Medical Device & Diagnostics Innovation Symposium 2013

Presented by

Chinese-American BioMedical Association (CABA)

New England Chinese Information and Networking Association (NECINA)

American Chinese Medical Association (ACMA)

Harvard Medical School- Chinese Scholars and Scientists Association (HMS-CSSA)

Bridging Innovation and Entrepreneurship in Medical Device and Diagnostics

The 2013 Medical Device & Diagnostics Symposium aims to build a platform of interaction for biomedical professionals in the New England area, highlight innovation and marketing trends, and uncover opportunities for entrepreneurship in both US and China.

Highlights

- **Cutting-edge Innovation in the Medical Device & Diagnostics Industry**
- **Market Trends and Industry Outlook**
- **Panel discussion on Medical Device & Diagnostics in the US and China**

When: December 7, 2013, 10:00am-5:00pm
Venue: IBM Innovation Center Cambridge – 1 Rogers Street, Cambridge, MA

CABA NECINA ACMA CSSA

www.cabaweb.org *www.necina.net* *www.acma.org* *www.hms-cssa.org*

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Harvard Medical School - Chinese Scholars and Scientists Association (HMS-CSSA)

This 2013 Medical Device & Diagnostics Symposium aims to enhance interactions of biomedical professionals, embrace innovation and entrepreneurship, identify the technical and market trends in medical device & diagnostics business in the US and China.

Symposium Organizing Committee

Chair

Xiang Yang Yu (CABA)

Co-Chairs

Ellen Fan (CABA) Yi Le (ACMA) William K Poon (NECINA) Wei Song (HMS-CSSA)

Committee

Chaoyang Dai (CABA) Ping Dang (NECINA) Mehjabin Kapasi (IBM) Bill Lian (ACMA)
Shiwen Lin (CABA) Zidong Wang (CABA) Li Xing (CABA) Jackie Yang (NECINA)
Jingzhong Zhang (CABA) Phil Zhang (CABA) Wei Zhang (CABA) Ru Zheng (NECINA)

Acknowledgement

We sincerely thank Mehjabin Kapasi, IBM Cambridge Innovation Center Business Development Manager, Joe Perry, IBM Regional Innovation Center Manager, and the IBM Global Entrepreneurship Program for providing the event venue and facility support.

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Symposium Agenda

9:30am -10:00am	Registration and Networking
10:00am -10:05am	Symposium Opening Remarks Xiang Yang Yu (CABA)

SESSION I - BUSINESS ON MEDICAL DEVICE Moderator: Ru Zheng

10:05am -10:35am	*The Opportunity for Commercialization and Marketing of Medical Devices in China* **Laisheng Chou, PhD**, Professor, Boston University
10:35am -11:05am	*E-TROLZ – Bridging the Gap between Research and Commercialization* **Jim Robertson**, President and CEO, E-TROLZ and COO, MindChild
11:05am -11:35pm	*Key to Place Your Device into Chinese Market* **Angelina Hao, MBA**, CEO, Normalline
11:35am -12:05pm	*Finding Our Way as an Entrepreneur in China* **Shallwei Sun,** President and General Manager, Callisyn Biomedical
12:05pm -1:00pm	Lunch Break, Networking

SESSION II - INNOVATION / TECHNOLOGY PERSPECTIVES Moderator: Jingzhong Zhang

1:00pm -1:10pm	Message from IBM Mehjabin Kapasi (IBM)
1:10pm -1:40pm	*HIV Viral Load Detection for Global Health Applications* **Dr. Utkan Demirci, PhD** - Assistant Professor, Harvard Medical School
1:40pm -2:10pm	*Enabling Site Specific Therapy with Medical Devices* **Upma Sharma, PhD**, Director, Arsenal Medical
2:10pm -2:40pm	*Opportunities and Strategies in Medical Device and Diagnostics* **Bill Lian, MD, PhD,** Assistant Professor, UMass Medical School
2:40pm -3:20pm	*Medical Innovations and Globalization – the Perspective from Surgeons and Mechanical Engineer* **Jiping Wang, MD, PhD**, Assistant Professor, Harvard Medical School, Associate Director, Brigham and Women's Hospital **Gita Mody, MD**, Resident, Brigham and Women's Hospital **Danielle Renee Zurovcik, PhD**, Founder & CEO, Worldwide Innovative Healthcare
3:20pm -3:35pm	Coffee Break, Networking

