

Regulatory & Reimbursement Considerations for Medical Device Companies

March 1, 2018 | 8:30am-1:00pm

North Carolina Biotechnology Center | 15 TW Alexander Drive, Research Triangle Park

What do you need to get a medical device to market? Regulatory and compliance requirements come first, but they can sometimes feel like a moving target. And once you get approval, who knows if it will sell? The sooner you start thinking about how your product will delight clinical AND non-clinical customers, the more likely you are to optimize the market access and patient access that is critical to your success.

This workshop will run the gamut, covering the following topics:

- Regulatory considerations and FDA approval pathways: Section 510(k) clearances, Premarket Approval (PMA), De Novo and Humanitarian Device Exemption (HDE) processes
- Things to consider when developing a regulatory strategy
- Tips for working effectively with FDA
- Market access & patient access landscapes
- Pricing and reimbursement strategies

Leaders from Johnson & Johnson's Medical Devices companies will be in attendance to give you the tools you need in order to bring your device to market. The speakers will also be meeting one-on-one with selected companies after the presentation. Don't miss this opportunity to meet with these experts and further discuss your specific market access or regulatory needs.

Speakers



**Ibraheem
Badejo**

*Senior Director,
New Ventures
Johnson & Johnson
Innovation*



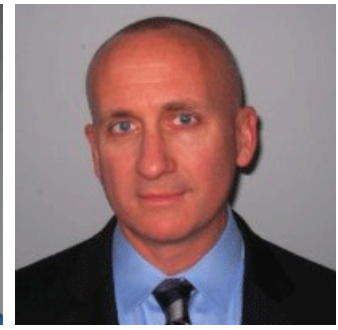
Diane Francis

*Senior Director, US
Field Health
Economics &
Market Access
Johnson & Johnson
Medical Devices*



**Sharon
Starowicz**

*Director,
Regulatory Policy
Innovation, Global
Orthopaedics
Johnson &
Johnson*



Brian Vaughn

*Franchise Lead -
Global Health
Economics &
Market Access,
ETHICON, Inc.
Johnson & Johnson
Medical Devices*

Presentation & Lunch \$25

[Register now](#)

1-on-1 Meeting FREE

1-on-1 Meeting: [apply here.](#)

Companies must apply for a one-on-one meeting ahead of time and be approved. The one-on-one application period ends on February 22.