

SPECIAL INTEREST GROUP

2017 BMES/FDA

FRONTIERS IN MEDICAL DEVICE CONFERENCE

Innovations in Modeling and Simulation:
Advancing Translational Science

College Park Marriott Hotel & Conference Center | University of Maryland
May 16 - 18, 2017



2017 BMES/FDA

Frontiers in Medical Devices Conference

**Innovations in Modeling and Simulation:
*Advancing Translational Science***

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TABLE OF CONTENTS

Thank you to our Sponsors & Exhibitors.....Page 2 - 3

Welcome Letter.....Page 5

Plenary Speakers.....Page 6 - 7

Schedule-at-a-glance.....Page 8 - 13

Poster Abstracts.....Page 14 - 16

Sponsor Seminars.....Page 17 - 20

Sponsors & Exhibitors.....Page 21 - 23

WELCOME!

Welcome to the 3rd annual BMES/FDA Frontiers in Medical Devices Conference, the yearly meeting for the BMES Special Interest Group on Medical Devices. The purpose of this group is to promote interdisciplinary research, communication, cooperation and education through balanced partnership among industry, academia, and government experts interested in the process of developing and translating safe and effective medical devices for society's good.

This year's conference theme is "Innovations in Modeling and Simulation: Advancing Translational Science." We selected this theme to highlight the role of modeling and simulation along the various steps along the translational pathway. This year's tracks will include the following aspects of the translational science process: Ideation, Pre-clinical, Product Development, Clinical Study and Market Release and Post-Market.

To kick-off each day, you'll hear keynote addresses from Vivian Riefberg, MBA (McKinsey & Company), Urs Wyss, Ph.D., P.E. (University of Manitoba) and Gary An, M.D. (Biophysics Institute, University of Chicago). Additionally, 34 podium speakers and 45 poster presenters were selected through a rigorous abstract review process to present their research in the topic areas described above.

Finally, you'll have the opportunity to get unique perspectives from experts in three distinct areas including Academia/NSF, Industry and FDA related to the topic of "How Good is Good Enough?" when it comes to the use of modeling and simulation for medical device development. We hope that the conference will continue to foster collaboration and innovative research to impact the translational science process.

Thank you for your participation and continued interest in our conference and special interest group.

Leadership Committee

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Leonardo Angelone, US FDA
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Adam Himes, Medtronic
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Melissa L. Knothe Tate, Univ. of New South Wales
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BMES SIG Treasurer

PLENARY SPEAKERS



**Vivian Riefberg, MBA - Senior Partner,
McKinsey & Company**

In her role as leader of McKinsey's Public Sector Practice in the Americas, Vivian works closely with state and federal government agencies to improve their performance and help them better fulfill their missions. She also serves on the leadership team of the McKinsey Center for Government and our Healthcare

Systems & Services Practice. She has more than two decades of experience advising institutions in both the public and private sectors on strategy, organization, and operations.

An expert on health economics, Vivian also helps direct McKinsey's work on the impact of government reforms on the US healthcare system, in collaboration with the McKinsey Center for US Health System Reform.

Since joining McKinsey in 1987, Vivian has led major performance-improvement programs for public, private, and nonprofit clients. She is a regular keynote speaker at public-sector and healthcare conferences. She serves on the board of directors of the Partnership for a Healthier America, a nonpartisan organization that mobilizes broad-based support for efforts to solve child obesity.

Vivian is a former member of the National Institutes of Health (NIH) Clinical Center Board of Governors and the NIH Advisory Board for Clinical Research. She is also a former board member of Mentors, Inc., a program for Washington, DC-area public-high-school students.

**Urs Wyss, Ph.D., P.E. - Professor of Mechanical
Engineering at University of Manitoba and former
VP of R&D for Sulzer Orthopaedics, Centerpulse
Orthopaedics and Zimmer**

As a former VP of R&D for Sulzer Orthopaedics, Centerpulse Orthopaedics and Zimmer, Professor Wyss has had an exciting career at the interface of academics and industry. He has actively participated and led computational modeling projects, from ideation through post market surveillance including recall of orthopaedic devices.



