Health Risk Assessment of Environmental Contaminants*
- 12:10 - 1:10 pm **Lunch**
- 1:10 - 3:20 pm **Session II. In Vivo Approaches in Carcinogen Risk Assessment; Session Chair - Richard Paules**  
**Laura Suter**, Hoffmann-LaRoche, Basel  
*Use of Gene Expression Profiling for the Prediction of Toxicity*



## Program (Continued)

**Hans-Juergen Ahr**, Bayer Healthcare AG

*Carcinogen Specific Expression Profiling In Vivo: Prediction of Carcinogenic Potential?*

**Richard Irwin**, NTP/NIEHS, NIH, US

*Prediction of Hepatocarcinogenic Potential of Chemicals Using Hepatic Transcript Profiles from Prechronic Exposure Data*

**Mark Fielden**, Amgen, US

*Integrating Predictive and Mechanistic Carcinogenomic Biomarkers into Drug Discovery and Development*

3:20 - 3:35 pm

Break

3:35 - 5:45 pm

**Session III. In Vitro Approaches in Carcinogen Risk Assessment;**  
*Session Chair - Jiri Aubrecht*

**Joost H. M. van Delft**, Maastricht University

*In Vitro Liver Models for Genomics Based Cancer Risk Assessment*

**Jiri Aubrecht**, Pfizer, US

*Scientific and Regulatory Challenges in the Development and Application of Toxicogenomic Biomarkers Derived from In Vitro Cell Systems*

**Robert J. Kavlock**, US EPA (ToxCast)

*Developing Predictive Bioactivity Signatures of Carcinogenesis with ToxCast HTS Data*

**Raffaella Corvi**, EC ECVAM, JRC, Ispra

*Validation of Alternative Methods for Genotoxicity and Carcinogenicity Safety Assessment*

6:30 - 7:30 pm

Poster Session

7:30 pm

Welcome Reception

*Friday, August 28, 2009*

8:30 - 10:40 am

**Session IV. Human Carcinogen Risk Assessment;** *Session Chair - Richard Paules*

**Leona Samson**, Massachusetts Institute of Technology, US

*Complex Biological Responses to Carcinogenic Agents*

**Martyn Smith**, University of California, Berkeley, US

*Toxicogenomic Profiling of Exposed Humans to Identify Hazards, MOA, Low-Dose Adverse Effects and Disease Risk*

**Kenneth Ramos**, University of Louisville (USA)

*TBD*

**Soterios Kyrtopoulos**, National Hellenic Research Foundation, Athens  
(the new EU FP7project EnviroGenoMarkers)

*Exploring the Potential of Omics in Population Studies: The EnviroGenomarkers Project*

## Program (Continued)

- 10:40 - 10:55      **Break**
- 10:55 - 12:35 pm      **Session V. 'Omics' and Risk Assessment in the 21<sup>st</sup> Century; Session Chair - Jos Kleinjans**  
**Vera Rogiers**, Free University, Brussels  
*Functional and Stable Culture Models are Key Factors in the Risk Assessment Process of Carcinogens*  
**Jonathan Moggs**, Novartis, Basel  
*Epigenomics - Novel Insights into Mechanisms and Biomarkers for Non-Genotoxic Carcinogenesis*  
**Christopher J. Portier**, NIEHS, NIH, US  
*Findings Pathways Associated with Toxicity*
- 12:35 - 1:45 pm      **Lunch**
- 1:45 - 3:25 pm      **Session VI. Challenges for the Future in Carcinogen Risk Assessment; Session Chair - Raffaella Corvi**  
**John Doe**, ECETOC & Syngenta  
*The Future Risk Assessment for Carcinogenicity for Chemicals and Pesticides*  
**Paul Carmichael**, Unilever, UK  
*The Contribution of 'Omics' into the Cancer Risk Assessment of Cosmetic Ingredients - The In Vitro Challenge*  
**James MacDonald**, Chrysalis Pharma Consulting, US  
*A View of Future Opportunities*
- 3:25 - 3:40 pm      **Break**
- 3:40 - 4:25 pm      **Keynote Address II**  
**Hans Lehrach**, Max Planck Institute for Molecular Genetics, Berlin  
*Omics in the Present and Future of Human Medicine*
- 4:25 - 5:45 pm      **Session VII. Panel Discussion - The Way Forward and the Role of Genomics; Session Chairs - Jiri Aubrecht and Jos Kleinjans**  
**David Rouquie**, BayerCropScience, Sophia Antipolis  
**James S. Bus**, Dow Chemical  
**Nina Hallmark**, ExxonMobil  
**Beatriz Silva Lima**, Natl. Auth. of Med. & Health Products, and University of Lisbon, Portugal  
**David Carlander**, European Food Safety Authority
- Workshop Concluding Remarks - Jos Kleinjans and Jiri Aubrecht**
- 6:30 pm      **Gala Dinner**