Technology Transfer in Life Sciences 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 global life sciences industry is undergoing a seismic shift, driven by Advanced Modalities like Cell & Gene Therapies and the integration of Generative AI and Multi-omics data. Successfully translating breakthrough academic research into viable, scalable, and commercially successful products from Personalized Medicine to mRNA Therapeutics is the critical challenge of the modern Biotechnology sector. This demands a highly specialized skillset in Technology Transfer (TT), bridging the gap between scientific discovery and market realization. Technology Transfer in Life Sciences Training Course is specifically designed to equip professionals with the strategic, legal, and commercial acumen to navigate this complex landscape, ensuring a faster Time-to-Market for life-saving innovations.

This intensive program focuses on the entire Knowledge Commercialization lifecycle, emphasizing robust Intellectual Property (IP) Strategy and mastering Risk Management in the context of stringent Regulatory and Compliance frameworks. Participants will gain hands-on experience through real-world Case Studies involving Spin-out Creation and global Licensing agreements for novel Diagnostics and Biomanufacturing technologies. By mastering the core principles of due diligence, valuation, and Strategic Partnerships, attendees will transform into effective Innovation leaders capable of driving organizational Competitive Edge in a rapidly evolving, data-rich global marketplace.

Programme Curriculum

Technology Transfer in Life Sciences Training Course

Introduction

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Course Objectives

Upon completion, participants will be able to:

1. Evaluate emerging research for commercial potential using Technology Readiness Levels (TRL).
2. Develop comprehensive Intellectual Property (IP) Strategies for Advanced Modalities
3. Apply QbD Principles (Quality by Design) to ensure robust and scalable Biomanufacturing processes.
4. Navigate complex Regulatory and Compliance pathways for global Drug Product transfer.
5. Perform accurate Technology Valuation and structure equitable Licensing agreements.
6. Formulate effective business plans for Spin-out Creation in the biotech space.
7. Integrate AI-Powered Data Analytics into early-stage technology assessment.
8. Mitigate operational and legal risks using proactive Technology Transfer Risk Management.
9. Streamline supply chain logistics for high-value products like Cell and Gene Therapies.
10. Foster Strategic Partnerships between academia, TTOs, and industry stakeholders.
11. Implement Lab Automation and digital tools for enhanced transfer efficiency.
12. Address ESG Initiatives and Sustainable Practices in new technology adoption.
13. Accelerate the commercialization pipeline for Personalized Medicine and RNA-Based Therapeutics.

Target Audience

1. Technology Transfer Officers (TTOs) / Knowledge Transfer Professionals (KTPs)
2. R&D and Process Development Managers (Pharma/Biotech)
3. Intellectual Property and Patent Attorneys (Life Sciences Focus)
4. Scientists and Inventors from Academia and Research Institutions
5. Project Managers overseeing CMC (Chemistry, Manufacturing, and Controls) and TT
6. Business Development and Licensing Executives
7. CMO (Contract Manufacturing Organization) Managers and Specialists
8. Early-Stage Bio-Entrepreneurs and Venture Capital Analysts

Course Modules

Module 1: Foundations of Life Sciences Technology Transfer

- The Technology Transfer Lifecycle.
- Understanding the Bayh-Dole Act and its global equivalents.
- Key Technology Transfer Mechanisms.
- Technology Readiness Level (TRL) and Market Attractiveness.
- Case Study: The commercialization path of the mRNA Vaccine platform from academic lab to global product.

Module 2: Intellectual Property Strategy & Protection

- Patenting Strategies for Biologicals, Advanced Modalities, and Digital Health.
- Non-Patent IP in Biotech.
- Global IP Filing and Maintenance
- Freedom to Operate (FTO) Analysis and Landscape Mapping.
- Case Study: IP protection challenges for a new CRISPR-Cas9 therapeutic application.

Module 3: Technology Scouting and Due Diligence

- Identifying High-Value, Disruptive Research in Multi-Omics and AI.
- Technical Due Diligence.
- Commercial Due Diligence.
- Legal and Regulatory Risk Assessment during the pre-transfer phase.
- Case Study: Assessing the technical and market readiness of a novel 3D Bioprinting platform for organoids.

Module 4: Technology Valuation and Deal Structuring

- Valuation Methodologies.
- Structuring Royalty Rates, milestones, and upfront payments.
- Negotiating terms for exclusive and non-exclusive licenses.
- Addressing anti-stacking provisions and sublicense income splits.
- Case Study: Valuing a next-generation Molecular Diagnostic tool for a Series A funding round.

