

2015 Medical Device & Diagnostics Innovation Symposium

Bridging Innovation and Entrepreneurship in Medical Device and Diagnostics

Presented by

Chinese-American Biomedical Association (CABA)
New England Chinese Information and Networking
Association (NECINA)
128 Chinese Union of Technology Enterprises (128 CUTE)

This 2015 Medical Device & Diagnostics Symposium is aimed 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.

Time: 1:00pm – 5:30pm, 01/24/2015 (Saturday)

Address: 93 Worcester Street, Wellesley, MA, 02481

Admission

CABA, NECINA, 128-CUTE, ACMA and HMS-CSSA members: FREE; Non-members: \$30, Student: \$15. On-site membership registration is available.

Symposium Organizing Committee

Chair

Wei Zhang (CABA)

Co-Chairs

Jingzhong Zhang

Ellen Fan

Ru Zheng

Jeff Hang

Zhiyong Yang

Committee

Jian Shao

Xiaoyong Zhao

Bo Ying

Qingqing Cao

Liping Zhou

Jeannie Li

Acknowledgement

We sincerely thank Harvard Pilgrim Health Care for providing event venue and facility.

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Symposium Agenda

12:30pm - 1:00pm Registration and Networking

1:00pm - 1:05pm Symposium Opening Remark
Wei Zhang, Ph.D. (CABA)

SESSION I - BUSINESS ON MEDICAL DEVICE

Moderator: **Qingqing Cao**, Ph.D. and **Jian Shao**, MBA.

1:05am - 1:50pm *Global Strategy in Medical Device Business (tentative)*
David Wang, Head of Corporate Strategy, Covidien

1:50pm - 2:20pm *The De Novo Pathway To Medical Device Market: Strategies and Tactics to Use and Avoid*
Mike Drues, Ph.D., President, Vascular Sciences

2:20pm - 2:35pm *The State Role: How the Massachusetts Life Sciences Center Helps Medtech Entrepreneurs Succeed*
Angus McQuilken, Vice President, Massachusetts Life Science Center

2:35pm – 3:05 *US-China Medical Device Marketing Strategy*
Grace Fu Palma, MBA, CEO, China Medical Device

3:05pm - 3:20pm **Coffee Break, Networking**

SESSION II – CUTTING EDGE TECHNOLOGIES

Moderator: **Jeff Hang**, Ph.D. and **Jeannie Li**, Ph.D.

3:20pm - 3:50 pm *Eastern Harmony Project (tentative)*
Shani Dowd, Director of Culture InSight, Harvard Pilgrim Healthcare

3:50pm - 4:20pm *Molecular Diagnostics Application (tentative)*
Hongshan Li, Ph.D., General Manager, QFW Consulting Company

4:20pm - 4:50pm *Point of Care Diagnostics*
Jingzhong Zhang, Ph.D. Medica Corporation

SESSION III - BUSINESS ON MEDICAL DEVICE

Moderator: **Ru Zheng**, MBA

4:50pm - 5:30pm *Panel Discussion*
Regina Au, **Hongshan Li**, **Shen Luan**, **Liang Yang**, **Xiaodong Wu**

5:30pm - 6:00pm Networking

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Biographical sketches of Speakers and Panelists



David Wang, MBA.; Vice President of Corporate Strategy, Covidien

David Wang currently serves as Vice President of Strategy, Insights and Portfolio Management for Covidien Corporate. Previously, David was Vice President of Strategy and BD&L for both Surgical Solutions Group and Vascular Therapies. He joined Covidien in 2010 after holding positions of increasing global marketing and strategic responsibility in the Cordis cardiovascular and DePuy neuroscience businesses of Johnson & Johnson. Before joining Johnson & Johnson in 2003, David served in various leadership positions at McKinsey & Company and at the University of Chicago's Biological Sciences Division of Academic Computing in Bioinformatics. David received both his bachelor's degree in biological sciences and Master of Business Administration degree in finance from the University of Chicago.



Mike Drues, Ph.D.; President, Vascular Sciences

Dr. Mike Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University in Ames, Iowa. He has worked for and consulted with leading medical device, pharmaceutical and biotechnology companies ranging in size from start-ups to Fortune 100 companies. He also works on a regular basis for the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world.

Dr. Drues is an internationally recognized expert and featured keynote speaker on cutting-edge medical technologies and regulatory affairs. He conducts seminars and short-courses for medical device, pharmaceutical and biotechnology companies, the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the US Centers for Medicare and Medicare Services (CMS) and other regulatory and governmental agencies around the world.

