Developing Your Global Medical Device Regulatory Strategy
Tuesday, 2 October 2018

7:00 am	**Registration and Continental Breakfast**
8:00 am	**Regulatory Strategies: A Living Document** This session will outline how to keep your regulatory strategy current as it progresses through development and how to deal with marketplace and regulatory changes. • Presentation of specific steps to keep the regulatory strategy alive and to make the necessary changes to your regulatory strategy during the entire product life cycle. **Patrick Lee, PE, MS, MBA, RAC,** senior director of RA/QA, Vascular Dynamics
8:30 am	**Group Work—Case Study Part 3: Finalization of Regulatory Strategy Workshop** Teams will be invited to rework on their case study based on the presentation information they heard the day before. • With the information from Part 1 and Part 2, participants will work as a team to prepare the overall product regulatory strategy roll out and communication plan • The faculty will provide considerations for the teams to examine in working to complete Part 3 of the strategy template. **Megha Deviprasad Iyer, MS, RAC,** director, global regulatory affairs, Thermo Fisher Scientific
9:30 am	**Hot Topics from Around the World: Part 1—USA** This session will discuss regulatory trends in the US with a special focus on product continuation, postapproval and strategies for product changes: Digital health, Software as a Medical Device (SaMD), Software inside of medical devices (SiMD), Premarket submissions, Presubs, Usability, UDI, Labeling, MDUFA IV Reauthorization (2018 to 2022), MDSAP, any other hot topics. **Nicole Landreville, Eng, RAC, FRAPS**, regulatory affairs manager, GE Healthcare
10:00 am	**Refreshment Break**
10:30 am	**Basics about Meeting with Regulators/Setting Up** How to integrate FDA meetings into a medical device regulatory strategy • Benefits and pitfalls of meetings: how, why, when and who. • Optimizing the outcome from a meeting; making informed decisions and planning **Patrick Lee, PE, MS, MBA, RAC,** senior director of RA/QA, Vascular Dynamics

11:00 am	**Hot Topics from Around the World: Part 2—EU** This session will discuss regulatory trends in Europe with a special focus on product continuation, postapproval and strategies for product changes: • Medical Device Regulations, In-Vitro Diagnostic Regulations, BREXIT, Software, Usability, Radio Equipment Directive (RED), eIFU, etc. **Megha Deviprasad Iyer, MS, RAC,** director, global regulatory affairs, Thermo Fisher Scientific **Nicole Landreville, Eng, RAC, FRAPS**, regulatory affairs manager, GE Healthcare
11:30 am	**Hot Topics from Around the World: Part 3—International—China** This session will discuss regulatory trends in China, with a special focus on Decree 650 implementation and policy direction changes in the last 12 months. **Brad Hossack**, international vice president, regulatory affairs, Stryker Corporation
12:00 pm	**Lunch**
1:00 pm	**Hot Topics from Around the World: Part 3—International – ASEAN** This session will discuss regulatory trends in ASEAN with a special focus on regulatory and PMS changes implemented in the past 12 months. **Nicole Landreville, Eng, RAC, FRAPS**, regulatory affairs manager, GE Healthcare
1:15	**Hot Topics from Around the World: Part 3—International – Rest of World** This session will discuss regulatory trends in Japan, Latin America, Africa, with a special focus on regulatory and PMS changes implemented in the past 12 months. **Brad Hossack**, international vice president, regulatory affairs, Stryker Corporation
1:45 pm	**Group Work—Case Study Part 3 (con't): Finalization of Regulatory Strategy Workshop** Last group work session where participants will work as a team to finalize the overall product regulatory strategy • The faculty will provide considerations for the teams to examine in working to complete Part 3 of the strategy template.
2:30 pm	**Refreshment Break**
3:00 pm	**Team Presentations—Regulatory Strategy Roll Out** In this session, groups will present their overall Regulatory Strategy to the panel representing Senior Managers of the fictional medical device company.
3:45 pm	**Roundtable** Group exchange on best practices (including global challenges, global submissions strategic formatting, hot topics raised by the team during the workshop, show graphical presentation when you need to present to different audiences, etc.) **Megha Deviprasad Iyer, MS, RAC,** director, global regulatory affairs, Thermo Fisher Scientific **Brad Hossack**, international vice president, regulatory affairs, Stryker Corporation **Nicole Landreville, Eng, RAC, FRAPS**, regulatory affairs manager, GE Healthcare **Patrick Lee, PE, MS, MBA, RAC,** senior director of RA/QA, Vascular Dynamics
4:00 pm	**Adjourn**


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