AGENDA

12:00 p.m. – 12:30 p.m.  Registration
12:30 p.m. – 12:35 p.m.  Welcoming Remarks
12:35 p.m. – 1:30 p.m.  Lunch & Keynote Address: What to Expect from FDA in 2017

Herbert Lerner, M.D., Senior Director of Regulatory and Clinical Sciences, Medical Device Practice Group, Hogan Lovells LLP; former Deputy Director of the Division of Reproductive, Gastro-Renal and Urological Devices, CDRH, FDA

1:30 p.m. – 2:15 p.m.  Post-Election Policies & Expectations: New Administration, New Congress, New Legal Developments

- What new medical device guidance is the FDA likely to issue in 2017?
- What new medical device legislation is Congress likely to enact in 2017?
- What are the medical device court cases to watch in 2017?

Panelists:

- Paul Kim, Partner, Foley Hoag, LLP
- Diana Zuckerman, President, National Center for Health Research

Moderator: Mary Pendergast, President, Pendergast Consulting

2:15 p.m. – 2:30 p.m.  Networking Break
2:30 p.m. – 3:15 p.m.  Cybersecurity: Rising Threats to Essential Medical Devices

- How will the FDA’s recent guidance affect your medical device development and marketing program in 2017?
- How will the Muddy Report on hacking of St. Jude’s pacemakers impact your cybersecurity policies?
- What are current best practices for protecting your IP and trade secrets?
- What practical measures should you take immediately to deal with imminent cybersecurity threats?

Panelists:

- Casper Uldriks, Founder, Encore Insight LLC
- Susan Garfield, Principal/Advisory, Life Sciences Sector, Ernst & Young
- Bill Pelletier, Principal, Product Development Security, GE Healthcare
Moderator: Judy Meritz, Partner, Meritz & Muenz LLP and former FDA Counsel, Medtronic

3:15 p.m. – 3:30 p.m. Networking Break

3:30 p.m. – 4:15 p.m. Mobile Apps and Digital Health: The Future (and Regulation) Is Now

- What FDA guidance can be expected on mobile apps and digital health in 2017?
- How does the FDASIA Health IT Report affect your digital health program?
- How do new clinical decision support software affect your development of new mobile apps?
- What’s the current definition of medical device accessories and classification pathway of new accessory types?

Panelists:

- Diane Johnson, Strategic Regulatory, MD&D at Johnson & Johnson
- Alex Miller, Senior Analyst, Clutch

Moderator/Panelist: Michael Gaba, Partner, Holland & Knight

4:15 p.m. – 4:30 p.m. Networking Break

4:30 p.m. – 5:15 p.m. Combination Products: Drug, Device or Both—Decoding FDA and Global Jurisdictional Determinations

- What’s going to happen with the 21st Century Cures Act and how will it affect your operations in 2017?
- Does FDA’s current regulation promote combination product innovation and what are you to expect in terms of agency policy in 2017?
- What’s the role of the new Combination Product Council and how will it affect agency actions?
- What are the best practices for complying with the new guidance from FDA on post-approval modification of combination products?

Panelists:

- Susan Wood, Assistant Professor, Department of Health Policy and Management Director, Jacobs Institute of Women’s Health, The George Washington Miliken Institute School of Public Health
- Heather Rosecrans, Executive Vice President, Medical Devices & Combination Products, Greenleaf Health LLC
- Elaine Tseng, Partner, King & Spalding
- Diane Johnson, Strategic Regulatory, MD&D at Johnson & Johnson

Moderator: Minnie Baylor-Henry, President, B-Henry & Associates

5:15 p.m. Adjournment