AGENDA

10:00 a.m. – 10:15 a.m. **Introductory Remarks**

Will Woodlee, Partner, Kaplan, Klein & Becker

10:15 a.m. – 11:15 a.m. **Emerging Medical Products: Developments Impacting Quality, Regulatory, and Compliance Professionals**

This panel will discuss recent medical devices in digital health, 3D printing, genetic testing, LTDs, and combination products that directly and indirectly affect quality, regulatory, and compliance professionals.

Moderator:
Suzan Onel, Partner, Kaplan, Klein & Becker

11:15 a.m. – 12:30 p.m. **Regulatory, Compliance and Policy Developments: Are You Up-to-Date?**

This panel will discuss user fees, inspections and reorganization of ORA, reorganization of CDRH and ODE, and FDA enforcement trends and their impact on medical device professionals.

Moderators:
Jackie Chan, Associate, Kaplan, Klein & Becker
Michael Swit, Law Offices of Michael A. Swit

12:30 p.m. – 1:00 p.m. Lunch Break

1:00 p.m. – 1:30 p.m. **Legislative Update: The View from the Hill**

This panel will cover current legislative initiates and key agency monitoring activities affecting the medical device community that are expected to take shape when the new Congress convenes in January.

Moderator:
Suzan Onel, Partner, Kaplan, Klein & Becker

1:30 p.m. – 2:15 p.m. **Clinical Trials and OUS Data: Understanding Requirements for Disclosure on ClinicalTrials.gov & Use of OUS Data in Premarket Submissions**

This panel will discuss how your clinical trials in the device area will be affected by new initiatives to expedite product approval and new incentives to encourage development of medical devices across-the-board. The panel will focus in the requirements for disclosure on ClinicalTrials.gov as well as deployment of OUS data in premarket medical device product submissions.

Moderators:
Will Woodlee, Partner, Kaplan, Klein & Becker
Kinsey Reagan, Partner, Kaplan, Klein & Becker

2:15 p.m. – 2:30 p.m. Break

2:30 p.m. – 3:30 p.m. **Industry Perspectives**

This panel will detail strategies for working with FDA in this current environment of medical device regulation and innovation, including discussions of key business decisions, risk management, and liability.

Moderators:
Dan Dwyer, Partner, Kaplan Klein & Becker
Jason Brooke, Director, Life Sciences Regulatory & Compliance, Navigant Consulting

3:30 p.m. – 3:45 p.m. Break

3:45 p.m. – 4:45 p.m. **Hypotheticals and Real-World Decisions: Thinking through Premarket Submissions in a "Least Burdensome" World**

This panel will get into crucial issues involved in premarket submissions in an evolving regulatory rubric, including:

- Whether to file or not to file;
- Whether or not to opt for the 510 (k) approval pathway;
- What are the current developments in de novo submissions: and
- What are the current developments regarding LTEs

Moderators:
Suzan Onel, Partner, Kaplan, Klein & Becker
Karen Becker, Managing Director, Translational and Regulatory Services, Precisions for Medicine
Heather Rosecrans, Executive Vice President, Medical Devices & Combination Products, Greenleaf Health and Vice President of Regulatory Affairs, MDMA

4:45 p.m. – 5:00 p.m. Wrap-Up, Q&A, and Adjournment