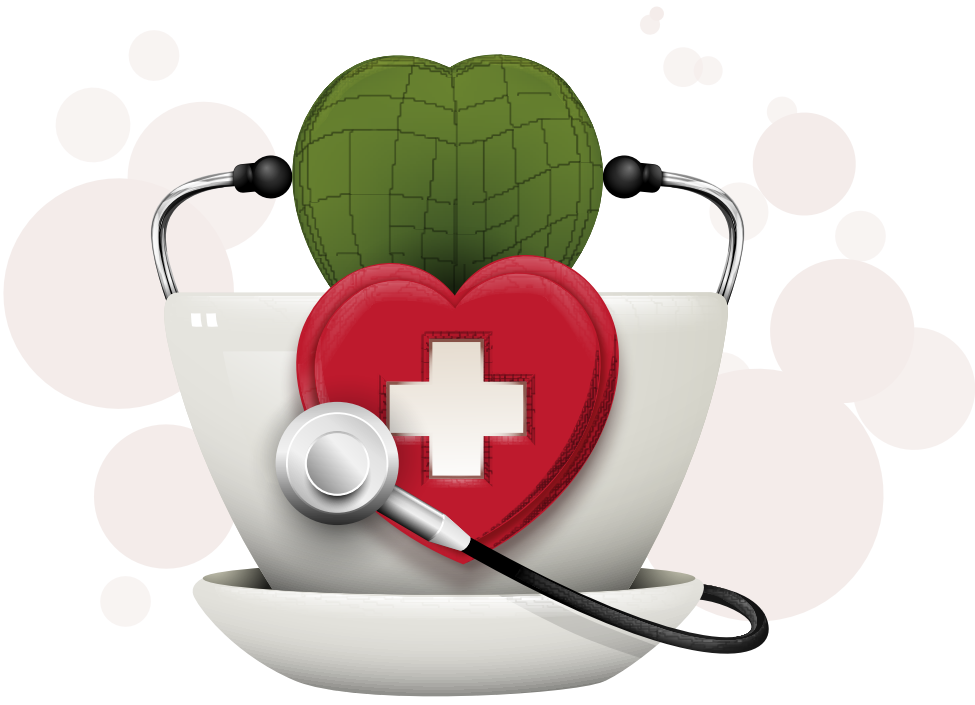
2017 CABA MDDI

Medical Device and Diagnostics Innovation Symposium

9 a.m. to 6 p.m., Saturday, December 9, 2017

INNOVATION
COLLABORATION
COMMERCIALIZATION



CABA

CSSA HMS
Chinese Scientists and Scholars Association at Harvard Medical School

2017 CABA MDDI

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2017 CABA Medical Device and Diagnostics Innovation Symposium (MDDI), organized by CABA, NECINA and Harvard Medical School CSSA, is to be held from 9 a.m. to 6 p.m., Saturday, December 9, 2017 at Folkman Auditorium of Boston Children's Hospital, Harvard Medical School, 300 Longwood Ave, Boston, MA 02115. Registration, check-in and networking will start at 9 a.m., and the official program will start at 10 a.m.

*The theme of this symposium is **"Innovation, Commercialization and Collaboration"**. Topics of this year's symposium includes new frontiers in medical device and diagnostics, entrepreneur experience, venture capital investment, partnership & collaboration, etc. The symposium provides a great opportunity to network with hundreds of professionals in the medical device field including scientists, entrepreneurs, investors, et al in the United States and China.*

Symposium Organizing Committee

Chair
Jeff Hang (CABA)

Co-chairs
CABA:
Lan Cao Jo Lee Jingzhong Zhang

NECINA:
Fan Wu

HMS CSSA:
Song Yang

Committee
-CABA-

Hao Cai	Qingqing Cao	Qinglin Che	Chaoyang Dai
Shujia Dai	Ruiyi Dong	Ellen Fan	Kevin Fang
Jing Huang	Pengyu Huang	Dandan Ling	Oscar Ouyang
Jian Shao	Eric Shi	Xue Shui	Shallwe Sun
Zhao-Kui (ZK) Wan	Shunqiang Wang	Winny Wang	Ben Wei
Sherry Xiao	Cindy Yang	Bo Ying	Yingqing Yu
Phil Zhang	Wei Zhang	Liping Zhou	Zhendong Zhu

