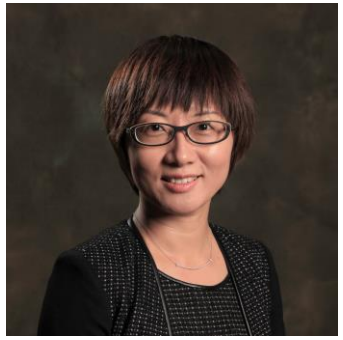
FDA/MDIC
Symposium on Computational Modeling and Simulation

Generating Regulatory In Silico Evidence

Panel Discussion: Opportunities & Challenges for CM&S of Medical Devices

Tuesday, April 16th
2:00 PM – 3:00 PM



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#ModSim2024

MDIC Medical Device Innovation Consortium

Opportunities & Challenges for CM&S of Medical Devices

Where are the biggest **opportunities** throughout *product lifecycle*?

- Early Concept Development
- New Product Development
- Regulatory submission
- Research and Marketing
- Post market surveillance

Opportunities & Challenges for CM&S of Medical Devices

- What *types of CM&S* has the biggest **opportunities**?
  - Physical testing simulation
  - Surgical procedure simulation
  - Manufacturing process simulation
  - Intra-op simulation and clinical decision making
  - *In vivo* post-op simulation
  - AI/ML combined with CM&S
  - Other

Opportunities & Challenges for CM&S of Medical Devices

- Where are the biggest *business* **challenges** for CM&S?
  - Budget and resource
  - Recruitment and employee training
  - Interactions with cross-functional teams
  - CM&S method development
  - Credibility assessment

Opportunities & Challenges for CM&S of Medical Devices

- Where are the biggest *technical* **challenges** for CM&S?
  - Solvers
  - Geometries
  - Material properties
  - Boundary and loading conditions
  - Interaction properties
  - Outputs
  - Model development
  - Other