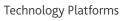




Technical Due Diligence Checklist

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



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



OPERATIONS

Electronic Batch Records

Enterprise Resource Planning (ERP)

Supply Chain Planning

Production Scheduling

Business Continuity Plans

STAFFING

Resourcing

Educational Breakdown

Turnover

Recruiting/Hiring

Training Program

Growth Rate

QUALITY SYSTEMS

Paper vs. Electronic

Quality Manual

Quality Standard Operating Procedures (SOPs)

Good Manufacturing Practice (GMP) Compliance

Documentation Practices

Data Integrity



History of Regulatory Interactions and Inspections

Product Approvals

Investigational New Drug (IND) Readiness

Biologics License Application (BLA) Readiness

MANAGEMENT TEAM

Organizational Leadership Experience

BUSINESS / FINANCIAL

Funding

Cost of Goods (COG)

Business Plan

Intellectual Property

Marketing



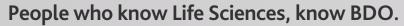


Track Record









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