Leonardo Mirandola, Ph.D.

Cell & Gene Therapy Development, Regulatory Strategy, Clinical Translation, cGMP Manufacturing

Lmirandola9@icloud.com | 806.702.3054 | linkedin.com/in/leonardomirandola

EXECUTIVE SUMMARY

Accomplished biotechnology executive with 15+ years leading cell and gene therapy development from concept to clinical trials. Expert in translating cutting-edge therapeutic platforms through IND submission, regulatory approval, and clinical implementation. Proven track record advancing multiple cell therapy modalities (allogeneic T-cell, CAR-T, dendritic cell vaccines) and gene therapy systems (adeno-associated virus vectors, retroviral constructs) from preclinical development to Phase 1 trials.

Recognized for securing FDA Fast Track designation, building cGMP-compliant manufacturing frameworks, and leading successful IND submissions across multiple therapeutic platforms. Brings unique expertise in integrating CMC requirements early in development, managing cross-functional teams in resource-limited environments, and executing regulatory strategy for first-in-human studies. Extensive international patent portfolio spanning engineered immune receptors, cell manufacturing processes, and AI-driven target discovery platforms.

Key Achievements in Cell & Gene Therapy

Regulatory & Clinical Translation:

- **Secured FDA Fast Track Designation** for Deltacel (allogeneic γδ T-cell therapy) within nine months of IND submission
- **Led IND submissions** for multiple cell therapy platforms, achieving rapid progression to dose-expansion cohorts
- **Advanced two distinct cell therapy products to Phase 1 trials**, including novel dendritic cell-based cancer vaccine demonstrating safety and tolerability in first-in-human studies
- **Authored CMC sections (Module 3)** for two monoclonal antibodies for FDA and EMA-regulated first-in-human studies

Manufacturing & Process Development:

- **Built complete cGMP-compliant cell therapy framework** including manufacturing, QA, and QC teams enabling clinical-grade production
- **Executed cGMP manufacturing process development** for three distinct allogeneic cell therapy platforms
- **Achieved 50% cost and time reduction** in dendritic cell manufacturing through process optimization

- **Designed retroviral vector systems** for CAR construct delivery with tunable expression in human T cells

Platform Innovation & IP Development:

- **Created Diamond AI Platform** accelerating CAR-T target discovery through tumor-specific splice variant identification
- **Inventor on 16+ international patents** across US, EU, Asia covering cell therapies, gene delivery systems, and manufacturing methods
- **Developed novel adeno-associated virus vectors** for gene therapy applications, securing >$2M in STTR funding
- **Pioneered orally-delivered microparticle vaccine platform** using single-step manufacturing process

EXPERIENCE

Biopharma Science Consultant
Self-Employed | March 2025 – Present

Provide strategic guidance to biotech companies in oncology R&D, cGMP process development, and clinical trial optimization for cell and gene therapy programs.

Scientific Development Advisor and Execution Lead
SOHM, Inc. | June 2025 – Present | Chino Hills, CA

Executive technical direction for biotechnology programs leveraging SOHM's proprietary ABBIE gene editing platform for next-generation CAR-T cell therapies.

- **Design experimental programs** translating R&D goals into actionable plans and timelines for gene-edited cell therapies
- **Lead laboratory teams** coordinating task assignment, progress review, and strategic alignment across CAR-T development programs
- **Drive data-driven decisions** through experimental data evaluation, troubleshooting, and strategic guidance for project advancement
- **Coordinate with CDMOs/CROs** as scientific point of contact ensuring alignment with quality standards and regulatory objectives

Scientific Advisory Board Member
SOHM, Inc. | May 2025 – June 2025 | Chino Hills, CA

Strategic scientific leadership supporting development and clinical translation of next-generation CAR-T cell therapies utilizing SOHM's ABBIE gene editing platform.

- **Guide integration of ABBIE editing platform** into CAR-T development reducing regulatory complexity and manufacturing costs

- **Design translational strategy** for first-in-human CAR-T studies including IND-enabling milestones and regulatory preparedness
- **Advise on cGMP-compliant manufacturing scale-up** aligned with clinical timelines for cost-efficient cell therapy production
- **Support IP development** for novel cell therapy manufacturing techniques and AI-driven target discovery platforms

Associate Editor
Frontiers in Immunology | August 2023 – Present

- Review submissions for scientific rigor, ethical standards, and publication guidelines in immunotherapy and cell therapy research
- Guide peer review process and make editorial decisions on cutting-edge cell and gene therapy manuscripts

Interim Chief Operations Officer
Kiromic Biopharma, Inc. | May 2022 – March 2025 | Houston, TX

- **Managed cell therapy manufacturing operations** including cGMP facilities, quality systems, and clinical supply chain
- **Oversaw clinical operations** and company interactions with clinical sites testing allogeneic cell therapy products
- **Maintained and developed IP portfolio** covering cell therapy platforms and manufacturing innovations

Chief Scientific Officer
Kiromic Biopharma, Inc. | July 2022 – March 2025 | Houston, TX

Developed strategic plans, research proposals, and budgets while managing scientific teams to ensure projects completed on time and within budget.

- **Directed cross-functional research teams** including principal scientists, cell therapy manufacturing specialists, quality oversight managers, and clinical research coordinators
- **Led development of company's lead product** achieving FDA Fast-Track designation in August 2024 and progression to dose-expansion phase within 9 months
- **Established analytical and manufacturing standards** for multiple allogeneic cell therapy platforms

Vice President of Research and Development
Kiromic Biopharma, Inc. | September 2021 – July 2022 | Houston, TX

Oversaw projects for development of new and existing cell therapy products, directing R&D and MS&T groups while ensuring efficient clinical translation.