PLENARY SPEAKERS



Gary An, M.D. - Professor of Surgery, Senior Fellow Biophysics Institute, University of Chicago

Prof. Gary An has over 10 years experience in the computational modeling of inflammation as it relates to sepsis, being the first researcher to publish on the use of agent-based modeling, a computer simulation method, in the area of acute inflammation and sepsis. He has partnered with collaborators at the University of Pittsburgh to expand and extend the use of mathematical modeling in the area of sepsis and acute inflammation and wound healing. More recently he worked with John Alverdy at the University of Chicago on the role of host-pathogen interactions in the gut with respect to surgical diseases, such as gut-derived sepsis, necrotizing enterocolitis and anastomotic healing. He actively develops means of integrating regulatory network models with

metabolic flux balance models. He is a co-Founder of the Society for Complexity in Acute Illness (www.scai-med.org), a scientific society designed to bring together laboratory scientists, clinical investigators and computational researchers to study systemic inflammation and acute disease. He serves as an external collaborator at the National Center for Biomedical Ontology (<http://www.bioontology.org/node/630>), aiming to extend agent-based modeling to link to bioinformatic knowledge representation as seen in bio-ontologies with the goal of facilitating the use of dynamic computational modeling as a means of biomedical knowledge representation and communication. He developed and directs the Fellowship in Translational Systems Biology at the University of Chicago, a 1-2 year program intended to train biomedical researchers in computational methods of dynamic knowledge representation and agent-based modeling in conjunction with a basic science lab. He also works on the use of artificial intelligence systems to aid in the semi-automation of model development. He is also involved in the application of evolutionary and ecological perspectives on the dynamics of the host-pathogen interactome, and, more basically, on foundational questions of biology.



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Advancing Translational Science

TUESDAY, May 16th

7:30am - 5:00pm	Registration & Information	Chesapeake Foyer
7:30am - 8:30am	Breakfast	Chesapeake Ballroom
8:30am - 9:00am	Welcoming remarks	Potomac Ballroom
9:00am - 10:00am	Plenary Speaker: Vivian Riefberg, McKinsey & Company	Potomac Ballroom
10:00am - 10:20am	Break	Chesapeake Ballroom
10:20am-12:30pm	TRACK I: IDEATION	Potomac Ballroom
	Chairs: 1. Andrew Drach (U.T. Austin) 2. Jeremy Rice (IBM)	
	Speakers:	
	• Electrodynamic modeling of bacterial biofilm impedance sensing <i>Ryan Huiszoon, University of Maryland, College Park</i>	
	• A Quantitative Study of the Effect of Wedge Deformity on Thoracic Volume by Virtual Scheuermann's Models <i>Po-Chih Lee, University of Minnesota</i>	
	• Optimizing an Endoscopic Bioimpedance-Based Surgical Margin Assessment Device <i>Ryan Halter, Dartmouth College</i>	
	• Biomechanical Effects of Femoral Component Axial Rotation in Total Knee Arthroplasty <i>Mohammad Kia, Hospital for Special Surgery</i>	
	• Leaflet Geometry and Anisotropy of Bioprosthetic Heart Valves: Do They Matter? <i>Rana Zakerzadeh, The University of Texas at Austin</i>	
	• Computer-assisted Design of Microfluidics <i>Junchao Wang, University of California, Riverside</i>	
• Optimizing the Cardiac Defibrillation Stimulus <i>Socrates Dokos, University of New South Wales</i>		



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10:20am-12:30pm	<ul style="list-style-type: none"> Local Specific Absorption Rate (SAR) in computational models of blood vessel compared to ASTM phantom <i>Kyoko Fujimoto, U.S. Food and Drug Administration</i> 	
12:30pm - 2:00pm	Buffet lunch: Gold Sponsor Seminars	See program insert
2:00pm - 2:15pm	Avicenna Group Presentation	Potomac Ballroom
2:15pm - 3:40pm	FDA Seminar <ul style="list-style-type: none"> Reporting on Computational Modeling Studies in Regulatory Submissions Risk-informed Credibility Assessment Framework – ASMEV&V40 Critical Thinking 	
3:40pm - 4:00pm	Break	Chesapeake Ballroom
4:00pm - 5:00pm	Panel: “How good is good enough?” The Academia/NSF perspective	Potomac Ballroom
5:00pm - 5:15pm	1st day closing remarks	
5:15pm - 7:15pm	Welcoming Reception: First Poster Session	Hall of Distinction

WEDNESDAY, May 17th

7:30am - 5:00pm	Registration & Information	Chesapeake Foyer
7:30am - 8:00am	Breakfast	Chesapeake Ballroom
8:00am - 8:45am	Booth Exhibitors	Potomac Ballroom
8:45am - 9:00am	Introduction to the day	
9:00am - 10:00am	Plenary Speaker: Urs Wyss, University of Manitoba, Canada	
10:00am - 10:15am	Break	Chesapeake Ballroom
10:15am - 12:30pm	TRACK 2: PRE-CLINICAL	Potomac Ballroom
	Chairs: Linda Knudsen (Synchroness, Inc.) Chris Scully (FDA)	



