THE MEDTECH CONFERENCE

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September 23-25, 2019

Boston Convention and Exhibition Center | Boston, MA

U.S. Market Access Seminar
Sunday, September 22, 2019
12:30-5:00 p.m.
Boston Convention & Exhibition Center, Room 156C
Sponsored by: McDermott Will & Emery LLP

Please be aware that lunch will not be served.
This event is closed to the press.

The U.S. Market Access Seminar is a pre-program for international delegates attending The MedTech Conference. It will address key issues for non-U.S. medtech companies seeking to launch products in the U.S. market. Instructors will cover regulatory and reimbursement pathways as well as perspectives about the changing landscapes in each of these areas in the U.S.

Agenda

12:30-12:35 p.m. Welcome (Angus McQuilken, McDermott Will & Emery LLP)

12:35-1:05 p.m. U.S. Market Overview (Steve Miller, SelectUSA)

1:05-1:50 p.m. Establishing a Company in the U.S.: Legal Considerations (Byron S. Kalogerou, Partner, McDermott Will & Emery LLP)
- Taxation, immigration, Other issues

1:50-2:50 p.m. Establishing a Company in the U.S.: Economic Development Support
Moderator: Christine Sarkisian
- Massachusetts (Mark Sullivan, MOITI)
- South Carolina (Mike Graney, Charleston Regional Development Alliance)
- California/Greater Los Angeles (Kwame Ulmer, Ulmer Ventures)

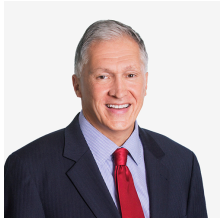
2:50-3:00 p.m. Break

3:00-5:00 p.m. Planning Your FDA and Reimbursement Pathways: How to Find Your Most Efficient Way to Market
This session, led by attorneys from McDermott Will & Emery's FDA practice, will focus on the benefits of simultaneously considering FDA & reimbursement pathways when formulating product development plans, helping MedTech Conference attendees understand their most efficient path to market for new and novel devices, diagnostics and digital health technologies. U.S. companies, and international companies that are looking to sell products in the U.S., will benefit from being part of this interactive session.
Speakers: Vernessa Pollard, Partner; Michael Ryan, Partner, McDermott, Will & Emery LLP

*Delegates are invited to proceed to the **International Reception**, Legal Seafood Harbourside, 250 Northern Ave., Boston, from 5:30-7:30 p.m.*

Reception sponsored by Québec

Speaker Biographies



Byron S. Kalogerou, Partner
McDermott, Will & Emery LLP

Byron S. Kalogerou is the founder of the Firm's Life Science Industry Group and the senior attorney in the Boston Corporate Practice. He focuses his practice on domestic and cross-border mergers and acquisitions, finance, and joint ventures and alliances. He has substantial on-the-ground experience structuring mergers, acquisitions, divestitures and joint ventures on six continents. Byron has extensive industry background in the life science, industrial and manufacturing sectors. He also acts as outside general counsel to a number of companies. Byron spent 17 years in-house, where he served in various general counsel roles at Tyco International, including as general counsel of its fire and security and telecom businesses and as general counsel of its international legal department, a function he created. Byron led many of Tyco's largest acquisitions, including the $12 billion acquisition of AMP Inc. and the $850 million purchase of AT&T Submarine Systems, and handled hundreds of middle-market deals around the globe. Byron also handled Tyco's initial foray into medical devices and led many of the deals that formed Covidien, now part of Medtronic. **Contact:** bkalogerou@mwe.com

Christine Sarkisian

Christine Sarkisian advises biotech and medtech entrepreneurs on the path to commercialization and assists companies with expansion to global markets. Based in the New England ecosystem, she connects emerging companies to local resources and global enterprises. She previously served as Life Sciences Business Development Officer at the Consulate General of Canada, Boston, and was a co-founder of the Canadian Technology Accelerator in Boston. Prior to joining the Government of Canada, Christine was a member of the executive team of a Massachusetts-based financial institution, and held positions in marketing and communications for Fortune 500 corporations. A native Bostonian, she holds a Master's Degree in Intercultural Relations with a specialization in Training and Consulting for Business from Lesley University; a Bachelor's in Business Communication and an Associate's Degree in Accounting from Bentley University. She has studied Cellular & Molecular Biology at Harvard University, and worked in the business cultures of Canada, France, Italy and the U.S. Ms. Sarkisian teaches courses in communication at Bentley University.

