AGENDA

9:30 a.m. – 10:00 a.m. Registration

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

Chris Markus, Partner, King & Spalding

10:15 a.m. – 11:30 a.m. **New Therapies & Methods: The Evolving Science that Regulatory, Quality, and Compliance Professionals Need to Know About**

(CAR-T cell therapy; gene therapy and its viral vectors; therapies involving combination products; innovative ways for potential treatment of breast cancer, Alzheimer's, and MS)

This is what FDA says about this new frontier: "We are at a critical moment where advances in science are leading toward fundamental changes in the way medical treatments and diagnostics are being developed and used. Groundbreaking discoveries in complex chemistry and biosynthesis have the promise of yielding new drug candidates, and cutting-edge electronics, nanotechnology and materials science have revolutionized medical devices. Emerging fields such as gene therapy, cell therapy, tissue engineering, ontogenetic, high intensity focused ultrasound and information technology are also yielding innovative approaches to improve our health. These novel and increasingly complex approaches to health, foods, and medical products present growing challenges to FDA's readiness to evaluate new products."

This first session of the day will focus on the science of emerging technologies, and consider fundamental differences from past products that necessitate evolution and/or fundamental realignment of regulatory science to bring the rewards of discovery safely forward to benefit patients.

Moderator: **Chris Markus, Partner, King & Spalding**

11:30 a.m. – 11:45 a.m. Networking Break

11:45 a.m. – 12:30 p.m. **Latest FDA Regulatory, Compliance & Policy Developments**

This session will address how FDA has regulated novel therapies within the scope of existing authorities, new approaches that have been discussed, and challenges that product developers and government officials have identified that may hinder practical

advancement. The discussion will consider recent changes to applicable law and regulations, guidance documents, and policy pronouncements. Specific issues will include incentives to encourage innovation (e.g., "regenerative advanced therapy" designation under the 21st Century Cures Act).

Moderator: **Elaine Tseng, Partner, King & Spalding**

Tom Poché, VP and Assistant General Counsel, Allergan (invited)

12:30 p.m. – 1:30 p.m. Luncheon Address

Hear from an invited representative of FDA's Center for Biologics Evaluation and Research about current initiatives and challenges FDA is addressing as it works to implement new mandates, and to approve and regulate advanced therapeutic products.

Julie Tierney, Senior Policy Advisor for Strategic Planning and Legislation, CBER, FDA

1:30 p.m. – 2:15 p.m. **Clinical Trials: The Shifting Landscape of Informed Consent – Implications for Emerging Biopharmaceuticals**

This session will highlight major recent changes in informed consent for human subjects, including disclosures and consent for future uses of biospecimens, that are already impacting clinical trials of emerging biopharmaceuticals. The panel will also discuss the heightened focus on "who pays for study-related injury" and current uncertainties regarding Expanded Access "compassionate use."

Moderator: **Beverly H. Lorell, M.D., Senior Medical and Policy Advisor, King & Spalding**

Preeya Noronha Pinto, Partner, King & Spalding

2:15 p.m. – 3:00 p.m. **Industry Perspectives: Risks & Rewards**

Industry representatives will discuss strategic business decisions, risk management approaches, and potential liability issues that have been encountered as companies execute steps for the development, testing, and introduction of new products to market. Considerations will include premarket challenges and resolutions, plus novel postapproval issues that have impacted marketing and distribution.

Moderator: **Nikki Reeves, Partner, King & Spalding**

Dwight Moxie, Vice President, Legal – Commercial and R&D, Ultragenyx Pharmaceutical

Sean Woo, General Counsel, Kolon TissueGene, Inc.

Susan Vargas, Bristol-Myers Squibb (invited)

Jonathan Williams, Head of Commercial Legal and Compliance, Kite Pharma (invited)

3:00 p.m. – 3:15 p.m. Networking Break

3:15 p.m. – 4:15 p.m. **Hypotheticals & A Look to the Future**

Engage with peers to discuss fact patterns that you may face, and brainstorm about options for resolution, potential associated risks, and benefits of these decisions.

Moderator: **Jessica Ringel, Counsel, King & Spalding**

Kara Coen, Director, Assistant General Counsel, Capital One Commercial Banking – Healthcare

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

4:30 p.m. – 5:00 p.m. **Q&A with Audience**

During a final session, the day's panelists and audience will engage on yet-to-be-answered questions and answers. Leave today's meeting with ideas and open discussion points to engage your teams back in the office.

Moderator: **Chris Markus, Partner, King & Spalding**

5:00 p.m. Adjournment & Reception