Computational Modeling in the Biomedical Industry – Skills, Trends, and the FDA

ASME BED Mini-Symposium and Virtual Networking Event

Agenda:

Wednesday, March 13th, 2024 6:00 – 8:00 PM Eastern Time Zone	
6:00 – 6:10 PM (10 min)	Introductions. Each participant will be provided with an opportunity to introduce themselves and briefly tell the group about the nature of their work.
6:10 – 6:20 PM (10 min)	Presentation by Martin Tanaka on ASME's Industry Committee and its mission. Martin has a PhD in biomedical engineering and over 11 years of experience designing commercial products in industry. He is interested in regulatory science and spends summers as a scholar in residence at the FDA (2022, 2024, & 2025). He will introduce the industry committee and share its mission to support engineers working in the biomedical industry by providing a mechanism for professional engagement, professional development, and engineering community outreach.
6:20 – 6:50 PM (30 min)	Keynote Presentation by Marc Horner. Highlight of the ASME V&V40, "Assessing Credibility of Computational Modeling through Verification and Validation: Application to Medical Devices" with a focus on how computational modeling may be used when seeking FDA approval.
6:50 – 7:30 PM (40 min)	Small group discussions. About two weeks before the event, we will ask participants to answer a few questions to collect information needed to form and place people into discussion groups. Small groups will consist of 4-6 participants and include a group moderator (one of the participants). Each member will be instructed to share with the other members of the group one thing that they do well and one area that they would like to improve. Breakout rooms will be formed in Zoom and participants assigned to the rooms. Participants who did not send prior information will be assigned to an existing room by the co-chairs.
7:30 – 7:40 PM (10 min)	Groups will briefly present a highlight from their discussion. A representative from each group will be given the opportunity to tell the event participants about one item discussed by their group. A PowerPoint template will be provided to each group and the representative can share their screen.
7:40 – 8:00 PM (20 min)	Discussion by entire group on any of the highlight points. Finally, the event will conclude with a free form discussion about any of the highlight topics presented. This will be moderated by the event co-chairs.
8:00 – 9:00 PM Overflow	Conversations after the event (undefined). We realize that some may want to continue talking after the event ends (like talking in the hall after a workshop). To accommodate this, the Zoom meeting will be kept open after the event ends.

Sponsoring Committee: Industry Committee

Event Chair: Martin Tanaka PhD, PE, Professor at Western Carolina University

Event Co-Chair: Lance Frazer PhD, Senior Research Engineer at Southwest Research Institute

Keynote Speaker: Mark Horner PhD, Distinguished Engineer, ANSYS

Abstract: This event will provide engineers working in the biomedical industry with knowledge of the latest developments at the FDA and the use of computational modeling. It will also be an opportunity to network with engineers who work at different companies.