-NECINA-

Litian He	Andy Li	Joan Ni	Tony Tian
Yuting Wang	Ru Zheng	Tony Zhu	

-HMS CSSA-
An Xiao Qiong Ye

Agenda

09:00am - 10:00am	**Registration and Networking**
10:00am - 10:05am	**Opening remarks** - MDDI Symposium Chair, Jeff Hang, PhD
10:05am - 10:10am	**Introduction of CABA** - Kevin Fang, PhD (CABA President)
10:10am - 10:15am	**Introduction of NECINA** - Andy Li, PhD (NECINA President)
10:15am - 10:20am	**Introduction of HMS CSSA** - Song Yang, PhD, (HMS CSSA President)
10:20am - 12:20pm	**Session 1: Entrepreneurship/Technology**, Session Chair, Fan Wu (NECINA)
10:20am - 10:50am	*Connected Health for Tomorrow - Wearable Sensors for Vital Signs Monitoring* Rong Xia, MBA, MPH, CEO, Raiing Medical
10:50am -11:20am	*The Democratization of Cryo-Electron Microscopy* Michael Shafer, President, Material and Structural Analysis, Thermo Fisher Scientific
11:20am - 11:50am	*The Unsung Role of Hydrophilic Lubricious Coating on Medical Devices* William Lee, PhD, VP of R&D and RA, AST Products
11:50am - 12:20pm	*From Industrial to Medical: The Story of an Optical 3-D Sensor Startup* Yi Qian, PhD, VP of Product Management, MRSI Systems
12:25pm - 1:30pm	**Lunch and Networking**
1:30pm - 3:30pm	**Session 2: 3-D Printing**, Session Chair, Lan Cao,PhD(CABA)
1:30pm - 2:00pm	*3-D Printing; How This Disruptive Technology Helped the Life Science and Healthcare Industry to Innovate.* Regina Au, MBA, Principal of BioMarketing Insight
2:00pm - 2:30pm	*Future Medical Applications in 3-D Printing* Mike Drues, PhD, President of Vascular Sciences
2:30pm - 3:00pm	*From 3-D Printing to Custom Medical Devices - Considerations for the Technical Review* Yue Min, MS, Reviewer, Division IV, Center for Medical Device Evaluation, CFDA
3:00pm - 3:30pm	*Trends and Investment Considerations for the Future of 3-D Printing in Healthcare* Stavros Stefanis, PhD, Principal and Laura Paulsen, MBA, strategy and operations consultant, Deloitte Consulting LLP
3:30pm - 3:45pm	**Coffee Break**
3:45pm - 5:30pm	**Session 3: Regulations and Commercialization** Session Chair, Jingzhong Zhang, PhD (CABA)
3:45pm - 4:30pm	Study of the Guiding Principles for the Registration of Custom Medical Devices in China Bin Liu, Director of Division IV, Center for Medical Device Evaluation, CFDA Moderator: Grace Fu, MBA
4:30pm - 5:00pm	CFDA In Vitro Diagnostics (IVD) Approval Process at CFDA Ellen Jiang, EMBA, Founder and President of RAMED Biosciences
5:00pm - 5:30 pm	What Makes You Succeed in China Medical Device Market? Grace Fu, MBA, CEO of China Med Device, LLC
5:30pm - 5:35pm	**Closing remarks** - Bo Ying, PhD (CABA)
5:35pm - 6:00pm	**Networking**

Topics & Speakers' Bio

1. 3D Printing; How This Disruptive Technology Has Helped the Life Science and Healthcare Industry to Innovate.

Abstract:

Today, everyone has heard about 3D Printing and how this disruptive technology has let people make almost anything they want in every type of material that exist. People are coming up with creative invention quicker and faster in the consumer industry and all you need is a creative idea, CAD software and a printer.