SESSION III - PANEL DISCUSSION Moderator: Bill Lian

3:35pm -4:30pm	**Angelina Hao, MBA**, CEO, Normalline **Peter Y. Li, PhD**, CEO, Nexcelom Bioscience **Shen Luan, PhD**, Co-Founder and COO, Berg Diagnostics **Shallwei Sun,** President and General Manager, Callisyn Biomedical **Ming Tong, MD, MBE**, Sr. Medical consultant & Director, Beijing Biopharma International **Jiping Wang, MD, PhD**, Assistant Professor, Harvard Medical School
4:30pm -5:00pm	Networking
5:00pm	Symposium Closes

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Biosketches of Speakers and Program Summay

Dr. Laisheng Chou, PhD, Professor, Boston University

Dr. Chou is a Professor at Boston University. His research interests include Molecular biocompatibility of implant biomaterials; Tissue engineering and clinical applications; and Oral cancer. He obtained his PhD from University of British Columbia and diploma in Oral Pathology and Oral Medicine from University of California, San Francisico.

Presentation Title: *The Opportunity for Commercialization and Marketing of Medical Devices in China*

Abstract: In 2017, China will have the second largest market after the United States for Medical devices. As part of the strategic planning, several national institutes of medical devices and instrument have been established in the past five years in China. A national industrial park is also established as a global accelerator of commercialization and marketing of medical devices in China. A brief of information about these institutions and industrial park is presented.

Dr. Utkan Demiric, PhD, Assistant Professor, Harvard Medical School

Presentation Title: *HIV Viral Load Detection for Global Health Applications*

Dr. Demirci leads a group of 30 researchers focusing on micro and nano scale technologies. He received his B.S. degree in Electrical Engineering in 1999 as a James B. Angell Scholar (*summa cum laude*) from University of Michigan, Ann Arbor. He received his M.S. degree in 2001 in Electrical Engineering, and dual degrees, a M.S. in Management Science and Engineering and PhD in Electrical Engineering from Stanford University. Dr. Demirci has published over 75 peer reviewed publications in journals including PNAS, Advanced Materials, SMALL, Trends in Biotechnology, Chemical Society Reviews and Lab-chip, over 150 conference abstracts and proceedings, 10 book chapters, and an edited book. His scientific work has been recognized by numerous national and international awards including the NSF Faculty Early Career Development (CAREER) Award (2012), and the IEEE-EMBS Early Career Achievement Award (2012). He was selected as one of the world's top 35 young innovators under the age of 35 (TR-35) by the MIT Technology Review.

Ms. Angelina Hao, MBA, CEO, Normalline

Presentation Title: *The Key to Place Your Device into Chinese Market*

Ms. Angelina Hao is the CEO of Normalline with Master degree of Business Administration (MBA) and Medicine. Angelina is a partner in founding Normalline, a professional service company committed to provide Chinese regulatory information and relevant management in the field of the Medical Devices (MD) and in vitro diagnostics (IVD). She has achieved a number of multinational companies transfer strategy, compliance

assessment of merger and acquisition, the strategy planning of manufacturing plant in China, the evaluation of research and development projects, and completed the customized training for the domestic and foreign enterprises for more than 50 times. She is the Center of Medical Device Evaluation (CMDE) Distinguished management and regulatory consultants, specially appointed as unique to participate in the key project "Exploring the Scientific Mode of Medical Device Evaluation" funded and approved by China Food and Drug Administration (CFDA). With her over 10 years' experience in the enterprise operation and regulatory management, she has abundant practical experience of Chinese, American and EU regulations in the field of medical devices.

Dr. Peter Y. Li, PhD, CEO, Nexcelom Bioscience

Discussion Title: *Innovation Fueled by Passion*

Dr. Li has extensive product development and business experience in large and small companies, where he has repeatedly contributed both as a technology inventor and as an effective leader to commercialize technology-driven products. While working at 3M, Eastman Kodak, SRU Biosystems, and Nexcelom Bioscience, he repeatedly took product ideas from invention and product design to production and commercialization. His past technical responsibilities included technical innovation, technology platform development, product design and testing, and manufacturing setup. With BS and PhD degrees in Physics from Peking University and Purdue University, Dr. Li became a productive innovator and prolific inventor with 33 issued US patents and more pending. He is a co-founder and CEO of Nexcelom Bioscience, which develops and markets Cellometer® brand image-based cell counters and analysis systems for the life science market. Nexcelom Bioscience was honored as an Inc 500 Company in 2009, as one of fastest growing private companies in America by Inc Magazine.

