CAR T-Cell and Other Adoptive Cell Therapy Development Training Course.

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

The field of medicine is undergoing a profound transformation driven by Adoptive Cell Therapy (ACT), with Chimeric Antigen Receptor (CAR) T-Cell therapy leading the charge. This precision medicine approach has revolutionized the treatment landscape for hematologic malignancies, delivering unprecedented clinical efficacy and challenging conventional therapeutics. The convergence of genetic engineering, advanced bioprocessing, and immuno-oncology principles has birthed a complex and high-stakes sector demanding a highly specialized workforce. Professionals must master the entire vein-to-vein lifecycle, from target discovery and vector design to GMP manufacturing, rigorous Quality Control (QC), navigating the dynamic regulatory landscape (FDA/EMA), and managing patient-specific toxicities like Cytokine Release Syndrome (CRS). CAR T-Cell and Other Adoptive Cell Therapy Development Training Course is an essential deep dive into the translational science and commercialization strategies propelling the next generation of cell therapies.

As the industry pivots toward addressing the formidable challenge of solid tumors and exploring new indications like autoimmune disorders, the focus shifts to next-generation CAR constructs such as allogeneic ("off-the-shelf") CAR T-cells, armored CARs (TRUCKs), and TCR-T cell therapy. The growth is exponential, with hundreds of clinical trials emphasizing the need for expertise in CRISPR-Cas9 gene editing, process scale-up and optimization, and robust supply chain management. This training provides a critical pathway for R&D, manufacturing, clinical, and regulatory personnel to acquire the in-demand skills necessary to accelerate product development, ensure patient safety, and maintain regulatory compliance. By integrating real-world case studies and interactive learning, participants will be empowered to drive innovation, reduce the cost of goods (CoG), and successfully bring life-changing cell and gene therapies to market.

Programme Curriculum

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Course Objectives

1. Analyze the mechanism of action for CAR T-cells, TCR-T, and TIL therapy within the context of immuno-oncology.
2. Design and optimize next-generation CAR constructs including VHH domains, dual-antigen targeting, and armored CARs (TRUCKs).
3. Evaluate and select appropriate viral and non-viral vector design platforms for gene transfer.
4. Master the end-to-end autologous and allogeneic CAR T-cell manufacturing process from leukapheresis to final product release.
5. Implement and maintain Good Manufacturing Practices (GMP) and Quality by Design (QbD) principles for cell therapy bioprocessing.
6. Develop robust Critical Quality Attribute (CQA) and Critical Process Parameter (CPP) testing strategies for potency and purity.
7. Navigate the complex global regulatory landscape (FDA, EMA, NMPA) for Cell and Gene Therapy (CGT) Investigational New Drug (IND) and Biologics License Application (BLA) submissions.
8. Formulate effective strategies to overcome solid tumor challenges, including tackling the Tumor Microenvironment (TME) and antigen escape.
9. Identify and manage key patient toxicities such as Cytokine Release Syndrome (CRS) and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS).
10. Design advanced clinical trial protocols and understand endpoints for relapsed/refractory (R/R) hematologic and solid malignancies.

11. Optimize the Cryopreservation and Cold Chain Logistics for global, patient-specific supply chain management.
12. Explore the burgeoning application of ACT in autoimmune diseases and other non-oncology indications.
13. Assess the commercialization, reimbursement, and Health Economics and Outcomes Research (HEOR) models for high-cost cell therapies.

Target Audience

1. Biotech & Pharmaceutical R&D Scientists
2. Process Development & Manufacturing Engineers
3. Quality Assurance (QA) & Quality Control (QC) Personnel
4. Regulatory Affairs Professionals
5. Clinical Development & Medical Affairs Specialists
6. Hematologists, Oncologists & Transplant Physicians
7. Graduate Students & Postdoctoral Fellows
8. Venture Capital, Business Development & Market Access Professionals

Course Modules

Module 1: Foundational Immuno-Oncology & ACT Principles

- The role of the tumor-immune microenvironment (TME) in cancer.
- T-cell and NK-cell biology, activation, and signaling pathways.
- Adoptive Cell Therapy (ACT).
- First, second, third, and fourth-generation CAR construct evolution.
- Principles of antigen targeting and on-target/off-tumor toxicity risk.
- Case Study: The pivotal role of CD19-targeting in B-cell malignancies.

