WORKSHOP ON ASSESSING CREDIBILITY OF IN SILICO TRIALS FOR REGULATORY PURPOSES

Workshop 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.

Organisers:
Marco Viceconti, University of Bologna  Liesbet Geris, University of Liege

Program

15:40 – 16:05  Credibility of In Silico Trials for orthopaedic devices following ASME VV-40 – Jeff Bischoff, Zimmer Biomet
16:05 – 16:30  Verification, validation, uncertainty quantification and applicability: a theoretical framing – Marco Viceconti, University of Bologna
16:30 – 16:55  Verification of mechanistic Agent-Based Models – Francesco Pappalardo, University of Catania

16:55 – 17:00  Break

17:00 – 17:25  Credibility of In Silico Trials for assessing tissue engineering constructs – Liesbet Geris, University of Liege
17:25 – 17:50  A taxonomy of possible contexts of use for In Silico Trials – Luca Emili, In Silico Trials Technologies
17:50 – 18:15  Credibility of In Silico Trials: a regulatory perspective - Pras Pathmanathan, FDA