So how has this influenced the Life Science and Healthcare Industry? Find out how this industry have also come up with innovative ways to solve critical unmet medical needs and achieve the ultimate definition of personalized medicine.

Regina Au, MBA, Principal, BioMarketing Insight

Regina Au is Principal, New Product Planning/Strategic Commercial Consultant at BioMarketing Insight with 25+ years experience in the biotechnology, pharmaceutical, medical device, diagnostic and healthcare industries. She helps companies to maximize the benefits of their technology by conducting the business due diligence early in product development to de-risk the process and increase commercial success. This ensures that the technology is the right product for the right market in meeting a critical unmet need and that the market opportunity for the product meets the business goals of the company. She will translate these unmet needs into a target product profile (TPP) or commercial profile. Ms. Au then develops marketing strategies to ensure market access and product adoption.Prior to BioMarketing Insight she worked for Merck & Co., Genzyme Corp., NMT Medical, and Radi Medical (St. Jude Medical) in various positions of increasing responsibility in new product planning, marketing and sales. She had P&L responsibility in managing six multimillion dollar product lines and has experience in upstream and downstream marketing including strategic marketing, product development, market development, product launches, and product management.

2. Future Medical Applications in 3-D Printing: Clinical Benefits, Regulatory Issues & Manufacturing Challenges

Abstract:

Is printing a knee really any different than printing a drug? The regulatory strategies are exactly the same! Interested in 3-D printing applications in medicine, not just what we are doing today but what we could be doing in the future and how do we get there? For example, can we 'print' medical devices? Can we 'print' permanent implants? Can we 'print' combination products? Can we 'print' drugs (i.e., new molecular entities)? Can we 'print' living tissue? What are the technical and regulatory challenges these new technologies pose? Using case studies from a variety of clinical specialties, all of these and more will be discussed in this talk. Strategies for using regulation as a competitive advantage will also be discussed.

- understand what is currently being done in biomedical 3-D printing
- appreciate the technical and regulatory challenges and how to address them
- be aware of applications and technologies underdevelopment

Michael Drues, Ph.D., President, Vascular Science

Michael Drues, Ph.D., is President of Vascular Sciences, an education, training, & consulting company offering a broad range of services to medical device, pharmaceutical & biotechnology companies including stimulating & innovative educational programing, creative regulatory strategy & completive regulatory intelligence, regulatory submission design, FDA presentation preparation & defense, brain-storming sessions, prototype design, product development, benchtop & animal testing, clinical trial design, reimbursement, clinical acceptance, business development & technology assessment. 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.

3. China CFDA In Vitro Diagnostics (IVD) Approval Process

Abstract:

This presentation will mainly focus on the approved applications by the CFDA for IVD reagents in the last three years, including various concerns about the CFDA IVD registration requirements and pathway on the base of classification, and the differentiation between China CFDA and US FDA in regulating laboratory developed test (LDT). As an important policy for promopting industry development of new devices, the newly published exempted products from clinical trial as well as a new guidance to clinical equivalence report will be introduced. Finally, the speaker will share her experience in how to manage registration work professionally and effectively.

Ellen Jiang, Founder, president and CEO, Ramed (Beijing) Medical Technology Co., Ltd, Co-founder, Ramed Bioscience, LLC

Ms. Ellen Jiang is the founder, also president and CEO of Ramed (Beijing) Medical Technology Co., Ltd, and co-founder of Ramed Biosciences, LLC, where she leads Ramed dedicating regulatory service for medical device industry. Ms. Jiang has 25 years of work experience in healthcare, and 21 years of her work specialized in regualtory affairs, quality system, regulatory compliance and government affairs for medical devices. Ms. Jiang also actively involved in the work for product standards. She was a member of the 5th SAC/TC136 (National Standardization Technical Committee for Clinical Laboratory and In Vitro Diagnostic Test System) and the 1st SAC/TC338/SC1 (National Standardization Technical Committee for Measurement, Control and Electrical Equipment Safety Laboratory). Previously, Ms.Jiang was director of regualtory affair and compliance for BD China (1996-2010), and director of regualtory affairs and compliance for Thermo Fisher Scientific (2012-2015). The team she led was rewarded global CEO award in 2015, and several times of award of best support team while she worked in BD.Besides the work experience associated with China CFDA, Ms. Jiang also has practice cooperating with other kinds of regualtory bodies.