Dr. William Lian, MD, PhD, Assistant Professor, University of Massachusetts Medical School

Dr. William Lian is an Assistant Professor of Medicine. Dr. Lian received his medical degree from Jilin University in China, and PhD degree in Neurosciences from Loyola University Chicago. He completed his residency training and research fellowships at the teaching hospitals of Harvard Medical School. Besides being an attending physician, providing patient care and teaching at the medical school, he is also an active investigator in medical research. Dr. Lian's research interests focus on epigenetic regulation of gene expression by histone and DNA modification and its role in aging and related diseases. Using molecular biology techniques and transgenic animal models, his research shows that the newly discovered histone demethylase LSD1 plays an important role in energy metabolism, aging and the pathogenesis of aging related diseases, such as cardiovascular diseases.

Presentation Title: *Opportunities and Strategies in Medical Device and Diagnostics*

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Abstract: US health care expenditure is 18% of GDP, by far the largest in the world. There are tremendous opportunities for medical device and diagnostics. Health care reform demands new care models which require more cost-efficient patient care. Emerging technologies in biomedical science and information technologies are in the unique position to meet these challenges. Dr. Bill Lian will discuss the trend in current health care reform, opportunities in medical device and diagnostics, and the strategies in product development for clinical application.

Dr. Shen Luan, PhD, Co-Founder and COO, Berg Diagnostics

Dr. Shen Luan is a Co-Founder and serves as Chief Operating Officer for Berg Diagnostics. He leads efforts on corporate governance, molecular diagnostics, multi-omics, CLIA-certified clinical diagnostics laboratory services, and overall technology management related to business operations. Prior to the merger of all Berg business units, Shen was the founding President and Chief Technology Officer in 2010 for Berg Diagnostics. Dr. Shen joined Cytotech Labs in 2009 as the Director of Bioanalytical and Diagnostics Division and was named as Vice President of Bioanalytical and Diagnostics later that year. Prior to Berg, Dr. Shen was a Technical Product Manager of Waters Corporation from 2004 to 2009. Prior to that, he was with Thermo Fisher Scientific for 9 years and has held various management positions. He is a current member of BayHelix since 2013, an organization of leaders of Chinese heritage in the global life sciences and healthcare community. He received a Ph.D. in Analytical Chemistry from Iowa State University and a B.S. in Analytical Chemistry from Peking University. He holds a Lean - Six Sigma Black Belt certificate.

Dr. Gita Mody, Resident, Brigham and Women's Hospital

Presentation Title: *Medical Innovations and Globalization – the Perspective from Surgeons and Mechanical Engineer*

Dr. Mody is a 5th year surgical resident at BWH. She is also very active in medical training and innovation. Gita's research interest is implementing low-cost innovations to address health care disparities in low income countries. Her current study is a phase I trial of a non-electrical negative pressure wound therapy device in Rwanda.

Mr. Jim Robertson, President, CEO, E-TROLZ and COO, MindChild

Presentation Title: *E-TROLZ – Bridging the Gap between Research and Commercialization*

Jim has 30 years experience in the electronics industry, 18 of which are in executive management. As Director of International Program Management and US R&D at Schneider Automation, a multi-billion dollar industrial electronics conglomerate, Jim directed 160 engineering resources in three countries with a $35m budget. Jim successfully started design service groups focused on real-time electronics at Cadence Design Systems in 1999 and Suntron Corporation in 2002. In 2004, he founded E-trolZ, a leader in Bio-medical computing

platforms and the core inside of MindChild's fetal monitor. He is currently the President and Chief Executive Officer of E-trolZ. In 2008, Jim founded MindChild Medical and serves as Chief Operating Officer.

Dr. Upma Sharma, PhD, Director, Arsenal Medical Inc.