Module 2: CAR Design and Genetic Engineering

- In-depth analysis of CAR domains
- Next-Generation CARs
- Lentiviral and Retroviral vector design and production.
- Non-Viral Gene Transfer.
- Strategies for enhancing CAR-T persistence and functionality.
- Case Study: Comparative analysis of the CD28- vs. 4-1BB-costimulatory domains in approved products.

Module 3: Pre-Clinical Development & Target Discovery

- In vitro and in vivo models for CAR-T screening and validation.
- Assays for specificity, cytotoxicity, proliferation, and cytokine release.
- Target identification for Solid Tumors
- Toxicity prediction and management in pre-clinical models.
- The path from lead candidate selection to Investigational New Drug (IND) filing.
- Case Study: Pre-clinical data and rationale leading to the selection of BCMA as a target for Multiple Myeloma.

Module 4: Autologous CAR T-Cell Manufacturing (Vein-to-Vein)

- Patient selection, leukapheresis, and T-cell collection strategies.
- T-cell activation, transduction/transfection, and ex vivo expansion.
- Washing, formulation, and cryopreservation of the final drug product.

- Automated systems and manual processing
- Process control and monitoring.
- Case Study: Kymriah (Tisagenlecleucel): Benchmarking the commercial-scale manufacturing process and timeline.

Module 5: Allogeneic ("Off-the-Shelf") Cell Therapy Development

- The scientific rationale and benefits of allogeneic therapies
- Strategies for preventing Graft-versus-Host Disease (GvHD) and host rejection
- Healthy donor T-cells, Induced Pluripotent Stem Cells (iPSCs), and Natural Killer (NK) cells.
- Large-scale manufacturing and master cell bank generation.
- Regulatory and ethical considerations unique to allogeneic products.
- Case Study: An allogeneic UCART19 trial demonstrating CRISPR/Cas9 application for gene knockout.

Module 6: GMP and Quality Management Systems (QMS)

- Principles of Good Manufacturing Practice (GMP) and regulatory frameworks for cell and gene therapy
- Establishing and maintaining the Quality Management System (QMS), including documentation and training.
- Cleanroom standards, environmental monitoring, and aseptic processing.
- Raw material sourcing, qualification, and control
- Deviation management, Change Control, and Corrective and Preventive Actions
- Case Study: Handling a critical GMP deviation event during viral vector production.

Module 7: Quality Control (QC) & Release Testing

- Critical Quality Attributes
- Key analytical methods
- Potency testing and release criteria.
- Sterility, mycoplasma, and adventitious agent testing.
- Validation of analytical methods and final product stability testing.
- Case Study: The impact of vector copy number (VCN) on final product potency and clinical outcome.

Module 8: Clinical Trial Design and Operations

- Phase I, II, and III clinical trial design for relapsed/refractory (R/R) cancers.
- Lymphodepletion regimens (Fludarabine/Cyclophosphamide) and bridging therapy.
- Overall Response Rate (ORR), Duration of Response (DoR), and Overall Survival (OS).
- Investigational site qualification, site monitoring, and patient enrollment challenges.
- Handling clinical material logistics and maintaining product integrity at the clinical site.
- Case Study: Review of the ZUMA-1 trial (Yescarta/Axicel) design and successful endpoints.

Module 9: Toxicity Management & Patient Care

- In-depth training on CAR T-cell-associated toxicities
- Tocilizumab (anti-IL-6R), corticosteroids, and supportive care.
- Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) diagnosis and treatment.
- Long-term follow-up (LTFU) protocols for CAR-T cell persistence and secondary malignancies.
- Hematology/Oncology, ICU, Neurology, and Pharmacy.
- Case Study: Clinical protocol for managing a Grade 3 ICANS event.