Dr. Drues is also an Adjunct Professor of Medicine, Biomedical Engineering & Biotechnology at several universities and medical schools. He regularly teaches graduate courses in Regulatory Affairs and Clinical Trials, Clinical Trial Design, Medical Device Regulatory Affairs and Product Development, Combination Products, Pathophysiology, Medical Technology, Translational Medicine and Biotechnology.

Vascular Sciences is an education, training, & consulting company offering a broad range of services to medical device, pharmaceutical & biotechnology companies including (but not limited to): stimulating & innovative educational programming, brain-storming sessions, prototype design, product development, benchtop & animal testing, regulatory strategy, intelligence & clinical trial design, FDA presentation preparation & defense, reimbursement, clinical acceptance, business development & technology assessment.

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Angus McQuilken, Vice President for Communications and Marketing, Massachusetts Life Science Center (MLSC)

Angus McQuilken joined the Massachusetts Life Sciences Center (MLSC) in 2008, and he currently serves as Vice President for Communications & Marketing. In this capacity he oversees media relations, electronic communications, event coordination, trade shows and other marketing activities. Prior to his work at the MLSC, Angus served as Vice President for Public Affairs for Planned Parenthood League of Massachusetts, as Deputy Communications Director for the Democratic National Convention Committee, and as Chief of Staff for State Senator Cheryl Jacques. Angus holds a BA in political science from the University of Massachusetts Amherst. In 2008 he received the Distinguished Citizen Award from the Massachusetts chapter of the American Society for Public Administration. He enjoys basketball, long-distance bicycling and politics.



Grace Fu Palma, MBA., Founder and CEO, China Medical Device

Grace Fu Palma is the Founder and CEO of China Medical Device, a consulting firm specializing in raising funds and commercialization for early stage (prototype onwards) and small companies in medical device industry between the West and China. Prior to this role, she held a variety of marketing and sales management positions at both large multinationals and start-up companies in the United States and China. At Hewlett Packard Medical Products and Philips Healthcare, she held the positions of North America marketing managers. She was responsible for product definition research and development, launches, product commercialization planning and execution with product revenues in the hundreds of millions across the spectrum of radiology, cardiology, critical care and point of care clinical areas through a wide range of diagnostic medical equipment and supplies. In the early 90s, she managed Hewlett Packard's the first medical production line transfer to China. As the head of Asia Pacific business at the start-up, she grew revenue from zero to millions by recruiting and managing indirect channels and partners' alliances in China and Asian countries without any budget, turning around money-losing countries into profit centers. She also spearheaded a fundamental strategic transformation from a technology-focused direction to a customer-centric market segment driven approach with detailed execution plan. She also led and managed sales and clinical team to meet annual targets and work through partners and alliances to cover large territories efficiently, built and managed OEM/indirect channels with multiple industry leaders to create and expand distribution and market awareness in surgery, intervention, and cancers. She received a BA degree from Beijing University in Beijing, China, and an MBA from Yale University in New Haven, CT.

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Shani Dowd, Director of Culture InSight, Harvard Pilgrim Health Care Foundation

Dr. Shani Dowd, B.A., LHD(hc), L.C.S.W. serves as Director of Culture InSight, a program of the Harvard Pilgrim Health Care Foundation, the charitable foundation of Harvard Pilgrim Health Care, Inc., a nationally recognized health plan. Ms. Dowd is Assistant Clinical Professor of Psychiatry, Department of Psychiatry at the Boston University School of Medicine, and is a member of the faculty of the Center for Multicultural Training in Psychology at Boston University. She serves on the Board of Trustees of the Massachusetts School of Professional Psychology, and on the Board of Trustees of the Fields, Hannagan, and Walters Charitable Foundation. She is a recipient of the Doctor of Humane Letters, *honoris causa*, from the Massachusetts School of Professional Psychology, in acknowledgement of her work to bring quality mental health care to diverse communities.



Hongshan Li Ph.D., General Manager of QFW Consulting Company

Dr. Hongshan Li has more than 20 years of experience in the development and optimization of biomarker detection platforms. Currently he is General Manager of QFW consulting group and President of 128 Chinese Union of Technology Enterprises. Previously, Dr. Li was senior application specialist in Quanterix, which is a life science company commercializing a revolutionary Simoa technology and platform for ultrasensitive protein detection. From 2011 to 2013, Dr. Li was a global technical support specialist for BioScale's novel non-optical detection and quantitation technology. Dr. Li was technical Lead and Senior Principal Scientist at Pall Corporation and was responsible for the development and execution of research projects for proteomics, diagnostics tool, chromatography products and applications development. Prior to joining Pall, he was Senior Application Specialist at Corning LifeSciences providing instrumentation and application of Epic label-free technology for HT drug screening. He also served as a program manager of Ciphergen applying genomics/proteomics research experience and hardware/software expertise to provide expert international technical support to both industry and academia. Dr. Li obtained his Ph.D. in Food Chemistry and Nutrition at Beijing Agricultural University in 1996.