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10:15am - 12:30pm	Speakers:	
	<ul style="list-style-type: none"> • Modeling The Role of Surface Interactions in Initiation of Thrombosis <i>Miriam Rafailovich, Stony Brook University</i> 	
	<ul style="list-style-type: none"> • Towards Validation of a Physiological Model Intended for Design & Evaluation of Automated Fluid Resuscitation Systems <i>Bahram Parvina, U.S. Food and Drug Administration</i> 	
	<ul style="list-style-type: none"> • A Novel Method in Predicting Aneurysmal Hemodynamics after Endovascular Coiling <i>Hooman Yadollahi-Farsani, Arizona State University</i> 	
	<ul style="list-style-type: none"> • Evaluation of DBS Implant Interaction with Brain Tissue Through Finite Element Simulation <i>Logan Miller, Wake Forest University</i> 	
	<ul style="list-style-type: none"> • A Numerical Study on the Feasibility of the Deep Brain Stimulation (DBS) Surgical Navigation based on Scalp Electric Potential Recordings <i>Giorgio Bonmassar, Massachusetts General Hospital</i> 	
	<ul style="list-style-type: none"> • Valve Interstitial Cell Phenotypic State After Surgical Repair: An Integrated Experimental-Computational Approach <i>Salma Ayoub, The University of Texas at Austin</i> 	
	<ul style="list-style-type: none"> • Towards Accurate Simulations of Patient-Specific Mitral Valve Annuloplasty Repair <i>Andrew Drach, University of Texas at Austin</i> 	
	<ul style="list-style-type: none"> • Interlaboratory Simulations of Compression-Bending Testing of Spinal Rods <i>Marc Horner, ANSYS</i> 	
12:30pm - 12:50pm	Student Lightning Round Presentations	Potomac Ballroom
12:50pm - 2:30pm	Buffet Lunch: Second Poster Session	Chesapeake Ballroom



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TRACK 3: PRODUCT DEVELOPMENT		Potomac Ballroom
2:30pm - 4:30pm	Chairs: Socrates Dokos, PhD (UNSW) Sudeep Sastry (W.L. Gore)	
	Speakers:	
	• Numerical Optimization of Scaffold Properties for Tissue Engineered Venous Grafts <i>Jason Szafron, Yale University</i>	
	• Development and Full Body Validation of a 5th Percentile Female Finite Element Model <i>Matthew Davis, Wake Forest University</i>	
	• Stent Mechanobiology: Impact of Endothelial Shear and Intramural Stress <i>Henry Chen, California Medical Innovations Institute</i>	
	• Applicability of Model-Based Design Quality Metrics to Medical Device Software <i>Dave Hoadley, Mathworks</i>	
	• Computer-controlled Design and Manufacture of Smart Materials Mimicking the Body's Own <i>Melissa Knothe Tate, University of New South Wales</i>	
	• Effects of Pore Size on 3D Printed Cast's Mechanical Properties <i>Devin Kiska, Robert Morris University</i>	
	• Impact of Modeling Assumptions on Stability Predictions in Reverse Shoulder Arthroplasty <i>Mehul Dharia, Zimmer Biomet</i>	
4:30pm - 4:50pm	Break	Chesapeake Ballroom
4:50pm - 5:50pm	Panel: "How good is good enough?" The Industry perspective	Potomac Ballroom
5:50pm - 6:10pm	Student poster awards & 2nd day closing remarks	Potomac Ballroom
6:30pm - 8:30pm	Networking Social	Art Gallery



