Tuula Heinonen, Professor, ERT, Ph.D. (toxicology)
e-mail: tuula.h.heinonen@gmail.com

1. Education

Professor Heinonen, Ph.D. is an European Registered toxicologist having extensive theoretical education and over 25 years´ experience in research, test method and testing strategy development, molecular and animal toxicology, project management, drug and diagnostic development in industry and academia. She was appointed as Adjunct Professor at the University of Helsinki (biochemistry, 1993) and University of Turku (biochemical toxicology, 1984). She gained doctor of philosophy in Faculty of Natural Sciences, University of Turku, Finland (1983) and M.Sc. in the same university (1979). Further she has passed successfully several international and national courses on leadership, project management, team building, lecturing/presentation, negotiation skills, drug development or regulatory related specific issues. One to mention is MMPI (Managing Medical product Innovations) degree, SIMI Copenhagen, Denmark, 2003.

2. Practical experience

Practical experience covers biomedical research, drug development, test method development and validation, acting as a project manager and R&D director in pharmaceutical industry, Study director in GLP and non-GLP tests (regulatory, mechanistic, in vitro and in vivo), writing study protocols and reports, investigators´ brochures, clinical trial protocols to be included into dossiers. Professor Heinonen has been responsible for planning, executing and reporting animal and in vitro toxicological and pharmaceutical safety and mechanistic investigations for new small molecules, biologicals and chemicals including biocides. In addition, she has been responsible for Phase I and II clinical trials and for whole drug development projects when acting as project manager and R&D director. Professor Heinonen has participated in pre-IND, NDA and scientific consultation meetings at FDA, EMA and some European pharmaceutical regulators. The therapy areas cover cardiovascular, neuronal, anti-infective, cancer and HRT.

She has also been responsible to set up and be director of OECD-GLP laboratories in pharma industry and academia (Tampere University, FICAM). The industry experience covers in addition to pharmaceutical industry (almost 20 years) in different positions (toxicologist, project manager, department head, R&D director), laboratory instrumentation and diagnostic developments (project manager, head of laboratory, marketing manager), too.

In academia she has been responsible to establish the OECD-GLP-accredited Finnish Centre for Alternative Methods (FICAM) and to act its director. The main field of FICAM was to develop human cellular tissue type of models and tests for biomedical research, drug and toxicity testing, provide education and training and testing services to academia and industry. Further, professor Heinonen´s role was to disseminate Next Generation Risk Assessment principles.

Tuula Heinonen, Professor, ERT, Ph.D. (toxicology)
e-mail: tuula.h.heinonen@gmail.com

3. Scientific and societal impact

3.1. Number of publications: **75** in international peer reviewed journals, **9** peer reviewed articles in scientific and conference books, **5** non-refereed scientific articles**,** personally been responsible for conduct and report of following studies according to the relevant regulatory requirements: **2** phase IIa (healthy volunteers) studies and **1** phase IIb study (patient study) clinical studies, **42** GLP (Good Laboratory Practice) non-clinical studies in pharma industry; **10** Mechanistic non-clinical studies (mostly in vitro) in pharma industry.

3.2. Supervision experience

Professor Heinonen has acted as tutor for **5** Ph.D. students and **5** M.Sc. students, being expert reviewer for **10** M.Sc, Ph.D. thesis and title of docent (adjunct professorships). She has acted as opponent for **5** Ph.D. thesis. She has acted as PM in vast amount of R&D drug development and other projects and as Study Director in several toxicological (Good Laboratory Practice) and mechanistic studies.

3.3. Chair or member of organizing committee of several international congresses such as 10th IUTOX, 11–16, July,2004, Tampere, Finland; EUSAAT2012-ETS Conference, September, 4-7, 2012, Linz, Austria; EUSAAT2013-ESNATS Conference, September, 15-18, 2013, Linz, Austria; 9th World Congress on Alternatives and Animal Use in the Life Sciences, August, 24-28, 2014, Prague, Czech Republic; 10th *World Congress on Alternatives* and Animal Use in the Life Sciences, 20-24 August, 2017 Seattle, USA

3.4. Key positions of trust, expert positions and assignments include e.g. Expert in ECVAM, ECHA, EFSA, OECD or other´s working groups, Finland´s PARERE person (Preliminary Assessment of Regulatory Relevance) for EURL-ECVAM, EPAA Mirror group member, member of National scientific advisory and project authorisation committees (Directive2010/63/EU), Associate Editor of several scientific journals, positions of trust in scientific societies including ecopa, EUROTOX, SSCT, Fincopa, Finnish Society of Toxicology. Mentor in SPARK Finland and HIH Helsinki (Health Incubator Helsinki).

4. Teaching and lecturing

Professor Heinonen is experienced speaker in international and national meetings and conferences. In addition she has been lecturing in different universities on how to use NAMs and in vitro methods in scientific and regulatory research. Further, she has also been lecturing on Good Laboratory Practice and how to develop in vitro models to meet regulatory acceptance.