4. The Unsung Role of Hydrophilic Lubricious Coating on Medical Devices

Abstract:

While various metal or plastic materials have been brought in from other areas of science and technology without substantial redesign for their medical device applications, characteristically their choice is based on achieving a suitable combination of physical properties with a biologically passive and minimally toxic response in the host. However, while these materials do enable the development of new medical treatments, critical problems including biocompatibility, thrombogenicity, fibrous encapsulation, infectious complications and biostability remained. Thus, a quest for the perfectly inert medical device coating, harmless to the host tissue environment ensued. This talk will focus on improving the surface properties of interventional medical devices via hydrophilic lubricious coatings for applications in various medical treatments.

William Lee, Ph.D., VP, R&D and Regulatory Affairs, AST Products, Inc. (USA)

Dr. Lee is a leading surface chemist in the field of nano/biotechnology. Dr. Lee had developed functionalized membranes for peritoneal dialysis, polymeric electrolyte fuel cells, microbial cell removal and immobilization, protein separation and collection of uranium from seawater. Dr. Lee is a co-inventor of 1 Japan-issued and 3 US-issued patents, and 3 US patent applications. Dr. Lee is the cofounder of ICARES Medicus, Inc., a company that manufactures intraocular lenses and their related delivery devices and a shareholder of AST Products, Inc., a company that develops and sells medical devices and medical device coatings. Prior to AST Products, Dr. Lee founded eMembrane, Inc., a company that develops and commercializes surface modification technologies for chemical and biological applications. Prior to eMembrane, Dr. Lee worked for JAFCO, Japan's largest venture capital firm, Harvard Medical School/Massachusetts General Hospital, Japan Society for the Promotion of Science and Japan Atomic Energy Research Institute. Dr. Lee has led a team to obtain 3 CE-marking and 1 FDA-510(k) approvals for medical devices. He has also received numerous awards including the 2008 Frost & Sullivan North America Technology Innovation of the Year Award. Dr. Lee teaches several entrepreneurship courses at the Graduate School of Engineering of the Kyushu University (Japan). Dr. Lee received his B.Eng. and M.Eng. in Chemical engineering, and his Ph.D. in Chemistry and Biotechnology from the University of Tokyo (Japan). Dr. Lee is fluent in 7 languages including English, Japanese, Mandarin and Malay and a serial calligraphy awardee in Japan.

5. Study of the Guiding Principles for the Registration of Custom Medical Devices in China

Bin Liu, Director of Division IV, Center of Medical Device Evaluation, CFDA

Bin Liu, a biological materials research professor, director of Division IV, Center for Medical Device Evaluation (CMDE), China Food and Drug Administration (CFDA), and a member of the State Ministry of Science and Technology's "Additive Manufacturing and Laser Manufacturing" focused special group of experts. Mr. Liu holds the positions of deputy director of the Committee for Bone Repair and Devices Branch of China Biological Materials Institute (CBMI), deputy director of the Committee for Advanced Manufacturing Branch of CBMI, and a member of the Sub-committee of Orthopedic Implants in the National Surgical Implants Standards Technical Committee. He engaged in orthopedic clinical research and orthopedic implants technical review each for more than 10 years, led the technology research for registration management policy theory for custom medical devices, and participated as a major contributor in drafting multiple national and industry standards for the National Surgical Implants and Orthopedic Devices Standardization Technical Committee.

6. From 3D Printing to Custom Medical Device – Considerations for the Technical Review

Yue Min, reviewer of Division IV, Center for Medical Device Evaluation, CFDA

Yue Min, master of biomedical engineering, is a reviewer for the technical review of orthopedic implants and surgical devices at Division IV, Center for Medical Device Evaluation (CMDE), China Food and Drug Administration (CFDA). Yue participated in the preparation of multiple guiding principles, such as the Guiding Principles for the Review of Hip Prostheses, contributed to the studies on the regulation mode for custom medical devices and prepared research reports. She is a member of the Regulated Product Submission (RPS) working group of the International Medical Device Regulators Forum (IMDRF).

