### CBA 2019 Workshop Series IV: Innovative Medtech Shaping the Medical Industry

**Date and Time:** November 16, 2019, Saturday 1:30 – 4:30 pm  
**Venue:** Jones Day Silicon Valley Office, 1755 Embarcadero Road, Palo Alto, CA, 94303

**Organizer:** CBA  
**Co-organizer:** CIE

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<th>Time</th>
<th>Topic</th>
<th>Speaker</th>
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<td>1:30-1:50pm</td>
<td>Registration Opens</td>
<td>CBA</td>
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<tr>
<td>1:50-2:00pm</td>
<td>Welcome and Introductions</td>
<td>Steve Wu, Director of R&amp;D and New Technology Development, Shockwave Medical Inc.</td>
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<td>2:00-2:25pm</td>
<td>Sweet Spot or Perfect Storm Coming? The Past, Present and Future of Medtech Challenges</td>
<td>Henry Yan, CEO of Luminor International</td>
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<td>2:25-2:50pm</td>
<td>What Investors Seek in Medical Device Companies and Their Business Opportunities in China</td>
<td>Shelley D Suggett, Principle Regulatory Affairs Consultant, Themistry Inc.</td>
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<td>2:50 - 3:05 pm</td>
<td>Regulatory Pathways for Device Approval</td>
<td>Joe Tai, PhD, JD, Attorney at law, Haverstock and Owens LLP</td>
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<td>3:05 - 3:15pm</td>
<td>Break</td>
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<td>3:15 - 3:30pm</td>
<td>Patent Strategy in Medtech</td>
<td>Henry Yan, Steve Wu, Shelley D Suggett and Joe Tai</td>
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<td>3:30 - 4:10pm</td>
<td>Panel Discussion</td>
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<td>4:10-4:30pm</td>
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Speakers:

Steve Wu: Sweet Spot or Perfect Storm Coming? The Past, Present and Future of Medtech Challenges

Abstract: I will review the past, present and future of Medtech challenges, then share my first hand experience and insight with Medtech startups in US

Steve Wu is a technologist and inventor with 33 years of experience in medical technology, holding various R&D, engineering and management positions in startups as well as leading medical device firms, including Acclarent, a JNJ companies, JNJ's Accelerated Medical Ventures Incubator and Cordis, a JNJ companies, InterVentional Technologies, a Boston Scientific companies, Medtronic, Micro-therapeutics, and Shockwave.

An experienced and hand-on leader with years of medical device design, development experience of moving innovative technologies from concept to commercialization. He is primary or co-inventor of 21 issued patents and 6 US Patent pending.

Mr. Wu has been the Director of R&D and New Technology Development and a shareholder of Shockwave Medical since 2012. Shockwave Medical has grown from 5 to current 250 plus employee now and it was selected as top cardiovascular technology award at CRT 2015 (Washington DC) and 2016 Red Herring North America Top 100 Most Promising Private Ventures Winner; Shockwave (SWAV) was successfully IPO in US Nasdaq on March 2019.

Henry Yan: What Investors Seek in Medical Device Companies and Their Business Opportunities in China

Abstract: In today’s speech, Yan will explore the decisive factors in medical device companies seeking investment through case analysis. The key points Yan will cover are product positioning, team, technology and product development, marketing strategy, and equity structure. Through Yan’s sharing, medical device startups will become better at their business and capital rising.

Henry Yan is the CEO of Luminor International. He comes from an engineering, law, and investment background. Working as a lawyer for over twenty years, Yan is also the founder of a large law firm in China. As the general partner of several funds, in the past decade, Yan’s funds have invested tens of companies, among which over ten companies have gone IPO in China, Hong Kong, U.S. and Singapore. Luminor is an investment and accelerator platform, providing companies investment in China and the U.S. and professional services (including but not limited to IP protection, legal, technological support, human resources). Luminor’s portfolio is currently consisted of over 50 companies.

Henry Yan obtained his Bachelor’s degree in Mechanical Engineering from Harbin Institute of Technology, School of Heavy Machinery. Then, Yan earned his Master’s degree in International Economic Law from Fudan University. Yan is currently a Doctor of Business Administration candidate at W.P. Carey School of Business – Arizona State University.

Shelley Suggett: Regulatory Pathways for Device Approval
Abstract: In that discussion, I will give the overview of the different types of devices and how they are regulated in the US, and I will try to touch upon the EU.

Shelley D Suggett is a Principle Regulatory Affairs Consultant, Themistry Inc. She has a broad range of experience in research, antibody development, regulatory and supply chain, and her achievements have been published in various industry forums and peer-reviewed journals. She enjoys using her diverse skill set to establish strategies that benefit the companies she works with and, more importantly, the patient. One of Ms Suggett’s favorite career memory was when she was the strategic RA CMC lead during the development and licensure of Lucentis for AMD (Age related Macular Degeneration). During this time, she had the privilege to meet one of the patients in the clinical trial. The woman described how, after many years of vision loss, due to the efficacy of this drug, she was able to see the faces of her grandchildren for the very first time.

That powerful moment always reminds Ms Suggett of the importance of the work she does and sets the tone for the passion she brings to her roles.

Currently, she manages her own consulting firm providing clients with cross functional regulatory advice and consulting, she has particular expertise in CMC and Scientific Advice Preparation for global Health Authorities (e.g. FDA, EMA, PMDA, CFDA).

Joe Tai: Patent Strategy in Medtech


Dr. Joe Tai is an attorney-at-law, an inventor, and an entrepreneur. Dr. Tai’s legal practice has a focus on intellectual property law, including patents, trademarks, and copyrights. Dr. Tai has been named as a Super Lawyer Rising Star from 2012-2019. Dr. Tai is named the Distinguished Alumni of Fu-Jen Catholic University (Taiwan).

Dr. Tai has served as advisors and officers of corporate and intellectual property strategy at tech companies in the U.S. and Asia including Astrid Pharma Corp, Bellavita Technology Inc. (Agricultural & Environmental tech), Humic Growth Solutions (Agricultural tech), Instant Care Inc (Personal Emergency Response) and Optolight (LED).

As an inventor and entrepreneur, Dr. Tai has successfully invented, patented, manufactured, and commercialized innovative products that are sold in national retail stores. Dr. Tai was awarded 2011 and 2014 Invention Gold Medals at INPEX. Dr. Tai and his inventions are frequently featured on various media, including newspaper articles, radio shows, business magazines, and TV shows, including TV shows on Food Network and DIY network.

Serving as an officer for non-for-profit organizations, Dr. Tai was the VP of the Chinese American Renewable Energy Society (CARES) and was a Board of Directors of Chinese Institute of Engineers (CIE-SF).
Dr. Tai received his B.S. and M.S degree from Fu-Jen University in Taiwan, received his Ph.D. in Chemistry from U.C. Davis, California and received his J.D. from the School of Law of Golden Gate University, California.