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THURSDAY, May 18th

7:30am - 4:00pm	Registration & Information	Potomac Foyer
7:30am - 8:00am	Breakfast	Patuxent Room
8:00am - 8:45am	Booth Exhibitors & Silver Seminars	See program insert
8:45am - 9:00am	Introduction to the day	Potomac Ballroom
9:00am - 10:00am	Plenary Speaker: Gary An, University of Chicago School of Medicine	
10:00am - 10:30am	Break	Patuxent Room
10:30am - 12:30pm	TRACK 4: CLINICAL STUDY	Potomac Ballroom
	Chairs: Mehul Dharia (Zimmer Biomet) Pras Pathmanathan (FDA)	
	Speakers:	
	<ul style="list-style-type: none"> Posing, Morphing and Image Registration of Anatomical Models for MRI RF Safety Assessments <i>Michael Oberle, IT'IS Foundation for Research on Information Technologies in Society</i> 	
	<ul style="list-style-type: none"> The method of relational correlations for determining subpopulation characteristics <i>William Pruett, University of Mississippi Medical School</i> 	
	<ul style="list-style-type: none"> Breast MRI Safety: Simulation of RF Coils with Breast Phantoms Fused to a Human Model <i>Xin Li, Purdue University</i> 	
	<ul style="list-style-type: none"> Simulating Disease States with the Living Heart Human Model <i>Brian Baillargeon, Dassault Systemes SIMULIA Corp.</i> 	
<ul style="list-style-type: none"> Automatic Construction of Population-Based Models of Left-Ventricle Mechanics <i>Paolo Di Achille, IBM TJ Watson Research Center</i> 		



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10:30am - 12:30pm	<ul style="list-style-type: none"> • Neuro-Functionalized Anatomical Models for Mechanism Investigation, Device Development, and Treatment Personalization <i>Esra Neufeld, IT'IS Foundation for Research on Information Technologies in Society</i> • Augmenting a Clinical Study with Virtual Patient Models: FDA and Industry Collaboration on a Mock Submission Sponsored by MDIC <i>Adam Himes, Medtronic</i> 		
12:30pm - 1:30pm	Lunch/Network	Patuxent Room	
1:30pm - 2:45pm	TRACK 5: MARKET RELEASE AND POST-MARKET		
	Chairs: Finn Donaldson (FDA) Mark Palmer (Medtronic)		
	Speakers:		
	<ul style="list-style-type: none"> • Hemodynamics Inside the MonaLSA Stent Graft <i>Rosamaria Tricarico, University of Florida</i> 		
	<ul style="list-style-type: none"> • Effects of Increasing Graft Overlap in Ventral Hernia Repair – Potential Guidelines from a Computational Study <i>Sambit Sahoo, Cleveland Clinic Biomechanical</i> 		
<ul style="list-style-type: none"> • Comparing Modeled Fretting and Observed Wear in Total Hip Arthroplasty Head-Neck Junctions <i>Andrew Baumann, U.S. Food and Drug Administration</i> 		Potomac Ballroom	
<ul style="list-style-type: none"> • Closed-loop blood glucose control in-silico and in the field <i>Benyamin Grosman, Medtronic</i> 			
2:45pm - 3:00pm	Break		Patuxent Room
3:00pm - 4:00pm	Panel: “How good is good enough?” The FDA perspective		Potomac Ballroom
4:00pm - 4:30pm	Student podium awards & closing remarks/Adjourn		

POSTER ABSTRACTS

Poster No.	First Name	Last Name	Institution/ Affiliation	Abstract Title	Track
1	Danielle	Fau	University of New South Wales	Using Statistical Interaction Modelling to Predict Cell and Tissue Response to Medical Devices	Ideation
2	Terman	Frometa-Castillo	Oncology Hospital of Santiago de Cuba	“Statistical models for evaluations of efficacy and toxicity, and dosage in Chemotherapy”	Ideation
3	Michele	Grimm	Wayne State University	Ideas Start with People: Fostering the Next Generation of Ideation Engineers	Ideation
4	Omar	Hafez	UC Davis	A Polyhedral Finite Element Approach to Patient-Specific Modeling and Simulation in Biomechanics	Ideation
5	Katherine	Lin	Yale University	Doc:A Mobile Training Platform for ECMO and Other Medical Technologies	Ideation
6	Alexander	Ringlein	Yale University	Virtual Reality Pathology	Ideation
7	Peyton	Tharp	Clemson University	3D Printed Brain Model for Preoperative Planning and Practice	Ideation
8	Nathan	Wilson	Open Source Medical Software Corporation	SimVascular:An Open-Source Integrated Environment for Anatomic Modeling and Blood Flow Simulation	Ideation
9	Mela	Christopher	University of Akron	Integrated Imaging Goggle: Preclinical Studies for Medical Diagnosis and Surgical Navigation	Pre-clinical
10	Luca	Emili	Promeditec	A Web-Based Platform for Simulating MRI RF-Induced Heating with Implanted Devices	Pre-clinical
11	Ahmet	Erdemir	Cleveland Clinic	Ten “Not So” Simple Rules for Credible Practice of Modeling & Simulation vs Considerations of Medical Device Development Tools Program	Pre-clinical
12	Mary	Foltz	University of Minnesota	Fusion and Non-Fusion Spinal Implants: Computational and Experimental Study	Pre-clinical
13	Ben	Holmes	Nanochon	Pre-clinical Testing of 3D Printed, Nanostructured Osteochondral Implant for Knee Repair in a Small Animal Model	Pre-clinical
14	Jinho	Kim	Columbia University	Minimally Invasive Delivery and Imaging of Therapeutic Stem Cells in the Lung	Pre-clinical
15	Melissa	Knothe Tate	University of New South Wales	Prospective Design of Combination Products/ Delivery Devices Exploiting Multiphysical Mechanisms for Wound Healing	Pre-clinical
16	Danny	Levine	Zimmer Biomet	Fatigue Testing of Femoral Hip Stems – Setup Variability Examined by FEA and DOE	Pre-clinical
17	Jaimit	Parikh	IBM TJ Watson Research Center	Evaluating the role of multi-channel blockage as a predictor of drug-induced cardiotoxicity using machine learning algorithms	Pre-clinical