7. What Makes You Succeed in China Medical Device Market?

Abstract:

Grace Fu Palma, 20+ year of medtech veteran, CEO of China Med Device will talk about the key factors for success in China medical device market. China medtech market is the 2nd largest in the world now. “Innovate in China” is the new thing under President Xi. High growth comes with challenges. CFDA regulatory approval has become harder to obtain than that of U.S. FDA. Key areas will cover China Politburo key initiatives in healthcare, unique characteristics of medical device market in general, CFDA regulatory approval and commercialization for new medical devices in China, differences between FDA and CFDA, and shifting to domestic made high end products.

Grace Fu Palma, CEO, China Med Device, LLC.

Grace Fu Palma, CEO of China Med Device, LLC, a seasoned medtech executive, specializes in accelerating U.S. medical device companies’ entry and growth in China with regulatory and commercialization services. With 20+ years of experience driving global product strategy, commercialization, partnerships, and China operations for both large multinationals and startup companies, she held a variety of management positions in marketing and operations at multinationals and start-ups. She founded China Med Device, LLC (CMD) in 2011. CMD (www.ChinaMedDevice.com) helps medical devices & IVD companies with turn key commercialization services from market assessment, regulatory (premarket approval, legal representation, clinical evaluation, clinical trial and post market), to distribution management in China. CMD has helped 50+ companies with their entry and growth in China since its inception.She founded the Chinese American Heart Association in 2005, a 500+ member society today consisting of clinicians and researchers with Chinese origin. She grew up in Beijing, China and received a BA degree from Peking University, China, and an MBA from Yale University in New Haven, CT.

8. Trends and Investment Considerations for the Future of 3D Printing in Healthcare

Abstract:

Stavros Stefanis, Deloitte Consulting Partner, and Laura Paulsen, also of Deloitte Consulting, will present a brief overview of current 3D printing capabilities and the evolution of 3D printing in the healthcare setting. They will describe current trends and impact 3D printing is expected to have on corporate business models and investments strategies. There will also be several spotlights on 3D printing success stories and benefits, both from clinical and business perspectives, to enable an interactive and engaging presentation.

Laura Paulsen, MBA, Biomedical engineering and strategy operations consultant, Deloitte Consulting

Laura Paulsen is a biomedical engineer and strategy and operations consultant specializing in medical technologies. She has focused her career in medtech and has worked at several medical device start-ups, in academia, at Medtronic, and now at Deloitte Consulting serving a wide range of medical device companies from start-ups to Fortune 100. She has expertise in business development and strategy, product development, and supply chain and operations. Laura received her B.S. and M.S. degrees in biomedical engineering from Johns

Hopkins University and Duke University and her M.B.A. from the MIT Sloan School of Management. She was a medical device innovation fellow at the University of Minnesota's Medical Devices Center for two years where she identified clinical needs, created novel medical device solutions, wrote and published several patents and peer-reviewed articles, and licensed technology to a leading medical device company.In a recent publication she has explored the impact of the combination of exponential technologies, including 3D printing, on the patient journey, specifically for total hip replacement, but has also developed points of view and has relevant project experiences on the future of the digitally connected healthcare ecosystem.

Stavros Stefanis, Ph.D., Principal, Deloitte Consulting LLP

Stavros has 18+ years of experience and has led more than 100 projects in the areas of product innovation, R&D operations, quality management, cost optimization, supply chain strategy and execution. Stavros is considered a thought leader in digital product development domain with multiple publications and extensive industry experience in the Life Sciences, Consumer Goods, Industrial Products, and Energy sectors. Prior to Deloitte, Stavros was the US leader for Supply Chain Strategy practice at KPMG.

