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CAR-T Therapy:

Overcoming Challenges from Culturing to Commercialization

Challenges and Opportunities

The Culture Media Matters

1

Harvesting, transducing and expanding viable T cells in sufficient numbers

- Using proven and high-performance raw materials, including cell culture media, cytokines, and leukapheresis products

2

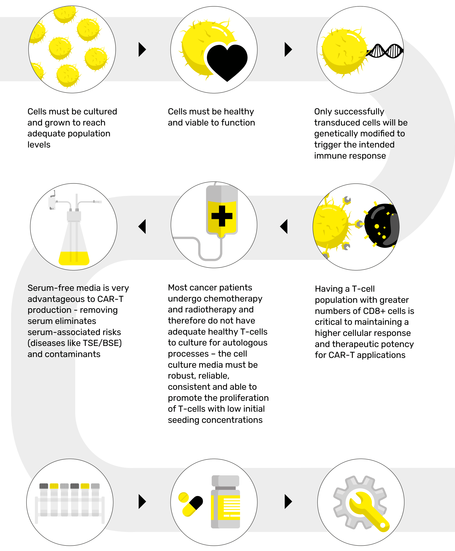
Safety concerns and risk of contamination

- Using Serum-free media to eliminate serum-associated risks
- Using GMP-grade raw materials which meet stringent quality standards

3

High costs and long commercialization process

- Having a robust supply chain with trusted suppliers ensures a steady supply of raw materials
- Using raw materials with Drug Master File (DMF) accelerates time to market
- Using raw materials with adequate scale-up and customization capabilities



Cells must be cultured and grown to reach adequate population levels

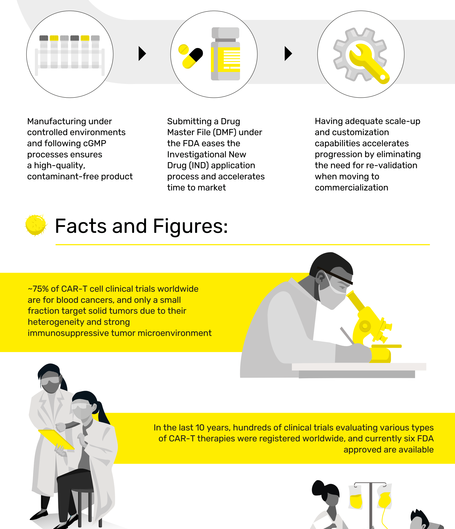
Cells must be healthy and viable to function

Only successfully transduced cells will be genetically modified to trigger the intended immune response

Serum-free media is very advantageous to CAR-T production - removing serum eliminates serum-associated risks (diseases like TSE/BSE) and contaminants

Most cancer patients undergo chemotherapy and radiotherapy and therefore do not have adequate healthy T-cells to culture for autologous processes – the cell culture media must be robust, reliable, consistent and able to promote the proliferation of T-cells with low initial seeding concentrations

Having a T-cell population with greater numbers of CD8+ cells is critical to maintaining a higher cellular response and therapeutic potency for CAR-T applications



Manufacturing under controlled environments and following cGMP processes ensures a high-quality, contaminant-free product

Submitting a Drug Master File (DMF) under the FDA eases the Investigational New Drug (IND) application process and accelerates time to market

Having adequate scale-up and customization capabilities accelerates progression by eliminating the need for re-validation when moving to commercialization

Facts and Figures:

~75% of CAR-T cell clinical trials worldwide are for blood cancers, and only a small fraction target solid tumors due to their heterogeneity and strong immunosuppressive tumor microenvironment

In the last 10 years, hundreds of clinical trials evaluating various types of CAR-T therapies were registered worldwide, and currently six FDA approved are available

Universal CAR-Ts – tumor antigen-specific T-cells from allogeneic healthy donors – are currently being developed by disrupting the TCR gene and/or HLA class I loci using gene editing

While CAR-T therapies are already commercially available, there are other approved immunotherapies, including TILs, CAR-NKs, dendritic cells, and hematopoietic

This infographic was brought to you by RegMedNet in partnership with Sartorius.

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