Biotech Merger & Acquisition Due Diligence 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 Biotech M&A landscape is a highly specialized and high-stakes environment where transaction success is critically dependent on rigorous, sector-specific Due Diligence (DD). The immense value in this industry resides in intangible assets primarily Intellectual Property (IP) portfolios, the integrity of clinical trial data, and the viability of the R&D pipeline. Standard corporate DD frameworks are insufficient; they often fail to capture the unique Scientific, Regulatory Compliance, and Development Risk inherent in life sciences acquisitions. Biotech Merger & Acquisition Due Diligence Training Course equips Corporate Development, Private Equity, and Transaction Advisory professionals with a Biotech Due Diligence Playbook to systematically assess target asset validation, accurately forecast post-patent cliff revenue, and structure contingent value mechanisms like CVRs and Earnouts. Our focus is on mitigating the catastrophic risk of acquiring hidden liabilities or scientifically non-viable assets.

This course transforms theoretical knowledge into actionable deal-making skills, focusing on translating complex technical findings from Mechanism of Action (MoA) to GMP compliance into strategic negotiation leverage. Participants will master cross-functional team collaboration (Scientific, Legal, Financial, and Regulatory), learn best practices for Virtual Data Room (VDR) management, and utilize modern analytical tools, including AI in M&A, to accelerate the diligence timeline. By integrating deep-dive modules on Pharmacovigilance, Freedom-to-Operate (FTO) analysis, and sophisticated Biopharma Valuation Models, the program ensures professionals can effectively drive synergy from Day One of the Post-Merger Integration (PMI), securing optimal deal value and long-term shareholder return in a rapidly evolving market.

Programme Curriculum

Biotech Merger & Acquisition Due Diligence Training Course

Introduction

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Course Duration

10 days

Course Objectives

1. Master the Biotech DD Playbook for structuring a Phase-Appropriate and risk-mitigating diligence strategy.
2. Evaluate Clinical Data Integrity and Statistical Significance across Phase I, II, and III trials.
3. Assess the R&D Pipeline Viability by scrutinizing Mechanism of Action (MoA) and Preclinical Validation.
4. Conduct robust Intellectual Property (IP) DD, focusing on Patent Enforceability and Freedom-to-Operate (FTO) analysis.
5. Identify and Quantify high-impact Regulatory Compliance Risk (FDA, EMA, GxP standards).
6. Apply advanced Biopharma Valuation Models to calculate Net Present Value (NPV) based on development stage.
7. Translate scientific and technical findings directly into Deal Structure and Negotiation Leverage.
8. Mitigate the impact of the Patent Cliff by forecasting Commercial Runway and Generic Entry.
9. Design Contingent Value Rights (CVRs) and Earnout Structures to bridge complex valuation gaps.
10. Analyze Technical Operations and GMP Manufacturing readiness and scalability.
11. Streamline DD using Virtual Data Room (VDR) Management and Generative AI tools for document review.
12. Prepare a detailed Integration Blueprint based on DD findings to ensure Post-Merger Synergy Capture.
13. Anticipate and address Antitrust and Governmental Policy changes impacting Life Sciences M&A.

Target Audience

1. Corporate Development & Strategy Executives
2. Private Equity & Venture Capital Investment Professionals
3. M&A Transaction Advisory Consultants
4. Legal Counsel specializing in IP and Regulatory Law
5. Scientific & Medical Affairs Leaders involved in R&D Pipeline assessments.
6. CFOs and Financial Analysts responsible for Biopharma Valuation and Modeling.
7. Program Management/PMI Leaders preparing for cross-functional integration.
8. Heads of Quality Assurance (QA) and GMP Manufacturing

Course Modules

Module 1: The Biotech M&A Context & Playbook

- Patent Cliff, Access to Novel Modalities (Cell/Gene Therapy), Portfolio Gap Filling.
- Difference between Biotech and traditional M&A.
- Structuring the DD Playbook
- Roles of the Scientific Lead, IP Counsel, and Financial Modeler.
- Case Study: Developing a DD checklist for acquiring an early-stage platform technology company.

Module 2: Scientific & R&D Pipeline Due Diligence

- Evaluating Mechanism of Action and Target Validation for lead assets.
- Assessing Preclinical Data Rigor
- Stage-gate progression, competitive landscape, and Time-to-Market analysis.
- Reviewing the strength of the Drug Discovery Platform or Technology Stack
- Case Study: Analyzing the scientific risk in acquiring an asset with limited Proof-of-Concept (PoC) human data.

Module 3: Clinical Trial Data Integrity DD

- Deep-dive into Clinical Study Protocol design, patient enrollment, and endpoints.
- Verification of Raw Data quality, Statistical Significance, and source data validation.
- Investigator Site Audits and review of Institutional Review Board (IRB) communications.
- Assessing Serious Adverse Event (SAE) reporting history and Pharmacovigilance Systems.
- Case Study: Uncovering data manipulation or site non-compliance that invalidates a Phase II result.

