Advancing Regulatory Science Through Integrative Engineering with COMSOL Multiphysics® Software Modeling

G. Zhang[1]

[1]Department of Bioengineering, Institute for Biological Interfaces of Engineering, Clemson University, Clemson, SC, USA

Abstract

The US Food and Drug Administration (FDA) faces significant challenges in its regulatory approval processes due to a lack of relevant science, and many practices are limited by laws enacted in the previous century [1]. Therefore, in recent years, the FDA has identified the need for advancements in regulatory science and innovation.

In a broader sense, advancing regulatory science is not just the responsibility of the FDA, but is in actuality a collective effort that belongs to the entire scientific community and society as a whole [2]. Traditionally, investigative approaches were compartmentalized, and are no longer sufficient for dealing with the unknowns and uncertainties of the real world. A 2014 report by the National Academies of Science, Engineering, and Medicine (NASEM) calls for the convergence of insights and approaches from originally distinct fields including the life sciences, physical sciences, and engineering in order to address complex problems [3].

To contribute to advancing regulatory science, my group has been exploring ways to use multiphysics-based mathematical modeling to provide a nonreductive and nondestructive, yet analytical and investigative means to address real-world problems. COMSOL Multiphysics® software provides practical tools for mathematical modeling allowing us to investigate and better understand our surroundings in an integrative way. We use the COMSOL® software to solve coupled, multiphysics problems that are not only mechanical, but also electrical, thermal, chemical, and biological in nature, which behave according to the governing laws of thermodynamics, chemistry, biology, and physics [4].

In this talk I will demonstrate how the COMSOL Multiphysics® software along with various add-on modules has helped us to gain better insight into numerous test standards for their improvement. Along the way, I will also highlight my views and recommendations on the crucial role of integrative mathematical modeling in facilitating convergence in our pursuit of innovation.

Reference

1. “The Cure in the Code – How 20th Century Law is Undermining 21st Century Medicine.” Peter Huber, Basic Books, 2013.

2. “Advancing the Discipline of Regulatory Science for Medical Product Development: An Update on Progress and a Forward-Looking Agenda: Workshop Summary.” The National Academies Press, Washington, DC. 2016.

3. “Convergence: Facilitating Transdisciplinary Integration of Life Sciences, Physical Sciences, Engineering, and Beyond.” The National Academies Press, Washington, DC. 2014.

4. “Introduction to Integrative Engineering – A Computational Approach to Biomedical Problems.” Guigen Zhang, CRC Taylor & Francis Group, 2017.