

Fimea Annual Seminar for GLP-Test Facilities and Applicants

**Venue: Finnish Medicines Agency Fimea (Meeting room Ursa 1st floor),
Mannerheimintie 103 b, Helsinki, Finland**

Date: 16.9.2014, 9.00 – 15.30

Preliminary programme:

Registration and coffee (9.00 – 9.30)

Opening (Anneli Törrönen, Ministry of Social Affairs and Health)

Short presentations of authorities in different countries

GLP News (Pirkko Puranen, Fimea)

Developing regulatory recognized *in vitro* –methods and PARERE- process (Tuula Heinonen, Finnish Centre for Alternative Methods, FICAM)

Questions, discussion

Short break (11.00 – 11.15)

Multi-site studies (Paula Korhola, Fimea)

Lunch break (12.00 – 12.45)

Out-sourcing of IT-activities (Kari Lönnberg, Fimea)

Electronic signature (Petri Pääkkönen, Fimea)

Questions, discussion

Coffee break (13.30 – 14.00)

GLP for biologicals and advanced therapies (ATMPs) (Tiina Palomäki, Fimea)

Certification of quality and/or non-clinical data for ATMPs (Paula Salmikangas, Fimea)

Discussion

End of the seminar (15.30)