FOCUS

VitroScreen Seminar on Substance Based Medical Devices BIOCOMPATIBILITY

Currently, there are no harmonized standards and common specifications available to drive the transition from the MD Directive 93/42/CEE to the EU MD **Regulation 2017/745 (MDR)** and a large number of questions arise from the industry as well as from the Notified bodies involved in the CE marking process.

The aim of the seminar was to bring together **Notified Bodies** (Dr R. Marcoaldi and Dr R. Feliciani – ISS; Dr A. Frabetti - Kiwa Cermet; Dr M. Magni – Italcert), **Toxicologists** (Prof. E. Corsini - UNIMI), Members of **Working Group of ISO/TC 194** (Dr C. Pellevoisin), **Experts in Regulatory Toxicology** and **Regulatory affairs specialists** to share their experience, expertise and vision on the future of MD biological evaluation.

The seminar offered a unique oppurtunity for an update on the evolution of standard **ISO 10993**, particularly **Part 1** on the biological safety evaluation within a risk management process and future **Part 23** on the assessment of the irritation potential of MD extracts using reconstructed human tissues. Importantly, it was discussed the applicability of OECD validated *in vitro* methods and non-animal testing approaches to the assessment of **skin irritation** and **skin sensitization potential** of MD extracts and other Devices.

These alternative methods may help the MD sector to move further and comply with new safety requirements requested by the MDR and '**Three Rs**' Principles addressed in EU Directive 2010/63.