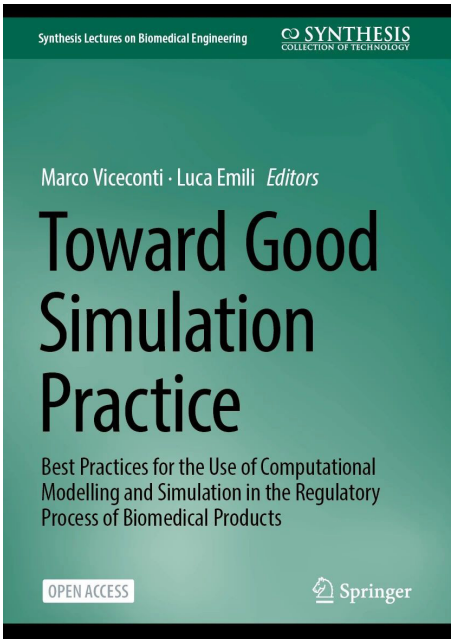
InSilicoTrials

NEWS ANNOUNCEMENT - FOR IMMEDIATE RELEASE

Launch of Ground-Breaking "Toward Good Simulation Practice" Book to Set New Standards in Biomedical Simulation



The publication of ***"Toward Good Simulation Practice - Best Practices for the Use of Computational Modelling and Simulation in the Regulatory Process of Biomedical Products"***, now available in open access via Springer Nature, is an exciting development for the field of in silico medicine. This comprehensive guide, edited by Prof. Marco Viceconti - chair of industrial bioengineering at the Alma Mater Studiorum (University of Bologna) and Luca Emili - CEO of InSilicoTrials' Technologies, is a cornerstone toward standardized practices in **Computational Modeling and Simulation** (**CM&S**) within the biomedical regulatory process.

The pharma and medical device companies are increasingly adopting CM&S to accelerate and amplify medical innovation, reportedly reducing the cost and time of specific R&D activities by up to 90%, without compromising patient safety. CM&S is also a very promising technology into the broader narrative of advancing regulatory science and healthcare innovation.

The book is a product of an extensive collaboration guided by the In Silico World Consortium, with key contributions from the Avicenna Alliance, VPH Institute, and experts from the FDA, advocating for the strategic use of CM&S as a regulatory decision support tool for drugs and medical devices. It aims to forge a clear, harmonized terminology, starting from "in silico (clinical) trials" to "in silico Methodology" for expanding regulatory discussions.

InSilicoTrials Technologies

Riva Grumula 2,
34123 Trieste, Italy

info@insilicotrials.com
www.insilicotrials.com

The book underscores the necessity for guidelines akin to the GxP standards, yet specifically tailored for in silico methodologies. It leverages the ASMEV&V40 – 2018 standard as a model, proposing a consensus-driven framework to support CM&S with good practices applicable across the spectrum of medical solutions.

A highlight of this publication is the **collaboration of** a team of **13 FDA** CM&S experts who provided chapter-by-chapter feedback and the insightful foreword by Pras Pathmanathan (Office of Science and Engineering Laboratories, Center for Devices and Radiological Health, FDA). This partnership illustrates the proactive engagement between regulatory agencies and the scientific community to foster advancements in medical product development.

This publication is a milestone in the in silico field, contributing to the maturation of CM&S for medical products; it will stimulate further conversations among stakeholders and eventually contribute to the development of community-accepted practices.

Download the book and discover more about Good Simulation Practice.

About the editors

Marco Viceconti has significantly contributed to in silico medicine, introducing the concept with the first European research roadmap in 2006 and founding the VPH Institute to coordinate the research community. He also established the Avicenna Alliance, advocating for the biomedical industry in this field, and led the Insigneo Institute for in silico Medicine for seven years. Recognized as a fellow of the UK Royal Academy of Engineering and a member of the World Council of Biomechanics, Viceconti's work, including 368 papers with an H-index of 52, has earned him the Huiskes Medal for Biomechanics in 2021.

Luca Emili is the founder and CEO of InSilicoTrials Technologies, a platform facilitating the use of modeling and simulation in healthcare and life sciences. Prior to this, he was the CEO of Emaze, a cybersecurity firm that specialized in automated security analysis for complex networks. He is actively involved in several advisory roles, (Cloud Security Consultative Group at EMA, Co-chair of Avicenna Alliance's Good Simulation Practice (GSP) Task Force and member of the committee for the adoption of In Silico Medicine of the Italian Ministry of Health.

InSilicoTrials Technologies

Riva Grumula 2,
34123 Trieste, Italy

info@insilicotrials.com
www.insilicotrials.com

InSilicoTrials