Module 4: Intellectual Property (IP) Portfolio Review

- Patent Life Cycle assessment.
- Validity challenges, Inter Partes Review (IPR) history.
- Auditing the Chain of Title and Inventor Assignment agreements for ownership clarity.
- Review of Trade Secrets, Know-How, and licensing agreements
- Case Study: Evaluating a patent infringement risk after a successful competitor challenge.

Module 5: Freedom-to-Operate (FTO) & Risk

- FTO Methodology.
- Low, medium, and high-risk infringement scenarios and quantification of legal exposure.
- Analyzing Geographical Scope limitations and defensive patent strategies.
- Developing Design-Around strategies or pre-emptive licensing/cross-licensing options.
- Case Study: A late-stage FTO discovery requiring a major modification to the asset's commercialization plan.

Module 6: Regulatory and Compliance Risk

- Review of FDA/EMA/PMDA interactions, warning letters, and inspection history.
- Assessing GxP Compliance across development, lab, and manufacturing sites.
- Marketing Authorization status, regulatory designation, and filing readiness.
- Evaluating potential impact of new legislation on asset value.
- Case Study: Identifying and valuing the cost of remediation for a significant GMP Quality System gap.

Module 7: Financial Due Diligence in Biopharma

- Normalization of Financials.
- Cash Burn Rate and runway analysis for pre-revenue targets.
- Reviewing Upstream Obligations.
- Analyzing Grant Accounting and compliance with federal/private funding terms.
- Case Study: Normalizing R&D expenses to reflect the true, recurring cost of running the scientific operation.

Module 8: Biopharma Valuation Models

- Risk-Adjusted Net Present Value.
- Determining appropriate Probability of Success factors by therapeutic area and phase.
- Forecasting Peak Sales and Commercial Runway
- Using Scenario Analysis to inform negotiation ranges.
- Case Study: Sensitivity analysis on PoS and Discount Rate to justify a high pre-revenue valuation.

Module 9: Deal Structure & Negotiation Leverage

- Translating DD findings into Warranties and Indemnities.
- Structuring Contingent Value Rights linked to clinical or regulatory milestones.
- Designing Earnout Mechanisms tied to future revenue or sales targets.
- Using DD findings to push for a Purchase Price Adjustment.
- Case Study: Negotiating a CVR structure to bridge a $500M valuation gap based on Phase III success.

Module 10: Technical Operations (Tech Ops) & Manufacturing DD

- Reviewing Chemistry, Manufacturing, and Controls documentation and process flow.
- Assessing GMP Manufacturing Scale and capacity.
- Supply Chain Resilience and single-source dependency analysis for critical raw materials.
- Cost of Goods Sold analysis and projection for future commercial volumes.
- Case Study: Vetting a target's transition plan from a clinical-scale process to a commercial-scale process.

Module 11: Commercial and Market Due Diligence

- Verification of Target Product Profile (TPP) and its fit with unmet medical need.
- Assessing Payer/Reimbursement Landscape and market access strategy for key geographies.
- Evaluating Commercial Team readiness, existing sales force, and Physician Opinion Leader (POL) relationships.
- Forecasting Market Penetration and competitive response analysis.
- Case Study: Analyzing the commercial risk of a me-too drug entering an already competitive therapeutic area.

Module 12: Legal, HR, and Cultural DD

- Review of Material Contracts and Change of Control clauses.
- Key Talent Assessment and retention risk for the scientific leadership and lead inventors.
- Analyzing Incentive Structures and associated liabilities.
- Assessing Cultural Alignment and potential friction points for PMI planning.
- Case Study: Designing a retention package for the target company?ÇÖs Chief Scientific Officer (CSO) to ensure deal value capture.

Module 13: Data Management & Technology DD

- Reviewing Clinical Data Management Systems and Electronic Health Record compatibility.
- Assessing Cybersecurity and Data Privacy compliance
- Evaluating the use of Generative AI and Machine Learning in R&D and its validation status.
- Analyzing IT Infrastructure Scalability for a merged entity.
- Case Study: Identifying a critical data security gap that necessitates a pre-closing technology escrow arrangement.

Module 14: Post-Merger Integration (PMI) Planning from DD

- Synergy Realization Planning: Identifying cost and revenue synergies.
- Developing the Scientific Integration Roadmap for R&D teams and platform technologies.
- Day-One Readiness checklist based on DD findings
- Prioritizing the integration of Critical Assets
- Case Study: Creating a phased R&D integration plan to avoid disrupting the lead asset?ÇÖs clinical timeline.

Module 15: Emerging Trends in Biotech M&A

- Scope Deals and the acquisition of non-product capabilities
- Navigating Antitrust Scrutiny in large-scale pharmaceutical consolidations.
- The rise of Tuck-in Acquisitions and strategic alliances over megamergers.
- Analyzing the DD implications for Cell and Gene Therapy (CGT) assets
- Case Study: Vetting a smaller company whose value is purely in its Proprietary Generative AI Model for drug design.

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
21 Sep 2026	02 Oct 2026	Online	$2,000
21 Sep 2026	02 Oct 2026	Physical	$3,000
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0
21 Sep 2026	02 Oct 2026	Physical	$0

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