**Cell, Tissue, and Gene Therapies**

We have significant experience guiding clients around the world at the forefront of stem cell, regenerative medicine, and advanced therapy innovations. Our experience spans research and development; licensing deals between inventors, universities and companies; manufacturing; complex regulatory and commercialization questions; reimbursement; distribution; and intellectual property.

We combine our deep legal and regulatory expertise with your scientific and business acumen to solve some of the most interesting issues with tremendous potential to help patients. Working together, we can improve the health of patients around the world by applying cutting edge scientific breakthroughs.

**Representative experience**

Intellia Therapeutics in the launch of a new autologous and allogeneic universal CAR-T cell therapy company in collaboration with Blackstone Life Sciences and Cellex Cell Professionals GmbH, the parent company of GEMoaB.

Spark Therapeutics on its US$161m IPO and on a wide range of regulatory, reimbursement, commercial, and compliance issues in connection with its development and product launch of Luxturna.

**Contacts**

Michael N. Druckman, Washington, D.C.
Kristin Anne Connarn, Boston
Randy J. Prebula, Washington, D.C.
Robert F. Church, Los Angeles

**Practices**

Pharmaceuticals and Biotechnology
Regulatory
Intellectual Property

**Industries**

Life Sciences and Health Care
Major universities, gene therapy inventors and numerous publicly traded companies on licenses and collaborations to develop therapies for the worldwide market.

Multiple clients in the CAR-T space on manufacturing clinical trial and quality agreements, and regulatory and launch planning.

Prepare for a Type B meeting with FDA to resolve issues with the development of anti-cancer vaccines based on the patients’ T-cell and the tumors’ immunological assessment.

A non-academic medical research institute on the current Good Tissue Practice requirements applicable to a contract laboratory performing tests on stem cells being used in clinical trials.

An international plasma protein therapeutic company on cGMP issues and in responding to FDA inspection findings.

A Mexican company developing therapies using allogenic pluripotent stem cells for repairing tissues and restoring their functions, focusing in particular on curing Parkinson’s disease.

An immune-oncology company on exporting its investigational cytotoxic T cell stimulating interleukin product to China for compassionate use.

General Electric Company on its US$1.06bn acquisition of the cell culture, gene modulation, and magnetic beads businesses of Thermo Fisher Scientific Inc.

**Latest thinking and events**

**News**
Inside the FDA Advanced Manufacturing Technologies Designation Program

**News**
JPM2024: Impact of China’s HGR Rules on clinical trials and scientific studies involving China sites

**News**
FDA clinical trial diversity workshop reveals agency’s expectations for sponsors

News
FDA proposal classifying wound dressings/washes with antimicrobials may require PMAs, new 510(k)s

News
The Genesis case: The beginning of the end of HRSA’s “patient” definition?

News
Horizons 2023: Panelists discuss key issues keeping APAC life sciences GCs up at night