

Satellite Symposium – PAGE Meeting 2016

Auditorium of the Faculty of Pharmacy, University of Lisbon

PKPD modelling of QT interval – Regulatory Perspective and impact of ongoing revision of ICH S7B and E14 guidelines

Final Program

13:15 – 13:30 h - Welcome and introduction by the chairs

Chairs: Oscar Della Pasqua and Vincent Dubois

13:30 – 13:55 h - QTc prolongation and characterisation of torsadogenic effects of drug candidates

Speaker: Derek Leishman, Eli Lilly, USA

13:55 – 14:25 h – Overview of the ICH E14 guideline – perspectives from industry

Speaker: Charles Benson, Eli Lilly, USA

14:25 – 14:55 h - Overview of the ICH E14 guideline and scientific rationale for using C-QTc modelling as primary analysis

Speaker: Jiang Liu, CDER, FDA, USA

14:55 -15:25 h - Modelling the C-QTc relationship with Case Examples (1)—Technical Discussion of Model, Model Selection, Goodness-of-fit, and Model Predictions

Speaker: Anne S Chain, Merck, USA

15:25 -15:50 h - Coffee break

15:50 – 16:15 h - Modelling the C-QTc relationship with Case Examples (2)—Technical Discussion of Model, Model Selection, Goodness-of-fit, and Model Predictions

Speaker: Georg Ferber, Statistik Georg Ferber GmbH, Switzerland

16:15 -16:45 h - Regulatory evaluation of CQTc modelling results

Speaker: Flora Musuamba, Modelling & Simulation Working Group, EMA, UK

16:45 -17:20 h - Round table

All speakers

17:20 -17:30 h - Wrap-up and closure

[Register for the symposium using this link](#)