

Workshop title:

Assessing credibility of *in silico* trials for regulatory purposes

Organizers

Marco Viceconti, University of Bologna

Liesbet Geris, University of Liege

Short Description

The use of modelling and simulation to evaluate the safety and efficacy of new medical products, usually referred to as In Silico Trials, is moving from the research labs to a concrete industrial reality. Probably the biggest barrier in this translation from research to innovation is the lack of a specific regulatory science to evaluate the credibility of this predictive model when used to assess medical products such as drugs or medical devices. This workshop provides an update on the latest developments in the field, by some of the leading experts.

Contents

Credibility of In Silico Trials for orthopaedic devices following ASME VV-40 – Jeff Bischoff (Zimmer). VV&UQ and applicability: a theoretical framing – Marco Viceconti (UNIBO). Verification of mechanistic Agent-Based Models – Francesco Pappalardo (UNICT). Credibility of In Silico Trials for assessing tissue engineering constructs – Liesbet Geris (ULIEGE). A taxonomy of possible contexts of use for In Silico Trials – Luca Emili (IST). Credibility of In Silico Trials: a regulatory perspective - Pras Pathmanathan (FDA).

CVs of the Organizers

**Liesbet Geris** is Collen-Francqui Research Professor in Biomechanics and Computational Tissue Engineering at the university of Liège and KU Leuven in Belgium, and current Director of the VPH Institute for *in silico* medicine.

**Marco Viceconti** is Full Professor of Industrial Bioengineering at the University of Bologna, and Director of the Medical Technology Lab at the Rizzoli Institute where he leads the In Silico Medicine Research Unit.