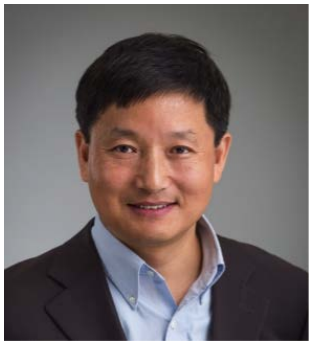
He plans to bring his experience in the areas of R&D operations, lean and value driven product development, portfolio optimization, quality management, organizational readiness and digital transformation.

Representative clients include J&J, Medtronic, Merck, Smith and Nephew, Philips, Novartis/Alcon, GE Healthcare, Unilever, Novartis, P&G, PepsiCo and BP. He has published a variety of engineering topics, sponsors the Product Innovation conference and authored more than 100 papers including chapters in multiple books.

9. From Industrial to Medical: The Story of an Optical 3D Sensor Startup

Abstract:

In this talk we will present a case study of an optical 3D sensor startup (Dimensional Photonics International) that has successfully transformed its business focus from industrial to medical products. Vision and execution were critical, great people and process were essential, platform technology and reputation from the initial industrial product were the enablers, and finally, close collaborations with partner customers were the key to develop a right product to meet market requirements at the right time.



Yi Qian, Ph.D., VP, Product Management in MRSI systems

Dr. Qian is a business and technology executive applying optoelectronics for multiple industries including medical devices. Over 20 years in China and USA with large companies and small startups, he successfully developed and commercialized technologies and products such as 3D dental sensors, automatic centrifuge bio-separation systems, semiconductor lasers for dermatology, and laser scanners for OCT/LASIK. He has Ph.D. in Physics from Chinese Academy of Sciences and was a postdoc at Cornell University.

Currently Dr. Qian is VP of Product Management in MRSI Systems making manufacturing robotic systems for medical devices and other industries. He helps MRSI Systems develop company's market strategy and product roadmaps, drive the development of new products, and diversify MRSI product offerings to target higher growth market segments. Prior to MRSI Systems he was the Head of Management and Marketing in Cambridge Technology, a Novanta company, delivering high performance laser scanners for medical and industrial applications. Before that, Dr. Qian worked at Oclaro as Director of Product Management for optical communication devices. He was VP of Project Management of Celeros Separations making automatic high speed centrifuge separations systems for large bio-pharmaceutical

companies. Previously He was VP of Engineering in Dimensional Photonics International, a 3D laser sensor system startup that was acquired by Danaher's Dental Division. Prior to that he was Director of Engineering in Corning's Lasertron division making high speed and high power semiconductor lasers for optical communications, dermatology, and industrial applications. He started his career in industry at Lasertron Inc. before Corning's acquisition.

10. The Democratization of Cryo-Electron Microscopy

Abstract:

Cryo-electron microscopy (cryo-EM) enables customers to routinely produce highly resolved, three-dimensional images of protein structures. This information is used to better understand biological function and leads to the design of novel therapies. The Nobel Prize in Chemistry 2017 was awarded to three researchers who had spent decades advancing cryo-EM.

This presentation will discuss how Thermo Fisher Scientific is actively working with the research community to address challenges in academia and bio-pharma. Our goal is to make cryo-EM accessible to the 4,000+ structural biology laboratories allowing scientists to accelerate scientific discovery and translate their breakthroughs to novel drugs and therapeutics.

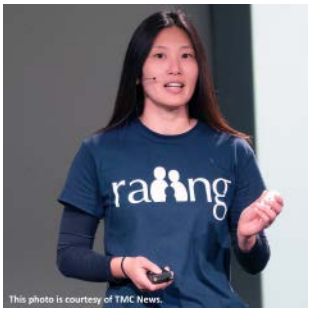
Michael Shafer, President, Materials and Structural Analysis

Mike Shafer, SSMBB, President, Materials and Structural Analysis, Formerly President of China Operations, Thermo Fisher. Mike joined Thermo Fisher in 2009 as Vice President and General Manager of China, based in Shanghai, and was named President of the company's China operations in 2012. In 2015, Mike was appointed President of the Chemical Analysis business, and in 2016, following the acquisition of FEI Company, he became President, Materials and Structural Analysis. Prior to joining Thermo Fisher, Mike worked at 3M Company for more than 15 years, managing various industrial and electronics businesses. With 3M, he spent seven years in the Asia-Pacific region, serving as APAC Business Director for the company's Industrial & Transportation Businesses as well as APAC Electronics Market Materials Division Manager. Mike earned his Bachelor of Arts degree from the University of Minnesota. He is a six sigma master black belt.

