



Dagmar Jírová and Horst Spielmann <b>Welcome</b>	U2
Sonja von Aulock <b>Editorial</b>	1
<b>Keynote lectures</b>	
M. Vácha <b>Animals: biomechanisms or evolving organisms on the way to a reflexive thought?</b>	10
M. Goldman <b>The rational use of animals in drug development: contribution of the Innovative Medicines Initiative</b>	10
R. Mokrý <b>European strategy for 3Rs and replacement of animal experiments</b>	10
U. Marx <b>Human-on-a-chip – a paradigm shift from animal testing</b>	11
N. Gillett <b>Industrial perspectives on the 3Rs and animal welfare</b>	11
R. Kolar <b>How long must they suffer? Success and failure of our efforts to end the animal tragedy in laboratories</b>	11
H. Zhengming <b>Future perspectives for alternatives to animal testing in China</b>	12
R. Kavlock <b>Lessons learned from ToxCast and prospects for the future</b>	12
<b>Theme I – New Technologies</b>	
Session I-1: Virtual tissue models	13
Session I-2: High throughput screening (HTS) models	16
Session I-3a: Tissue-on-a-chip / Human-on-a-chip	21
Session I-3b: Regulatory science panel discussion: Human-on-a-chip – Advancing regulatory science through innovation and worldwide networking for alternative testing	23
Session I-4a: 3D liver models	28
Session I-4b: 3D miscellaneous organ models	29
Session I-4c: Novel technology for 3D cell cultures	31
Session I-5: Bioreactors	42
Session I-6: High-content imaging	47
Session I-7: Monitoring (telemetry)	49



---

**Theme II – Predictive Toxicology**

Session II-1:	Pathways approaches in toxicology	53
Session II-2:	Systems biology	61
Session II-3:	Computational modeling and chem-informatics	64
Session II-4:	Risk assessment	70
Session II-5:	Discussion session: Application in decision making and testing strategies	81
Session II-6:	Updates on research activities from the USA and Japan	85
Session II-7:	Update from Europe – Alternative testing strategies program	88
Session II-8:	Meeting new regulatory challenges following the cosmetic ingredients ban – Cosmetics Europe's research programme on alternatives	91
Session II-9:	Exposure	93
Session II-10:	Topical toxicity	97
Session II-11:	Repeated dose toxicity	111
Session II-12:	Skin sensitization	115
Session II-13:	Endocrine disruption	130
Session II-14:	Reproductive & developmental toxicology	134
Session II-15:	Genotoxicity / Carcinogenicity	139
Session II-16:	Inhalation toxicology	144
Session II-17:	Ecotoxicology	149

---

**Theme III – 3Rs in Academia & Education**

Session III-1:	3Rs in academic education, training programs and anticipated needs	153
Session III-2:	Funding agencies and funding programs	159
Session III-3:	Innovative teaching and training tools	161
Session III-4:	Implementing the "Montreal Declaration on the Synthesis of Evidence"	167
Session III-5:	Sharing best practices in LAS education and training	168
Session III-6:	Discussion: The role of journals in implementing the 3Rs	170

---

**Theme IV – Communication, Dissemination and Data Sharing**

Session IV-1:	Information requirements on project proposals	172
Session IV-2:	Scientific reporting standards ( <i>in vivo</i> and <i>in vitro</i> )	173
Session IV-3:	Retrospective analysis / non-technical summaries (2010/63)	175
Session IV-4:	Information systems and databases	177
Session IV-5:	Intellectual property, data sharing and data ownership	181

---

**Theme V – Efficacy and Safety Testing of Drugs and Biologicals**

Session V-1:	Pathways based assays in drug development	183
Session V-2:	Disease models <i>in vivo</i>	188
Session V-3:	Potency testing of human and veterinary vaccines	192
Session V-4:	Medical devices and biologicals	200




---

**Theme VI – Human Relevance**

Session VI-1: <i>In vitro</i> disease models	208
Session VI-2: Use of stem cells in screening	216
Session VI-3: Human biomarkers	219
Session VI-4: Absorption, distribution, metabolism and excretion (ADME)	222
Session VI-5: Epithelial biobarriers	227

---

**Theme VII – Ethics**

Session VII-1: Ethical and normative aspects of human-based approaches	232
Session VII-2: Ethics of using animals	233
Session VII-3: Ethical evaluation	238
Session VII-4: Distress evaluation	244
Session VII-5: Benefit evaluation	246

---

**Theme VIII – Refinement and Welfare**

Session VIII-1: Non-human primate use and welfare	249
Session VIII-2: Best practice welfare approaches – Mouse	253
Session VIII-3: Humane principles in experimental techniques and benefits of 3Rs	263
Session VIII-4: Avoidance of severe suffering	266
Session VIII-5: Culture of care	268
Session VIII-6: Transgenic animals – Approaches to reduction and refinement in the production and use of GM mice	271

---

**Theme IX – Global Cooperation, Regulatory Acceptance and Standardization**

Session IX-1: Activity updates from international scientific societies	274
Session IX-2: Animal welfare implementation across the world	278
Session IX-3: Activity updates from international validation centres	282
Session IX-4: Novel approaches to validation	285
Session IX-5: Regulatory acceptance of alternatives	287
Session IX-6: Breaking down barriers and promoting international cooperation on 3Rs	290
Session IX-7: Harmonising ways to capture pathway-knowledge in toxicology	295
Session IX-8: Towards harmonisation in the application of alternative approaches within chemical regulation and management	297
Session IX-9: Establishing criteria for an independent 3R-index: “Access to 3R’s”	298

---

**Theme X – Additional sessions**

Session X-1: Young Scientists Travel Award Short Presentations	299
Session X-2: Cosmetics around the world	302
Session X-3: Special lectures	305

Author Index	307
Imprint	321