Presentation Title: *Enabling Site Specific Therapy with Medical Devices*

Dr. Sharma leads product development for Arsenal Medical's novel foam-based technology platform for treatment of non-compressible hemorrhage, directing a core team through ideation and filing of intellectual property, proof of concept and pre-clinical testing, and clinical system design. Under Dr. Sharma's scientific leadership, the company gained significant funding from DARPA/ARO for development of this hemorrhage control system. Prior to Arsenal, Dr. Sharma served as a core team member at 480 Biomedical, advancing the company's innovative bio-degradable vascular scaffold from concept to pre-clinical proof-of-concept. Dr. Sharma was responsible for materials selection and drug formulation efforts for the scaffold. Dr. Sharma earned a PhD from Princeton University in Chemical Engineering and a B.S.E. with Honors from Purdue University. During a post-doctoral fellowship in Bioengineering at Rice University, Dr. Sharma was awarded a NIH Training Grant in Nanobiology. Dr. Sharma has authored 12 peer reviewed scientific publications and is an inventor on 10 issued or pending patents.

Shallwei Sun, President and General Manager of Callisyn Biomedical

Presentation Title: *Finding Our Way as an Entrepreneur in China*

Ms. Sun is the co-founder and general manager of Callisyn Biomedical, Inc. Callisyn Biomedical is a medical device company, which mainly focuses on innovation, development, manufacture and marketing devices for minimally invasive surgery. Callisyn's first commercial product in China: a drug-carrier capable CalliShperes™, used for TACE for treating hyper-vascular tumors, has recently been approved by CFDA. Ms. Sun has many year working experiences in pharmaceutical business. She has extensive experiences on medical device development and GMP production. She has led the team working with doctors, hospitals and CFDA to complete multi-center clinical trial and PMA application. With her leadership, Callisyn is transforming from R & D to GMP production and commercialization.

Dr. Ming Tong MD, MBE, Sr. Medical consultant & Director, Beijing Biopharma International

Discussion Title: *The Medical Community and the Industry Perspective of Medical Devices*

Dr. Ming Tong studied Physics and Psychophysics under Nobel laureate Donald Glaser at UC Berkeley. He got his master degrees from universities of Berkeley-UCSF and Harvard. Prior to completing his MD degree from Boston Medical, he conducted Phase I & Phase II new drug investigations at the federal National Institutes of Health (NIH) Clinical Center. Engaged in basic sciences with faculty at Yale, he published

abstract in Cell Biology and the journal of experimental neurology respectively. His discovery of integrins receptors was posted on the front cover of the journal Investigative Ophthalmology. Ming was recipient of the Award in Research from the National Radiology Society of N. America (RSNA) while he was medical student in Boston Medical Center and spent postdoctoral clinical research in Nuclear Medicine imaging. He was the former Medical Director at Pfizer USA Headquarter in NYC & with strong interest in developing new drug products for patients worldwide."

Dr. **Jiping Wang, MD, PhD**, Assistant Professor, Harvard Medical School and Associate Director, Brigham and Women's Hospital

Presentation Title: *Medical Innovations and Globalization – the Perspective from Surgeons and Mechanical Engineer*

Dr. Wang received his PhD training in Biostatistics at University of Pittsburgh. He served as a biostatistician at National Surgical Adjuvant Breast and Bowel Project, where he participated in multiple phase III breast cancer clinical trials upon his graduation. During Dr. Wang's surgical residency training at the State University of New York at Buffalo, he was appointed as an adjunct assistant professor in the Department of Biostatistics and a statistical consultant at Roswell Park Cancer Institute. Subsequently, Dr. Wang obtained the Fineberg Fellowship to receiving training at Brigham and Women's Hospital, Massachusetts General Hospital and Dana Farber Cancer Institute. Dr. Wang practices oncologic surgery with a focus on minimally-invasive cancer surgery for gastrointestinal malignancies including liver cancer, colorectal cancer, liver metastasis, pancreatic, gastric, colorectal cancer and neuroendocrine tumor.

Dr. Danielle Renee Zurovcik, PhD, Founder & CEO, Worldwide Innovative Healthcare, Inc. (WiCare)

Presentation Title: *Medical Innovations and Globalization –the Perspective from Surgeons and Mechanical Engineer*

WiCare develops innovative medical devices that are clinically effective and affordable worldwide: from rural clinics in the developing world to state-of-the-art clinics in the U.S. It is my goal to prove that you can both help people on a global scale and grow/sustain a large, for-profit company. Through our proprietary design process, we can reach the simplest, least expensive device designs that do not sacrifice the efficacy or quality of currently available devices and treatments. I love the challenges in both engineering and business that we face, and I am confident that we will pave the way to a new medical device paradigm, one which expands high-end treatment availability and significantly reduces healthcare costs.