Module 10: Regulatory Affairs and Global Submissions

- Overview of global CGT regulatory bodies
- Structure and content of the Investigational New Drug (IND) application.
- Preparing the Biologics License Application (BLA)/Marketing Authorization Application
- Orphan Drug Designation, RMAT, and Accelerated Approval.
- Post-marketing commitments, risk evaluation and mitigation strategies (REMS), and pharmacovigilance.
- Case Study: Analysis of a successful BLA/MAA approval and the key data packages required.

Module 11: Supply Chain and Cold Chain Logistics

- Complexities of the Vein-to-Vein supply chain for personalized medicine.
- Management of Chain of Custody (CoC) and Chain of Identity (CoI) to prevent mix-ups.
- Cryoshipping protocols, packaging, temperature monitoring, and disaster recovery.
- Integration of digital solutions and blockchain technology for tracking.
- Global shipping regulations and customs clearance for biological materials.
- Case Study: Troubleshooting a temperature excursion event during international cryoshipping.

Module 12: Overcoming Solid Tumor Challenges

- Immunosuppressive factors within the Tumor Microenvironment (TME)
- T-cell trafficking, locoregional delivery, and co-stimulatory signals.
- CAR-T with checkpoint inhibitors, oncolytic viruses, or chemotherapy.
- In vivo CAR-T engineering and gene editing directly within the patient.
- TCR-T cell therapy targeting intracellular antigens.
- Case Study: Early-phase clinical data using CAR-T for Glioblastoma (GBM) or Pancreatic Cancer.

Module 13: New Frontiers in Cell Therapy (Non-Oncology)

- Application of CAR-T and ACT in Autoimmune Disorders
- Use of ACT for chronic infections
- NK-cell therapies, Macrophages, and regulatory T-cells
- Gene Editing for genetic disorders.
- Ethical and bioethical considerations of human genetic modification.
- Case Study: Recent clinical success of CD19 CAR-T in systemic lupus erythematosus

Module 14: Biostatistics and Data Interpretation

- Design and analysis of complex biological experiments
- Biostatistical methods for analyzing clinical trial data
- Pharmacokinetics (PK) and Pharmacodynamics (PD) of CAR-T cells in vivo.
- Importance of correlative studies and biomarker discovery.
- Translating laboratory findings and clinical outcomes into actionable insights.
- Case Study: Interpretation of clinical data to determine Dose Limiting Toxicities (DLTs) and the Maximum Tolerated Dose (MTD).

Module 15: Commercialization and Market Access Strategy

- Market analysis, pricing strategies, and value-based contracting.
- Health Economics and Outcomes Research (HEOR) for demonstrating value.
- Reimbursement models and payer engagement.
- Building a scalable commercial infrastructure, sales force, and medical affairs.
- Patient access programs and ethical considerations for equitable access.

- Case Study: Analyzing the market launch and reimbursement challenges of an approved CAR T-cell product in major global markets.

Training Methodology

The training utilizes a Blended Learning Approach to facilitate a deep, practical, and comprehensive understanding of the complex material.

- Interactive Lectures & Seminars.
- Real-World Case Studies & Analysis.
- Virtual Lab Simulations/Workshops.
- Regulatory & QA/QC Problem-Solving Groups.
- Q&A/Live Office Hours.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.com or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to FINESKILL TRAINING CENTER account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
07 Sep 2026	18 Sep 2026	Online	$4,000
14 Sep 2026	25 Sep 2026	Online	$4,000
21 Sep 2026	02 Oct 2026	Online	$4,000

Start Date	End Date	Location	Price
28 Sep 2026	09 Oct 2026	Online	$4,000
05 Oct 2026	16 Oct 2026	Online	$4,000
12 Oct 2026	23 Oct 2026	Online	$4,000
19 Oct 2026	30 Oct 2026	Online	$4,000
26 Oct 2026	06 Nov 2026	Online	$4,000

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