WORKSHOP TITLE
Sunday, 22 September 2019
8:00 am – 4:00 pm

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,** Director of Regulatory Affairs, BioCardia, Inc.
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.
9:30 am	**Hot Topics from Around the World: Part 1—USA and Canada** This session will discuss regulatory trends in the US and Canada with a special focus on product continuation, postapproval and strategies for product changes: Digital health (Software, Precertification), Premarket submissions, Presubs, Usability, UDI, Labeling, MDSAP, FDA Inspection for cause and other hot topics. **Nicole Landreville, P.Eng, RAC, FRAPS**, Regulatory Affairs Manager, GE Healthcare
9:45 am	**Hot Topics from Around the World: Part 2—LATAM** This session will discuss regulatory trends in the Latin America regulated countries. **Nicole Landreville, P.Eng, RAC, FRAPS**, Regulatory Affairs Manager, GE Healthcare *Potential Guest Speaker expert for this region.
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,** Director of Regulatory Affairs, BioCardia, Inc.
11:00 am	**Hot Topics from Around the World: Part 3—EU** This session will discuss regulatory trends in Europe with a special focus on product continuation, post-approval and strategies for product changes: Medical Device Regulations, In-Vitro Diagnostic Regulations, BREXIT, MEDTEC Europe, etc. **Megha Deviprasad Iyer, MS, RAC**, Global Director Regulatory Affairs, Thermo Fisher Scientific **Nicole Landreville, P.Eng, RAC, FRAPS**, Regulatory Affairs Manager, GE Healthcare
11:15 am	**Group Work—Case Study Part 3 (con't): Finalization of Regulatory Strategy Workshop** 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 and prepare a presentation to the virtual executive team of their fictional company.
12:00 pm	**Lunch**
1:00 pm	**Hot Topics from Around the World: Part 4—International—China** This session will discuss regulatory trends in China, with a special focus on Decree 650 & 680 implementation and policy direction changes in the last 12 months. **Brad Hossack,** VP Global Regulatory Affairs - Corporate, Stryker **Guest Speaker: Grace Fu Palma,** CEO, China Med Device, LLC
1:45 pm	**Hot Topics from Around the World: Part 5—International – ASEAN, Japan, Korea and Rest of World** This session will discuss regulatory trends in ROW (Rest of world regulated countries) with a special focus on regulatory requirement and PMS changes implemented in the past 12 months. **Brad Hossack,** VP Global Regulatory Affairs - Corporate, Stryker
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**, 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.
4:00 pm	**Adjourn** ***Reminder to attend the Convergence opening reception at 5:30 pm until 7:30 pm**