POSTER ABSTRACTS

Poster No.	First Name	Last Name	Institution/ Affiliation	Abstract Title	Track
18	Veda	Ravishankar	University of Maryland- College Park	Integration of 3D Printed Microvilli and Sensors into a Microfluidic Gut-on-a-Chip Model	Pre-clinical
19	Erin	Ritzer	Robert Morris University	Effect of Fin Length/Shape of Stemless Humeral Component of the Reverse Shoulder Implant	Pre-clinical
20	Peter	Serano	U.S. Food and Drug Administration	Variation in RF Heating Characteristics of Insulated vs. Bare Metal Stents	Pre-clinical
21	Gurtej	Singh	Stony Brook Medical Center	Tissue-Engineered Vascular Grafts For Use In Vascular And Reconstructive Surgeries	Pre-clinical
22	Min Jae	Song	National Eye Institute	Engineered Outer Blood Retina Barrier for Disease Modeling of Age-related Macular Degeneration	Pre-clinical
23	George	Banis	University of Maryland	Modeling and Verifying Capacitance Response of Hydrogel Degradation over Enzyme Sensors	Product Development
24	Rebecca	Butler	Thayer School of Engineering at Dartmouth	Design of a Smart-Sensing Dental Drill	Product Development
25	Henry	Chen	California Medical Innovations Institute	Biomechanical Comparison between Mono-, Bi-, and Tri-cuspid Valve Architectures	Product Development
26	Mayuresh	Kothare	Lehigh University	Modeling and Feedback Control of a Rapid Pressure Swing Adsorption Medical Oxygen Concentrator	Product Development
27	Steven	Lathers	Arizona State University	Additive manufactured FFF 3D printed osseointegrated prosthesis for a transhumeral amputation using Nylon 680	Product Development
28	Jessica	Martinez M	UCLA	Impact of Patient Orientation on Pacemaker Lead Tip Heating During MRI Exams	Product Development
29	John	Stribley	CaelynX	Meeting the Needs and Challenges of a Growing Biomedical Device Industry: An Example of How Teams of Mechanical Engineers and Software Designers Can Collaborate to Optimize the Development of Various Biomedical Devices and Equipment Utilizing their CAE Si	Product Development
30	Tre	Welch	UT Southwestern Medical Center	Large Bioresorbable Stents for Congenital Heart Disease	Product Development
31	Ahmet	Erdemir	Cleveland Clinic	Logistics of Building Virtual Specimens for In Silico Biomechanics	Clinical Study
32	Scott	Gayzik	Wake Forest University School of Medicine	Real-time MRI Motion Tracking of the Cardiac Cycle in Breath-Held, Normal and Heavy Breathing	Clinical Study

