IMS Health & Quintiles are now IQVIA™

UNDERSTANDING EMERGING REGULATORY REQUIREMENTS IN CELL & GENE THERAPY

Insights specific to cell and gene therapy markets

Cell and gene therapies (CGTs) are fast-growing and fast-moving areas in healthcare. This niche area is producing innovative products that are transforming the treatment of diseases, providing curative solutions.

CELL & GENE THERAPIES ARE DEVELOPING FAST

- CAR-T cells that treat cancer
- Oncolytic viruses that treat unresectable tumors
- Gene therapies that treat blindness
- Mesenchymal stem cells that treat ALS

AN EMERGING MARKET NEEDS ESTABLISHED EXPERTISE

CGTs are often innovative, high-tech approaches, and the evolving regulatory practices are causing uncertainties that span the entire development process. Whether you are new to this field or established, your regulatory team may struggle to keep up-to-date with the information and understanding of the global regulatory requirements, limiting your ability to develop optimal and cost-effective regulatory strategies.

COUNTRIES COVERED

USA, EUROPE, JAPAN AND SOUTH KOREA

OVER 100 QUESTIONS WITH ANSWERS PER COUNTRY OR AUTHORITY

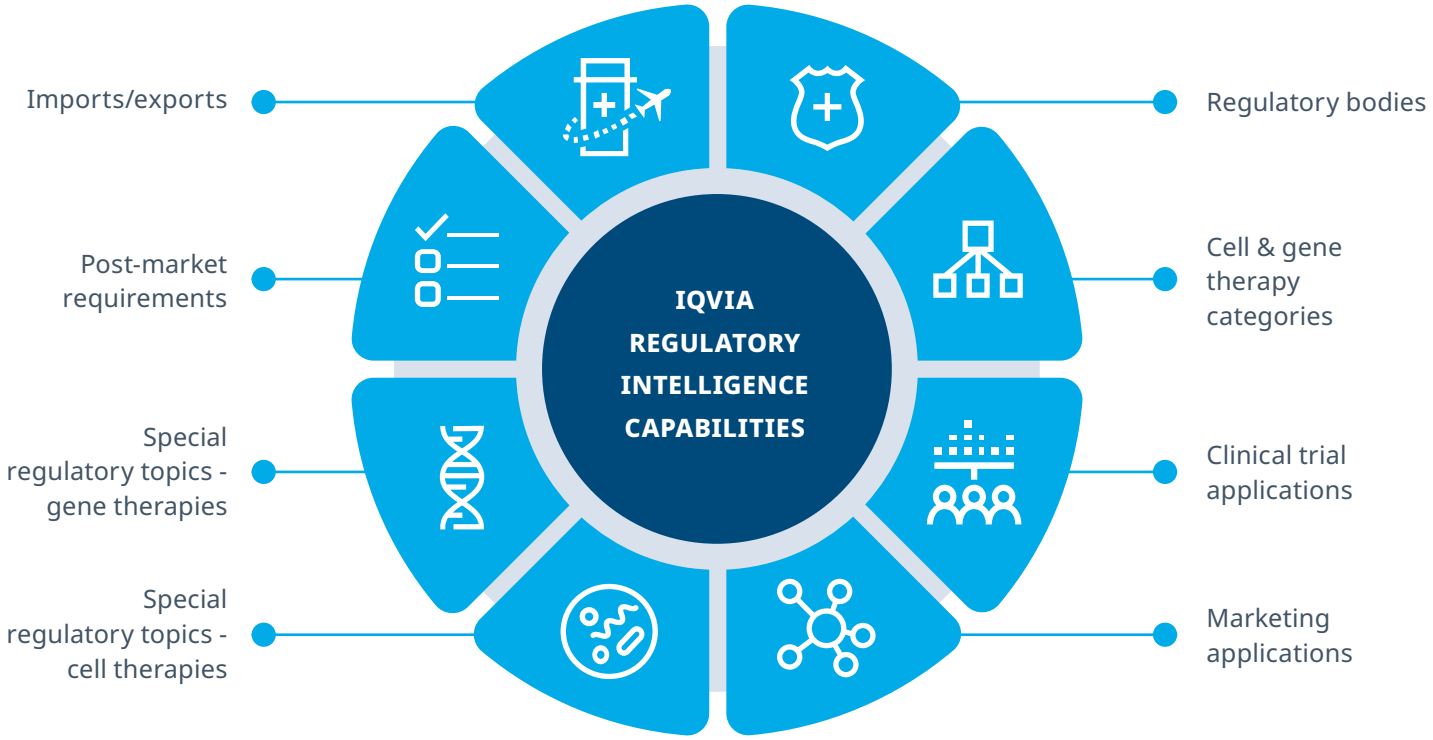
NAVIGATING THE CGT LANDSCAPE

As regulations evolve to keep up with the advancements made in this field, cell and gene therapy regulatory teams are met with varying levels of regulation complexity.

UNEVEN GLOBAL REGULATORY LANDSCAPE	• Differences in pre-market vs post-market requirements across countries • Country-specific donor eligibility determinations • Non-standardized good manufacturing practices and good tissue practices
REGIONAL VARIATION ON INCENTIVES AND SPECIAL DESIGNATIONS	• Orphan drug pathways • Expedited approval pathways • Market exclusivity and other incentives
RAPIDLY CHANGING REGULATORY ENVIRONMENT	• Evolving regulatory schemes • New guidance documents and product approvals

IQVIA REGULATORY INTELLIGENCE PROVIDES THE SOLUTION

The cell and gene therapies (CGTs) data within the IQVIA™ Regulatory Intelligence has been developed and is maintained by IQVIA CGT specialists. Collating unique expertise and intelligence from the IQVIA CGT Centre of Excellence, the database gives you access to high-quality and detailed information and guidance on the emerging regulations in the niche CGT market. These insights can support the development of your CGTs all the way through clinical trials and onto the market.



REMAIN ON TOP OF GLOBAL REGULATORY REQUIREMENTS WITH IQVIA REGULATORY INTELLIGENCE

IQVIA has decades of regulatory experience across biopharma, medical devices and in vitro diagnostics. Supported by access to local and global experts, the IQVIA Regulatory Intelligence database collates this unrivaled expertise to provide you with the insights you need to achieve success for your product at every stage.

- Keep up-to-date with the latest information, safeguarding compliance across the product lifecycle, from clinical trials, through new product approvals, to manufacturing, import/export, adverse event reporting, and more.
- Teams can access a curated regulatory database, meaning you save time and reduce duplicating regulatory research activities across your company.
- Have rapid access to translated localized information and updates, meaning you can cross-check the accuracy of business-critical information.

If you're looking for full-enterprise access to all regulatory requirements for human drugs, biologics, medical devices and in vitro diagnostics, contact IQVIA today.

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