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