AGENDA

8:30 a.m. – 9:00 a.m. Registration & Continental Breakfast

9:00 a.m. – 9:15 a.m. **Welcoming Remarks**

Quynh Hoang, Consultant, King & Spalding LLP
David Fox, Partner, Hogan Lovells LLP

9:15 a.m. – 9:45 a.m. **Keynote Address: Combination Products — Perspective of the Combination Products Coalition**

Formed in 2003, a year after the FDA established the Office of Combination Products, the Combination Products Coalition has advocated many of the regulatory changes being discussed today. Representing the Coalition, Mr. Thompson will provide some insights into its past efforts and the challenges still ahead.

Bradley Merrill Thompson, Member, Epstein Becker & Green P.C.

9:45 a.m. – 11:00 a.m. **Combination Products Determination and Review Processes: Impact of 21st Century Cures Act and Recent FDA Initiatives**

Last year, the FDA established the Combination Products Policy Council, formalized the pre-Request for Designation (pre-RFD) process and began a pilot for improving the inter-center consult review process. The 21st Century Cures Act provided further measures and expanded the roles of the Office of Combination Products. This session discusses the strategies for utilizing these developments to obtain jurisdictional determination, assure certainty with submission requirements and overcome barriers.

Panelists:

Kirsten Paulson, Senior Director, Global CMC-Medical Device, Pfizer
Suzanne O'Shea, Director, Navigant Consulting
Heide Gertner, Partner, Hogan Lovells

Moderator: **David Fox**, Partner, Hogan Lovells

11:00 a.m. – 11:15 a.m. Networking Break

11:15 a.m. – 12:15 p.m. **Postmarket Adverse Event Reporting and cGMP: What You Absolutely Need to Know**

The FDA issued two final rules that set forth the postmarket safety reporting and current good manufacturing practices (cGMP) requirements for combination product and constituent part sponsors. This session summarizes key concepts and provides insightful case studies.

Panelists:

Khaudeja Bano, Senior Medical Director, Medical Device Safety Head, AbbVie
Beverly Lorell, Senior Medical & Policy Advisor, King & Spalding LLP
Julia Ding, Associate Director of Regulatory Affairs, Becton Dickinson

Moderator: **Steve Niedelman**, Lead Quality Systems and Compliance Consultant, King & Spalding LLP

12:15 p.m. – 1:15 p.m. Lunch

1:15 p.m. – 2:15 p.m. **Promotion and Advertising of Combination Products: Key Postmarket Considerations**

The FDA took a number of actions related to the promotion and advertising of medical products in January 2017. This session explores advertising and marketing issues for combination products.

Panelists:

Glenn Byrd, Senior Director, Promotional Regulatory Affairs, AstraZeneca
Suzanne O'Shea, Director, Navigent Consulting
Heather Bañuelos, Counsel, King & Spalding LLP

Moderator: **Lisa Dwyer**, Partner, King & Spalding, LLP

2:15 p.m. – 3:15 p.m. **Human Factors Study of a Generic Combination Product with a Device Delivery Constituent Part: When Is It Needed and How to Conduct One**

Demonstrating that a generic drug delivers the same amount of active ingredients as the reference listed drug is key in obtaining FDA approval. For a generic combination product, a human factors study may be needed to show that the device delivery constituent part does not impact drug delivery. This session discusses the important considerations in such a study.

Panelists:

Tor Alden, President, HS Design
Kirsten Paulson, Senior Director, Global CMC-Medical Device, Pfizer
Dick Horst, President, UserWorks, Inc.

Moderator: **David Fox**, Partner, Hogan Lovells

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

3:30 p.m. – 4:30 p.m. **Planning to Submit 510(k), De Novo or PMA with Drug Constituent Part? Know Your 21st Century Cures Act Requirements**

Currently, there are many combination products submitted directly to CDRH that have a drug constituent part. The 21st Century Cures Act has additional mandates for these device-led submissions related to the drug constituent part. This session shares the lessons with submitting combination products directly to CDRH and discusses the implications of the Cures Act on these submissions.

Panelists:

Elaine Tseng, Partner, King & Spalding LLP
Janine Morris, Vice President & Senior Research Fellow, Global Regulatory Affairs—Devices, Eli Lilly and Company
Sugato De, Consultant, Parexel International

Moderator: **Quynh Hoang**, Senior Regulatory Consultant, King & Spalding LLP