11. Connected Health for Tomorrow - Wearable Sensors for Vital Signs Monitoring

Abstract:

Raiing Medical was incorporated in 2014 and is incubated in Harvard Launch Lab and Texas Medical Center Innovation Institute. Our product iThermoitor is a FDA 510(k) cleared wearable thermometer that transmits real-time core body temperature via Bluetooth. Our clinical collaborators include Boston Children's Hospital, Massachusetts General Hospital, Cleveland Clinic, and Peking Union Hospital, etc. iThermonitor is the only wearable thermometer that has clinical validation. The study and results are going to be published by the Anesthesia and Analgesia journal. Our goal is to develop clinical applications based on the wearable technology and AI solutions for disease diagnosis, management, prediction, and prevention.



Rong Xia, MBA, CEO, Raiing Medical

Rong Xia is the CEO of Raiing Medical – a Boston based medical device startup incubated in Harvard Launch Lab and Taxes Medical Center Innovation Institute. Rong is passionate about applying new technologies to digital health. She has 15 years experiences in pharmaceuticals, medical devices, and digital health with Sanofi, Covidien and Agfa HealthCare before she joined Raiing Medical. She received her MBA from the KEDGE Business School and MPH from Harvard University School of Public Health. She grew up in China and is a purple belt of Brazilian Jiu Jitsu.

NOTES

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6. Future Medical Applications in 3-D Printing

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8. Trends and Investment Considerations for the Future of 3-D Printing in Healthcare

9. Study of the Guiding Principles for the Registration of Custom Medical Devices in China

10. In Vitro Diagnostics (IVD) Approval Process at CFDA

11. What Makes You to Succeed in China Medical Device Market?

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CABA Mission Statement

- To promote science, technology, and business collaboration in biotech/pharmaceutical industry ;
- To build and maintain a platform through cohesive scientific, professional, and cultural connection that provides high quality services;
- To facilitate networking among scientists, professionals, and entrepreneurs in academia, biotech/pharmaceutical industry and regulatory agencies;
- To embrace advancement of science and commercialization of innovation that will benefit human health;
- To foster collaborations between the United States and China for the development of better biotech/pharmaceutical therapeutics.

About CABA

CABA is a 501(C)(3) not-for-profit professional organization registered in Massachusetts since May 2007. CABA is committed to promote public awareness of advancement in the pharmaceutical and biomedical industry, professional interactions in the fields of life sciences, global biomedical innovations and business development. As the majority of its members are scientists with Chinese heritage, CABA will operate in two important areas. One is to serve as a platform for its members to develop and advance their careers in the US pharmaceutical and biomedical industry, the other is to serve as a bridge to connect members including corporate members with the scientific and business resources in China thus facilitating collaboration between the pharmaceutical and biomedical industries across continents. To fulfill these goals, we will organize scientific and business symposia, conferences, workshops, in US and China, as well as social events to promote networking and communication among members. We will bring together members, scientists, professionals, government officials and business leaders across the continents under a collaborative environment and achieve their best potential.

CABA is a volunteer-based society. We rely on members to contribute their time and efforts to build the organization. We rely on corporate members and sponsors to raise fund to support the above activities. We value integrity, honesty, professionalism, community service, scientific excellence, responsibility and accountability. We invite you to explore our organization, and we are confident you will share our values and are interested in becoming a member, devoting your time or efforts, or sponsoring CABA activities. In summary, CABA is built by its members and serves its members.

Contact Us

If you have any comments, suggestions or feedback to our organization and our events, please feel free to contact us at **info@cabaweb.org**. Your comments are important for us to improve in the future. Thank you very much!

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