

EuroLabFocus News

The 3rd EFLM-UEMS Congress

Laboratory Medicine at the Clinical Interface



The Association for
Clinical Biochemistry &
Laboratory Medicine
www.acb.org.uk



Liverpool, UK • 7-10 October 2014

Issue 15 • August 2014

Symposium Spotlight: Clinical implications of regulation, or the lack, on implementation

Wednesday 8 October 2014, 0845 - 1045

The impact of poorly defined regulatory frameworks for medical devices and technologies was most clearly exposed recently through the PIP breast implants health scare in which unauthorised silicone fillers had been granted European safety certificates. As highlighted by Sir Bruce Keogh (NHS England Medical Director) "... *the current regulatory framework doesn't do enough to support consumer rights or patient safety*". For *in vitro* diagnostic technologies is a CE-mark enough assurance of clinical efficacy? Should people and patients be offered greater assurance that devices bought over the counter, via the internet or mainstream manufacturers do what they say on the tin? Should there be tougher regulations on who can provide healthcare-related services?

This symposium presents opportunities to hear how standards are being addressed by industry, laboratories and national governments. We are delighted to welcome **Professor Linda Thienpoint** from the University of Ghent, Belgium, whose theme will be the impact of the failure to implement IVD standards and her belief that the system needs to be rebuilt from scratch. Her main research interests focus on development/implementation of standardisation/harmonisation concepts, and improvement of clinical laboratory measurements. In this area, she has published over 150 peer reviewed papers.



Professor Linda Thienpoint

Joining her to give an industry perspective is **Jesus Rueda Rodriguez** who is head of the regulatory team of the European Diagnostics Manufacturing Association. He ensures EDMA's active participation in the regulatory debates that affect IVDs in the EU. He is also involved in work at the international level, acting as the EDMA representative to the WHO and ISO, as well as a liaison to other associations on regulatory matters. Finally, **Dr Michel Vaubourdolle**, Head of the Department of Laboratory Medicine at Saint-Antoine Hospital, Paris and author of the 2012 book *Recommandations pour l'accréditation des laboratoires de biologie médicale* gives his perspective on the contribution of ISO 15189 to quality of services provided by pathology.



Dr Michel Vaubourdolle

Organisers

UEMS Union of European Medical Specialists
EFLM European Federation of Clinical Chemistry
& Laboratory Medicine
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