Regulatory Strategy Forum for Medical Devices
Saturday, 9 September 2017

All attendees need to bring their laptop to the workshop

8:00 am	**Registration and Continental Breakfast**
9:00 am	**Introductions and Icebreakers** • This session will focus on introducing the panel members as well as introduction of participants to their assigned team. • Participants will be assigned to a team / table before they enter the conference room. **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
9:20 am	**Regulatory Strategies: Where Should You Start?** This session will examine the basics of regulatory strategy formulation: • Why strategy is important? What is involved in developing a strategy? • The importance of assessing the regulatory landscape, the intended claims and speed to market when determining your regulatory strategy from both the medical device and IVD's perspective. **Nicole Landreville, Eng, RAC, FRAPS**, regulatory affairs manager, GE Healthcare **Megha Deviprasad Iyer, MS, RAC,** director, global regulatory affairs, Thermo Fisher Scientific
9:50 am	**Group Work—Case Study Introduction:** • This session will introduce participants to their fictional medical device, the global regulatory strategy template and the expectations for its three parts completion. • The panel will provide description of the work ahead, what the expectations are and some tricks about how to start and how to divide the work ahead. • Team will have 30 minutes to discuss amongst themselves about how to organize their efforts and start completing part 1 of their strategic plan. **Patrick Lee, PE, MS, MBA, RAC,** senior director of RA/QA, Vascular Dynamics
10:30 am	**Refreshment Break**
11:00 am	**Business Considerations: Regulatory's Role and Partnerships** This session will evaluate:

	• The role of the regulatory professional as a strategic partner in business. • How regulatory strategy fit into the overall business strategy. • Factors impacting regulatory strategy: product claims, product differentiation, pricing, competition, predicate devices, supplier power, customer power, local regulatory environment, distribution channel, business model, and others. • Business arrangements and environment changes, such as in-licensing, mergers, partnership, international expansion and line extension.. **Patrick Lee, PE, MS, MBA, RAC,** senior director of RA/QA, Vascular Dynamics
11:30 am	**Group Work—Case Study Part 1: Product Definition and Analysis Workshop** • Teams will each prepare a global regulatory strategy plan (GRS) for a fictitious medical device and will work together to prepare a detailed definition of the product/device, its intended use, its current regulatory status, comparable existing products from the competition, etc. • The faculty will provide considerations for the teams to examine in working to complete Part 1 of the strategy plan. **Brad Hossack,** international vice president, regulatory affairs, Stryker Corporation
12:00 pm	**Team Presentations—Case Study Part 1: Product Definition and Analysis Team** In this session, groups will present their results from completion of Part 1 of GRS with an active Q&A session.
12:30 pm	**Lunch**
1:30 pm	**Developing Regulatory Strategies for a Global Market** • This session will focus on incorporating global requirements into your regulatory strategy. • You will learn how to drive the project team to think globally and how to address key international hurdles often encountered. • This session also will highlight some of the unique registration requirements in major and emerging growth markets outside the US. **Brad Hossack,** international vice president, regulatory affairs, Stryker Corporation
2:00 pm	**Obtaining Buy-in for Regulatory Strategy** • This session will evaluate the process involved in presenting your regulatory strategy to organizational decision makers to obtain buy-in and approvals. • Project planning needs for successful execution of your strategy also will be highlighted. **Megha Deviprasad Iyer, MS, RAC,** director, global regulatory affairs, Thermo Fisher Scientific
2:30 pm	**Role of Regulatory Intelligence in Strategy Development** • This session will provide a brief overview of the role of regulatory intelligence in developing a global regulatory strategy document.

	• Presentation of various sources of information available to stay current on the global regulatory environment. • Provide tips on how to search for different type of information. • These methods will be useful in the case study work assigned. **Nicole Landreville, Eng, RAC, FRAPS**, regulatory affairs manager, GE Healthcare
3:00 pm	**Refreshment Break**
3:30 pm	**Group Work—Case Study Part 2: Market Definition & Analysis Workshop** • Work together as a team to prepare a detailed definition of the targeted markets for the fictitious medical device. • Team will perform and document their analysis of relevant considerations including regulatory requirements, regulator communication requirement, market application/submission approach, etc. • The faculty will provide considerations for the teams to examine in working to complete Part 2 of the strategy template. **Nicole Landreville, Eng, RAC, FRAPS**, regulatory affairs manager, GE Healthcare
4:30 pm	**Team Presentations—Case Study Part 2** In this session, groups will present their results from completion of Part 2 of GRS with an active Q&A session.
5:00 pm	**Adjourn**
6:00 pm	**Optional Networking Activity**

Sunday, 10 September 2017

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. **Brad Hossack,** international vice president, regulatory affairs, Stryker Corporation
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** • This session will discuss regulatory trends in ASEAN, 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. **Megha Deviprasad Iyer, MS, RAC,** director, global regulatory affairs, Thermo Fisher Scientific
2:30 pm	**Refreshment Break**
3:00 pm	**Team Presentations—Regulatory Strategy Roll Out** In this session, groups will present their overall Regulatory Strategy.
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**