

## 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

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### Practices

Pharmaceuticals and  
Biotechnology  
Regulatory

Intellectual Property

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### 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

Spotlight on Greater China: antitrust and regulatory risks in life sciences distribution channels

### Insights and Analysis

Accelerating Innovation: A New China Rule for Innovative Drug Registration Communication and Review

### Sponsorships and Speaking Engagements

## 2023 FDLI Annual Conference

### News

French decree regarding the “direct access”: a half-hearted step forward for pharmaceutical innovations

### Sponsorships and Speaking Engagements

The American Bar Association’s 33rd National Institute on Health Care Fraud

### News

FDA issues milestone draft guidance on decentralized clinical trial design & implementation