

Cell, Tissue, and Gene Therapies

We have significant experience guiding clients in the new and exciting area of cell and gene therapies. 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

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.

Valeant Pharmaceuticals on the sale of Dendreon Pharmaceuticals and its immunotherapy cell-based product Provenge to China-based SanPower Group.

Intrexon Corporation, a leader in synthetic biology, on the acquisition of Oxitec, a pioneer in biological insect control solutions.

Licenses between major universities and gene therapy

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Practices

Health

Medical Device and
Technology Regulatory

Intellectual Property

Pharmaceuticals and
Biotechnology Regulatory

Industries

Life Sciences and Health
Care

inventors and numerous publicly traded companies developing therapies for the worldwide market.

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

Helping a client 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.

A cross-border team advised an immune-oncology company on exporting its investigational cytotoxic T cell stimulating interleukin product to China for compassionate use.

Viventia Bio on its acquisition by Eleven Biotherapeutics to create a targeted protein therapeutics oncology company.

Advised 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

FDA leads global work on continuous manufacturing approaches to up quality, supply chain resilience

News

After a long and winding road, FDA finalizes much-debated "intended use" rule

News

Time's really up! FDA authority to crack down on regenerative medicines upheld as grace period ends

Insights

Report of the French Court of Auditors on budget multiannuality

News

FDA expands mutual reliance and harmonization with foreign regulators for inspectional oversight

News

Biden Administration supports waiver of WTO IP rights for COVID-19: Next steps for innovators