- **Executed cGMP-compliant manufacturing processes** for three proprietary allogeneic cell therapy technologies

- **Directed validation of standard protocols and assays** for clinical translation of cell therapy product leads
- **Developed comprehensive AI-driven CAR target discovery platform** resulting in 3 international patent applications and identification of prioritized tumor biomarkers

Head of Clinical Translation
Kiromic Biopharma, Inc. | January 2021 – September 2021 | Houston, TX

Translated preclinical hypotheses into clinical strategies, leading cross-functional teams and managing cGMP-compliant manufacturing processes.

- **Implemented stage-appropriate analytical methods** ensuring compliance with regulatory standards for cell therapy development
- **Managed MS&T completing product and process development** for manufacturing and GLP release of two genetically engineered cell therapy products progressed to cGMP clinical-grade manufacturing

Independent Biotechnology, Pharmaceutical, Life Sciences Consultant
Self-employed | July 2019 – January 2021 | Dallas, TX

Comprehensive consultation on clinical research projects and development planning for sophisticated cell and gene therapy programs.

- **Authored WHO INN applications** for two monoclonal antibodies for autoimmune disease
- **Co-authored CMC sections (Module 3)** for two monoclonal antibodies for FDA and EMA first-in-human studies
- **Designed retroviral vector systems** for CAR construct delivery with tunable expression including full preclinical validation outline

Director Of Clinical Operations
Kiromic, Inc. | August 2018 – July 2019 | Houston, TX

Developed clinical operations quality systems and directed cGMP manufacturing of dendritic cell-based therapy following FDA regulatory guidelines.

- **Conducted training sessions** at MD Anderson Cancer Center Department of Leukemia on handling and administration of dendritic cell vaccine
- **Ensured compliance with protocol specifications and FDA regulations** while managing delivery of autologous dendritic cell vaccine to patients
- **Recorded and analyzed immune monitoring data** from patients treated with therapeutic anti-tumor vaccine

Executive Director
Kiromic, Inc. | May 2016 – July 2019 | Houston, TX

Supported R&D activities for clinical product development, performing validation of new immunological targets and acquiring research funding.

- **Completed discovery and validation** of new cell therapy for anti-CD19 CAR T cell-resistant hematological malignancies through novel bioinformatic prediction and wet-lab validation
- **Improved dendritic cell manufacturing protocol** achieving 50% cost and time reduction
- **Developed orally delivered M-cell targeting microparticle vaccine** using cost-effective single-step manufacturing, resulting in new patent and $225,000 STTR grant with MD Anderson
- **Designed adeno-associated virus vector** for anti-inflammatory gene therapy treating arteriosclerosis, securing >$2,000,000 STTR Fast-Track grant with Methodist Hospital
- **Wrote five patents** covering new technologies and methodologies expanding company IP portfolio

Post-Doctoral Researcher
Texas Tech University Health Sciences Center | September 2013 – May 2016 | Lubbock, TX

Discovered new Cancer/Testis Antigens as vaccine targets and studied non-invasive imaging systems for cancer detection and treatment.

- **Authored 13 peer-reviewed publications** (4 as first author) advancing cancer immunotherapy and vaccine development
- **Mentored over 10 medical students** in research projects spanning immunotherapy and therapeutic development

Post-Doctoral Research Associate
University of Milano, Dept. of Medicine, Surgery and Dentistry | 2007 – 2009 | Milan, Italy

Molecular pathology research focusing on therapeutic development and novel treatment mechanisms.

- **Discovered molecular mechanisms of Notch-mediated signals** affecting chemokine response in acute leukemias and multiple myeloma
- **Developed new treatment for multiple myeloma** in murine models based on Notch inhibitors
- **Identified Notch-CXCR4-SDF1 axis** as novel druggable target reducing chemotherapy resistance and bone marrow infiltration

EDUCATION

Ph.D. in Molecular Medicine
Doctorate School in Molecular Medicine, University of Milano, Italy

Master of Science in Medical Biotechnology (*Summa Cum Laude*)
University of Milano, Italy

PATENT PORTFOLIO

International patent portfolio spanning US, PCT (WO), Europe (EP), China (CN), and Mexico (MX) with focus on:

- **Cell Therapy Platforms**: Allogeneic gamma-delta T cell therapies, CAR-T systems, dendritic cell vaccines
- **Gene Therapy Systems**: Adeno-associated virus vectors, retroviral delivery systems
- **Engineered Immune Receptors**: Chimeric PD1 receptors, mesothelin isoform binding molecules
- **Manufacturing Processes**: cGMP-compliant cell therapy production, AI-driven target discovery
- **Novel Therapeutic Targets**: Disease-associated isoforms, cancer-specific antigens, galectin inhibitors

Selected Recent Patents:

- **US10717774B2** (Granted): Compositions and Methods for Treating Cancers (Galectin-3 therapy)
- **Multiple 2024 Publications**: Mesothelin Isoform Binding Molecules and Chimeric PD1 Receptors
- **WO2022108778A1**: Disease-Associated Isoform Identifier platform
- **Multiple Applications**: Gamma-Delta T Cell Manufacturing Processes

RESEARCH SUPPORT

R42 HL144342-01 "Development and non-clinical GLP testing of anti-arteriosclerosis gene therapy delivered by engineered adeno-associated viral vectors" - Fast-Track STTR Grant (Co-Investigator)

1R41CA206652-01A1 "Microparticulate mucosal vaccine for triple-negative breast cancer" - Phase I STTR Grant (Principal Investigator)