Developing Your Global Medical Device Regulatory Strategy
Saturday, 21 September 2019
9:00 am – 5:00 pm

8:00 am	**Registration and Continental Breakfast**
9:00 am	**Welcome and Workshop Introduction** **Introductions and Icebreakers** This session will focus on introducing the panel members as well as introduction of participants to their assigned Workshop Team. • Participants will be assigned to a team color at random before they enter the conference room. **Megha Deviprasad Iyer, MS, RAC**, Global Director Regulatory Affairs, Thermo Fisher Scientific **Brad Hossack,** VP Global Regulatory Affairs - Corporate, Stryker **Nicole Landreville, P.Eng, RAC, FRAPS**, Regulatory Affairs Manager, GE Healthcare **Patrick Lee, PE, MS, MBA, RAC,** Director of Regulatory Affairs, BioCardia, Inc.
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. **Megha Deviprasad Iyer, MS, RAC**, Global Director Regulatory Affairs, Thermo Fisher Scientific **Nicole Landreville, P.Eng, RAC, FRAPS**, Regulatory Affairs Manager, GE Healthcare
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 40 minutes to discuss amongst themselves about how to organize their efforts and start completing part 1 of their strategic plan.

	Teams will be invited to assign specific roles to each team members in an effort to efficiently work together as a team.
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,** Director of Regulatory Affairs, BioCardia, Inc.
11:20 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 template.
12:10 pm	**Team Presentation - 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	**Ice Breaking activity** **Megha Deviprasad Iyer, MS, RAC**, Global Director Regulatory Affairs, Thermo Fisher Scientific
1:45 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, VP Global Regulatory Affairs - Corporate, Stryker
2:10 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,** Global Director Regulatory Affairs, Thermo Fisher Scientific
2:35 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, P.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.
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 in a location that will be determined at a later date**