POSTER ABSTRACTS

Poster No.	First Name	Last Name	Institution/ Affiliation	Abstract Title	Track
33	Yogesh	Karpate	Children's National Medical System	A Smartphone Stethoscope and Application for Automated Identification of Innocent Still's Murmur	Clinical Study
34	Kevin	Kerr	University of Illinois-Chicago	Tongue Computer Interface	Clinical Study
35	Bryn	Lloyd	IT'IS Foundation	Non-rigid Registration of Computational Phantoms for Personalization and Population Coverage	Clinical Study
36	Miriam	Rafailovich	Stony Brook University	Monitoring Facial Nerve Function with Digital Analysis: a Non-contact EMG Equivalent	Clinical Study
37	Saumya	Tiwari	University of Illinois at Urbana Champaign	Discrete Frequency Infrared Imaging as a Tool for Stainless Histopathology of Clinical Biopsy Samples	Clinical Study
38	Ashley	Weaver	Wake Forest University School of Medicine	Postural Influence on Thoracoabdominal Organs of 5th, 50th and 95th Percentile Male Subjects	Clinical Study
39	Lisa	Lohmueller	Carnegie Mellon University	The Cardiac Outcomes Risk Assessment (CORA) Counselor: Design of a Personalized LVAD Patient Decision Aid	Market Release and Post-Market
40	Kaspars	Maleckis	University of Nebraska Medical Center	Mechanical Evaluation of Peripheral Artery Stents	Market Release and Post-Market
41	Yuval	Shmueli	Stony Brook University	Thermal Imaging and Modeling of the FDM Printing Process and Its Influence on Stem Cell Differentiation	Market Release and Post-Market
42	Markus	Reiterer	Medtronic	The Role of Judgement in the Assessment of Model Credibility	
43	FDA, Center for Devices and Radiological Health			FDA Center for Devices and Radiological Health - Medical Device Development Tool	
44	FDA, Center for Devices and Radiological Health			The Office of Science and Engineering Laboratories in the Center for Devices and Radiological Health at FDA	
45	FDA, Center for Devices and Radiological Health			Risk-informed Credibility Assessment Framework - ASME V&V40	

GOLD SPONSOR SEMINARS

TUESDAY, 12:30PM - 2:00PM

ANSYS

System-Level Design of Medical Products: A Medical Device Industry Imperative
Marc Horner, Ph.D., Technical Lead, Healthcare, ANSYS, Inc.

Great products are composed of great individual components that are increasingly assessed from every possible physical perspective. But optimally designed components do not necessarily result in optimal systems. Eventually, the components are assembled, powered, sensed and controlled as an integrated system, and must therefore be designed as a system to meet peak performance requirements and stringent safety standards.

Computational modeling is a recognized alternative to physical testing, but has historically been used in silos with minimal collaboration between various design disciplines. To address the needs of today's product development teams, ANSYS has developed a multidomain, digital system prototyping platform that enables multispecialty teams with diverse engineering backgrounds to work in unison to achieve a deep understanding of integrated product behavior.

This seminar will review a multi-domain model of an insulin pump as an example of how the ANSYS digital system prototyping platform enables a deep understanding of integrated product behavior. The seminar will start with an overview of how ANSYS tools can be used to analyze various pump components, followed by a live demo of a circuit model of the insulin delivery sub-system. The circuit model incorporates many of the key elements of this sub-system, including a display, controller, power electronics, hydraulics, and a ROM, all working together as a system.

SIMULIA

Dassault Systèmes SIMULIA for Life Sciences

Nothing is more personal than Healthcare. The progress towards personalized medicine is critical to our future, yet faces tremendous scientific, regulatory, and logistical challenges. The BMES luncheon meeting will showcase SIMULIA technology strategy, solutions, and latest news to illustrate the transformational impact that simulation is having on Life Sciences. This forum will include detailed discussion of modeling and simulation for the medical device development process, including personalization, and the move towards virtual clinical trials. Additional insights on pharmaceutical drug discovery and delivery, patient care (including pre-surgical planning), and personalized device selection will be offered. The SIMULIA platform and technology strategy will be reviewed from the viewpoint of Life Sciences applications, covering multiphysics (structures, fluids, electromagnetics, and thermal effects) and multiscale (designed materials) topics, and show how these technologies are coming together to enable Virtual Human Modeling (such as with the Living Heart Project) and other innovative approaches. We will provide a glimpse into existing customer applications of realistic simulation in Life Sciences and in other domains where modeling and simulation of the human body is important. We strongly encourage all users, influencers, and thought leaders in simulation to attend as this meeting will provide an opportunity to learn, network, discuss, and look ahead to where Life Sciences simulation is headed.

Meeting Highlights:

- SIMULIA strategy and updates
- Modeling and simulation on medical device development
- Virtual Human Modeling
- Electromagnetic simulations in Life Sciences
- Opportunity to network, discuss, and look ahead

GOLD SPONSOR SEMINARS

TUESDAY, 12:30PM - 2:00PM

TotalCAE

Private and Public Cloud High Performance Computing for Simulation Case Studies

Learn how companies are adopting the latest trends High Performance Computing to accelerate simulation including HPC cluster and public HPC cloud technologies. Several customer case studies will be presented to show real-world solutions.

