




Acquiring a Biotech Company?

Follow Our Technical Due Diligence Checklist



When private equity (PE) firms prepare for an M&A transaction, due diligence assessments help mitigate risk and safeguard a successful integration. The due diligence process becomes even more critical when acquiring niche, highly technical companies like those that operate in the life sciences and biotech industries. While these transactions often lead to growth and value creation opportunities, they can pose serious consequences when they are not vetted correctly.

Due diligence requires technical knowledge, which is why it's important for PE firms to enlist specialists in the target company's field. These specialists can better facilitate the due diligence process by helping firms assess the rewards and industry-specific risks inherent to these acquisitions.

BDO created a due diligence checklist for PE firms to help inform their decision-making and identify potential barriers. By enlisting an advisor to focus on technical due diligence, firms can ultimately focus on strategy and deal execution.

Technical Due Diligence Checklist

While every target acquisition company is different, especially considering the size of the business and the industry in which it operates, the following checklist outlines the common areas to consider when performing due diligence on a life sciences or biopharmaceutical company.

TECHNICAL CAPABILITIES



- Technology Platforms
- Process, Analytical, and Formulation Development
- Analytical Method Qualification/Validation
- Stability Testing
- Comparability Studies
- Clinical In-Use Studies
- Biophysical Characterization
- Protein Production (Transient vs. Stable)
- GMP Manufacturing
- Manufacturing Scale and Capacity
- Internal vs. Outsourced Services

PROCESS AND PRODUCT DEVELOPMENT



- Timeline and Budget
- Target Product Profile (TPP)
- Quality Target Product Profile (QTPP)
- Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs)
- Product Specifications
- Product Characterization
- Process Description
- Process Flow Diagrams
- Control Strategy
- Process Consistency
- Manufacturing History
- Stability Data
- Product Inventory
- Raw Materials and Consumables
- Supply Chain
- Cost of Goods Manufactured

FACILITIES



- Size
- Expansion Opportunities
- Age and Condition
- Facility and Equipment Maintenance
- Building and Equipment Monitoring Systems
- Security
- Site Master File

OPERATIONS

- Electronic Batch Records
- Enterprise Resource Planning (ERP)
- Supply Chain Planning
- Production Scheduling
- Business Continuity Plans



REGULATORY

- History of Regulatory Interactions and Inspections
- Product Approvals
- Investigational New Drug (IND) Readiness
- Biologics License Application (BLA) Readiness



STAFFING

- Resourcing
- Educational Breakdown
- Turnover
- Recruiting/Hiring
- Training Program
- Growth Rate



MANAGEMENT TEAM

- Scientific Leadership Experience
- Organizational Leadership Experience
- Track Record



BUSINESS / FINANCIAL

- Funding
- Cost of Goods (COG)
- Business Plan
- Intellectual Property
- Marketing



QUALITY SYSTEMS

- Paper vs. Electronic
- Quality Manual
- Quality Standard Operating Procedures (SOPs)
- Good Manufacturing Practice (GMP) Compliance
- Documentation Practices
- Data Integrity



When executed correctly, due diligence covers a thorough examination of every facet of a target company's operations. By enlisting a technical due diligence professional, PE firms can feel more confident knowing they have a more accurate and complete understanding of the target company and its strengths, weaknesses, risks, and opportunities.



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