Shen Luan, Ph.D., Director of Regulated Products, Thermo Fisher Scientific

Dr. Shen Luan is currently Director of Regulated Products at Thermo Fisher Scientific. Previously, he served as the President and CTO after co-founding Berg Diagnostics (now part of

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Berg) in 2010 and was named as COO in 2011. He led efforts on molecular profiling, pan-omics, CLIA-certified clinical diagnostics laboratory services, and overall technology management related to business operations. Prior to Berg, Dr. Luan was the Technical Product Manager of Waters Corporation for 5 years responsible for LC/MS system solutions and laboratory informatics and participated in the ISO13485 compliance program. Dr. Luan started his career with Thermo Fisher Scientific (originally Thermo Jarrell Ash Corporation) and held various management positions including Engineering Manager, Research Manager, and Product Manager during his 9 years there. Dr. Luan received a Ph.D. in Analytical Chemistry from Professor Robert Samuel Houk of Iowa State University and a B.S. in Chemistry from Peking University. He holds a Lean - Six Sigma Black Belt certificate. He is a member of BayHelix, an invitation-only organization of leaders of Chinese heritage in the global life sciences and healthcare community.



Regina Au, Strategic Marketing Consultant at BioMarketing Insight

Ms. Regina Au has over 20 years' experience in the biotechnology, pharmaceutical, medical device, and diagnostic industries. She helps companies evaluate their technology upfront by conducting an in-depth business due diligence to de-risk the product development process. This ensures that the technology is the right product for the right market in meeting a critical unmet need and that the market potential for the product meets the business goals of the

company. She will translate these unmet needs into a product profile or specification. Ms. Au then develops marketing strategies to ensure a successful product launch and product adoption.

Ms. Au also serves as an advisor for the Massachusetts Technology Transfer Center Platform Meetings and as a mentor for "Entrepreneurs for All" (formerly Merrimack Valley Sandbox) with entrepreneurs. She has written and published numerous articles on market trends in the industry. Her expertise is in various therapeutic areas such as cardiology, interventional cardiology, infectious disease, immunology, surgery, gastroenterology, and pulmonology. Prior to BioMarketing Insight she worked for companies such as Merck & Co., Genzyme Corp., NMT Medical, and Radi Medical Systems (now St. Jude Medical) in various positions of increasing responsibility in marketing and sales. She had P&L responsibility in managing a number of multimillion dollar product lines and has experience in upstream and downstream marketing including strategic marketing, product development, market development, product launches, and product management.

Her background includes an MBA in Marketing from the University of Connecticut, a Microbiology degree from the University of Michigan and a Masters in International Management from Thunderbird School of Global Management.



Liang Yang, Ph.D.; President and CEO, Bio-Detail Corporation.

Dr. Liang Yang is the President of Bio-Detail Corporation in Worcester, MA. He founded the company in 2013 and has run the company ever since. Previously, Dr. Yang was an assistant professor at Department of Neuroscience and Physiology, Upstate Medical University, SUNY, Syracuse, New York. He had research experiences in several areas including biochemistry, molecular and cellular biology, neuroscience, behavior biology, chronic pain, obesity and

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diabetes. Dr. Yang conducted postdoctoral research at John Hopkins Medicine School and MIT. He has published more than 10 original research articles. Dr. Yang obtained his Ph.D. in Neurobiology from the Chinese Academy of Science.



Xiaodong Wu, Ph.D.; Consultant.

Dr. Xiaodong Wu is a consultant in genetic technology. Most recently he helped Good Start Genetics, a genetic testing company specializing in carrier screen using next generation sequencing technology, develop new technology in genetic testing for a number of diseases. Previously Dr. Wu was a Senior Manager of Clinical Research and Senior Clinical Research Scientist at Interleukin Genetics, Inc. He ran clinical studies in several disease areas including osteoarthritis, periodontitis, osteoporosis and heart disease and helped the company develop two commercial products. Dr. Wu conducted postdoctoral research at Harvard Medical School and Massachusetts General Hospital. He has published more than 20 original research articles. Dr. Wu holds a B.S. in Biology and an M.S. in Ecology from East China Normal University. He obtained a Ph.D. in Cellular and Molecular Neurobiology from the Medical College of Ohio.