Speaker Bio:

Rodney Mach is President of TotalCAE, a leading provider of Private and Public Cloud Simulation platforms for FEA/CFD. Rod is a 20 year veteran in utilizing High Performance Computing.

Mr. Mach has a B.S.E in Electrical Engineering from the University of Michigan, and MBA from Wayne State. Prior to starting TotalCAE in 2006, he led the University of Michigan High Performance Computing department.

Zurich MedTech

Sim4Life - Advanced Tools for Personalized Model Generation & Neuronal Dynamic Modeling

The ZMT Zurich MedTech AG team will focus on ZMT's latest advancements in personalized model generation and neuronal dynamic modeling. We will showcase a range of innovative products for our Sim4Life in silico life sciences platform, including sophisticated neuronal dynamics solvers and solutions for the seamless registration and morphing of high-end anatomical models. We will also demonstrate some of our important and most recent application-specific tools such as IMAnalytics, a new platform solution for the comprehensive safety evaluation of implantable devices. Come and join us to learn about our vision of how Sim4Life will meet the growing demand for in silico trial solutions in the future!

SILVER SPONSOR SEMINARS

THURSDAY, 8:00AM - 8:45AM

Csimsoft

Geometry Matters: Accurately Modeling Biomedical Applications

Biomedical simulation is only as good as the model and the mesh representation it uses. CertasIM and csimsoft discuss how accurately representing geometry with high order elements is key to getting accurate simulation results with the IMPETUS Afea Solver®.

InSilicoTrials

InSilicoTrials.com: Democratizing simulations in healthcare

InSilicoTrials.com is the first web-based platform for in silico trials, providing healthcare companies and researchers with an easy-to-use tool to perform computational testing on medical devices during the development, validation and regulatory process.

In this seminar, we will present a specific application of our platform, created in collaboration with ANSYS and FDA: an innovative web-based tool to perform electromagnetic safety analysis on implanted stents, creating a report based on FDA Guidance: Reporting of Computational Modeling Studies in Medical Device Submissions (2016).

During the seminar, further applications of the platform in orthopaedics and cardiovascular field will be shown.

Moreover, we will present collaboration opportunities for industry and researchers, to streamline the design process and reduce medical devices development costs.

SILVER SPONSOR SEMINARS

THURSDAY, 8:00AM - 8:45AM

Mathworks

Model-Based Design for Medical Devices: Infusion Pump as a Case Study

Getting today's complex medical devices ready for the market, and approved by the FDA is becoming increasingly harder with stronger enforcements, higher expectations of quality, and market pressures. Traditional software development, verification, and testing methods have become the bottleneck and are inadequate for today's complex devices.

By using models as abstractions of both the physical device and its corresponding software systems, engineers can accelerate the product development process significantly by increasing virtual design iterations and reducing the need for physical prototypes. Furthermore, they can also ensure all quality goals are hit more efficiently by automating and reusing test harnesses and protocols, while also automating the creation of documentation for regulatory purposes.

Using an Infusion Pump as a case study, we'll show through live technical demonstrations how Model-Based Design can be used to:

- Create executable models in MATLAB and Simulink of the design specs/requirements
- Perform extensive testing in simulation to evolve and satisfy requirements
- Perform requirements traceability between models, generated code, and test case
- Generate C code and verify its performance in PC and embedded hardware
- Generate Reports from various steps during the workflow to show compliance with IEC 602304 standards

Synopsys

Simpleware: 3D Image-Based Solutions for Medical Devices

Join this seminar to learn about how to generate high-quality models from 3D image data (MRI, CT...) in Simpleware software for medical device research and development. Use the software to accurately reconstruct anatomical scans and integrate them with CAD medical devices. These models are suitable for export directly to physics-based Finite Element solvers, and enable detailed analysis of the interaction between devices and patient-specific geometries. Learn about the benefits of image-based meshing and the key features of the software, as well as typical workflows and case studies that demonstrate the many applications of Simpleware to medical device projects.

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Ansys

If you've ever seen a rocket launch, flown on an airplane, driven a car, used a computer, touched a mobile device, crossed a bridge, or put on wearable technology, chances are you've used a product where ANSYS software played a critical role in its creation. ANSYS is the global leader in engineering simulation.