Module 5: Licensing Agreements: Core Components

- Defining the scope, territory, and field-of-use (FoU).
- Drafting diligence obligations and performance milestones.
- Indemnification, warranties, and representations in biotech licensing.
- Handling improvements and derivative works.
- Case Study: Analyzing a real-world Drug Product Licensing agreement for oncology.

Module 6: Creating and Funding Spin-out Companies

- The process of converting a licensed technology into a viable start-up.
- Structuring equity, founder shares, and university equity stakes.
- Attracting Seed and Venture Capital funding in the Life Sciences.
- Building the initial management team.
- Case Study: The journey of an academic lab creating a CAR-T Cell Therapy spin-out.

Module 7: Technology Transfer Project Management

- Defining the Sending and Receiving Site Responsibilities and project scope.
- Developing the Project Master Plan and Gantt charts for complex transfers.
- Utilizing digital tools and Knowledge Management Systems for data integrity.
- Implementing a robust Change Control and deviation management process.
- Case Study: Project plan for transferring a sterile **Fill-Finish** process to a CMO.

Module 8: Quality by Design (QbD) in TT

- Principles of QbD and its necessity for successful transfer.
- Identifying Critical Process Parameters and Critical Quality Attributes
- The importance of Process Knowledge and establishing the Design Space.
- Using Risk Assessment tools to predict and mitigate transfer issues.
- Case Study: Applying QbD to the process transfer of a complex Biologic drug substance.

Module 9: Regulatory Compliance and GxP

- Understanding and adhering to GMP, GLP, and GCP during a TT.
- Process Validation and performance qualification requirements.
- Global regulatory submissions (FDA, EMA) and post-transfer reporting.
- The role of the Qualified Person (QP) in transfer sign-off.
- Case Study: Addressing a major deviation during the validation of an overseas manufacturing site.

Module 10: Transferring Advanced Modalities

- Unique challenges for Cell and Gene Therapy (CGT) technology transfer.
- Specific regulatory and stability considerations for mRNA Therapeutics.
- Logistics and Cold Chain Management for living or highly sensitive therapies.
- Transfer of analytical methods for novel biological assays.
- Case Study: Transferring the analytical testing method for an AAV Vector gene therapy.

Module 11: Digital Transformation and TT

- Integrating AI and Machine Learning into drug discovery data transfer.
- The role of Digital Twins and modeling in predicting process performance.
- Data integrity, cybersecurity, and Blockchain applications in supply chain traceability.
- Leveraging Lab Automation for high-throughput screening transfer.
- Case Study: Transferring an AI-driven Drug Candidate Screening workflow to a partner.

Module 12: Biomanufacturing and Scale-Up Transfer

- Transferring Upstream and Downstream processes for Biologics.
- Scaling from pilot plant to commercial volume, addressing geometry and fluid dynamics.
- Technology transfer for single-use systems vs. stainless steel reactors.
- Equipment qualification (IQ, OQ, PQ) requirements.
- Case Study: Scaling up the fermentation process for a monoclonal antibody transfer.

Module 13: Strategic Partnerships and Collaboration

- Developing effective engagement strategies with CMOs and CROs.
- Negotiating and managing Research Collaboration Agreements (RCAs).
- Best practices for alliance management and ensuring cultural alignment.
- Structuring Public-Private Partnerships (PPPs) for translational research funding.

- Case Study: Managing a multi-year Strategic Partnership between a Big Pharma company and a University TTO.

Module 14: Global TT and Commercialization

- Navigating international regulations, tariffs, and local market access.
- Ethical and access considerations for global Technology Diffusion.
- Supply chain resilience and diversification in a geopolitical landscape.
- Addressing Biosafety and Biosecurity concerns in global transfers.
- Case Study: Launching a Point-of-Care Diagnostic product in a developing market.

Module 15: Future Trends and Ethical Considerations

- The impact of Personalized Medicine and Decentralized Clinical Trials on TT.
- Future of Regenerative Medicine and tissue engineering transfer.
- Ethical and societal impact of Gene Editing (CRISPR) technology transfer.
- Ensuring Sustainable Practices and ESG reporting in TT operations.
- Case Study: The ethical debate and public licensing of a De-Extinction Science technology.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org 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
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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