Michael J. Graney, Vice President, Global Business Development
Charleston Regional Development Alliance (CRDA)

Michael J. Graney leads the CRDA's comprehensive, strategic global business development efforts focused on five industry clusters - Aerospace, Automotive, Information Technology, Life Sciences and Advanced Logistics. Mike joined the CRDA after successfully managing the Business Development program at the Economic Development Council of Western Massachusetts for more than eight years. Mike's focus is on inward investment to Charleston, with a particular emphasis on European FDI. Mike is active with our Investor Relations program, engaging public and private sector investors and allies to support our business attraction strategy. **Contact**: mgraney@crda.org

Kwame Ulmer, Principal
Ulmer Ventures

Kwame Ulmer serves as the Principal at Ulmer Ventures, a regulatory strategy consulting firm. He brings nearly twenty years of experience evaluating medical technologies in the government and serving in senior operating roles at medical device companies. Mr. Ulmer previously served as Vice President, Regulatory Affairs and Quality Assurance at Implant Direct, a Danaher Corporation operating company. Kwame has served in progressive leadership roles at the US Food and Drug Administration (FDA) and personally evaluated over 1,000 medical technologies. Mr. Ulmer is also a Venture Partner at Wavemaker Three-Sixty Health - the leading Southern-California based, early stage venture capital firm (Seed and Series A) focused on the healthcare industry, member of the Executive Committee of Tech Coast Angels (LA), the world's largest angel investing network, and a member of the steering committee for ScaleLA, the leading healthcare innovation space in Los Angeles. Kwame earned his B.S. in Physics from Lincoln University (Pennsylvania) and both an M.S. in Materials Engineering and M.B.A. from the University of Virginia. **Contact:** kulmer@wavemaker360.com

Vernessa T. Pollard, Partner
McDermott Will & Emery LLP

Vernessa T. Pollard advises companies on regulatory, compliance, enforcement and policy matters involving pharmaceuticals, medical devices, health information technology (HIT) and digital health solutions, services and software. She advises companies and investors on regulatory and compliance issues arising from mergers, acquisitions and other transactions involving Food and Drug Administration (FDA)-regulated products. She also counsels manufacturers, distributors and retailers on regulatory and compliance issues related to food and cosmetic marketing and safety. Vernessa regularly counsels companies on product development and premarket strategy, Good Manufacturing Practice (GMP) and Quality System (QS) requirements, advertising and promotion, adverse event reporting, FDA warning letters,

FDA inspections, recalls, import detentions and corporate compliance programs. She has represented companies and executives in FDA and Department of Justice (DOJ) investigations and enforcement matters. She also conducts due diligence evaluations and analyses of FDA regulatory issues relating to mergers and acquisitions. Previously, Vernessa spent six years as an associate chief counsel for enforcement in the Office of Chief Counsel at the FDA, where she represented the FDA in a variety of litigation, compliance and regulatory matters. In conjunction with the DOJ, she handled civil injunction and consent decree actions involving pharmaceutical, medical device, food and cosmetic manufacturers. She obtained FDA's first administrative civil money penalty (CMP) judgement for violations of the Medical Device Report (MDR) requirements. **Contact:** vpollard@mwe.com

Michael W. Ryan, Partner
McDermott, Will & Emery LLP

Michael W. Ryan advises manufacturers, health care providers, developers, and investors on the legal, regulatory, and reimbursement issues that arise during the development and commercialization of medical devices, drugs, biological products, and clinical laboratory testing services. Michael advises clients on the regulatory issues that arise throughout the life cycle of FDA-regulated medical devices, drugs, and biological products. He is particularly experienced in the review of promotional/marketing materials for FDA-regulated medical products, as well as the FDA's evolving requirements for mHealth products, including mobile medical applications and clinical decision support software. Michael regularly counsels clinical laboratories on federal (CLIA) and state regulatory issues, as well as the FDA's ongoing efforts to regulate laboratory-developed tests (LDTs). Michael also helps clients develop and implement strategies to persuade Medicare, Medicaid, and other third-party payers to establish adequate coverage and reimbursement for their products and/or the services in which their products are utilized. **Contact:** mryan@mwe.com