Dassault Systèmes SIMULIA

As an integral part of the Dassault Systèmes 3DEXPERIENCE platform, SIMULIA applications enable users to leverage physics-based simulation and virtual human models, such as the Living Heart Model, to accelerate the evaluation and optimization of device performance, reliability and safety before committing to costly and time-consuming physical prototypes. www.3ds.com/simulia



Medtronic

We're committed to helping the healthcare community better align patient care with patient outcomes. But we can't do it alone. That's why we're collaborating with physicians, hospital administrators, payers, and patients across the care continuum to create more sustainable models of care. Our goal? Better patient outcomes for everyone.

Let's take healthcare Further, Together.

Learn more at medtronic.eu



TotalCAE

TotalCAE is a fully managed High Performance Computing (HPC) private and public cloud solution provider for engineers that makes it easy and affordable to adopt HPC to reduce turnaround time for FEA/CFD.

TotalCAE is the single vendor to call for managing all your onsite HPC, public cloud, and engineering applications.



Zurich MedTech

ZMT Zurich MedTech AG offers cutting-edge computational simulation tools (Sim4Life) and dedicated validation hardware solutions (MITS and piX) for Life Sciences applications in complex anatomies. Our key product Sim4Life enables researchers, clinicians, and manufacturers to mimic real biomedical/physiological environments, optimize device design and safety, accelerate decisions, and achieve lower costs.

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Avicenna Alliance

“Avicenna Alliance” is an Association of Industries & Academics that have a commercial or research interest in the development of policy on in silico medicine. Representing the Medical Devices, Pharmaceutical and Software Sectors, Avicenna works to promote the positions of its members to policy makers in the EU and beyond.



BD

BD is a global medical technology company that is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. BD's associates work with customers to help enhance outcomes, lower health care delivery costs, increase efficiencies, improve health care safety and expand access to health. (www.bd.com)

Csimsoft

Csimsoft's Trellis and Bolt software are meshing tools for generating high-quality meshes for challenging simulations. Bolt is a grid-overlay tool for meshing irregularly-shaped models at the push of a button. Trellis is a full-feature, tetrahedral and hexahedral meshing tool for getting the precise mesh you need.

csimsoft.

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CertaSIM is the distributor for the IMPETUS Afea Solver®, an Explicit Transient Dynamic Nonlinear Solver that takes full advantage of massively parallel processing with GPU Technology. The Aset™ Solid Element Technology, at the heart of the solver, is the key to accurate results and fast computation times. Combined with a robust SPH solver, FSI models of mitral valves and cerebrospinal fluid flow is easily accomplished.



InSilico Trials

InSilicoTrials aims to help healthcare companies and researchers reducing medical device development costs. We created an innovative web-based platform that provides R&D, regulatory and HTA teams an easy-to-use tool for setting computational models. Individualized simulations and post-processing are performed in public or private cloud, to streamline the design and development process.



MathWorks

The MATLAB and Simulink product families are fundamental applied math and computational tools adopted by more than 5000 universities and colleges. MathWorks products help prepare students for careers in industry, where the tools are widely used for data analysis, mathematical modeling, and algorithm development in collaborative research and new product development.



Synopsys

Simpleware software provides a complete environment for visualizing, analyzing and converting 3D image data (such as MRI, CT, micro-CT...) into models for CAD, CAE and 3D Printing. The software has FDA 510(k) clearance and is used as part of medical device development workflows to improve design decisions and reduce time-to-market.

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Cleveland Clinic BioRobotics

The BioRobotics Lab's product, simVITRO, seamlessly unites software and hardware components for robotic, orthopaedic, biomechanical testing. simVITRO can be used to validate computational models through robotic testing of knee, spine, hip, shoulder, elbow, hand/wrist, and foot/ankle joints. The BioRobotics Lab does fee-for-service testing and sells simVITRO systems.



Elemance

Elemance's vision is to protect and improve human life using virtual human body model based tools to enable human centered design. Elemance licenses the GHBM family of models, including simplified and detailed male and female models. Elemance can support human modeling needs related to biomechanics and medical device development.



Materialise

Materialise incorporates 27 years of 3D printing experience into a range of software solutions and 3D printing services, forming the backbone of the 3D printing industry. Materialise Medical has pioneered many leading medical applications of 3D printing, enabling researchers, engineers and clinicians to revolutionize innovative patient-specific treatment that help improve and save lives.



Siemens

Siemens PLM Software (www.siemens.com/mdx) is a leading global provider of simulation software with a vision for Multidisciplinary Design eXploration. Our simulation tools, including STAR-CCM+®, allow engineers to discover better designs, faster across a wide range of disciplines including Computational Fluid Dynamics, Computational Solid Mechanics, heat transfer, particle dynamics, and reacting flow.

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