



Your Portfolio Companies Deserve *Operational Excellence* from Day One

The 10-Point Operational Due Diligence Checklist for Pre-Seed or Early Series Biotech Investments

De-Risk Your Early-Stage Life Science Investments Through Operational Excellence

Introduction

For Venture Capital firms evaluating Pre-Seed biotech investments, promising science is only half the equation. The difference between a startup that stalls and one that successfully navigates the path from the lab bench to Series A (and beyond) is **operational execution**.

At BioVertex Consulting, we've found that assessing operational readiness prior to committing seed capital is critical to identifying hidden gaps and de-risking the investment thesis. Use this 10-point checklist to pressure-test the development plans of your prospective portfolio companies.

The 10-Point Operational Due Diligence Checklist

PHASE 1

Strategic Alignment & Planning

1	2	3
<p>Is there a clear, pressure-tested Target Product Profile (TPP)?</p> <ul style="list-style-type: none">• The Risk: Developing a drug or device without a clear end-goal leads to wasted capital and misaligned clinical endpoints.• What to look for: A well-defined preliminary TPP that outlines the intended patient population, mechanism of action, efficacy requirements, and safety profile compared to the future standard of care.	<p>Does the team have a realistic Development Roadmap?</p> <ul style="list-style-type: none">• The Risk: Academic founders often underestimate the time and complexity of IND-enabling studies.• What to look for: An integrated timeline or Gantt chart detailing the critical path, parallel workstreams, and clear value-inflection milestones required to unlock the next round of funding.	<p>Is Competitive Intelligence (CI) continuously assessed?</p> <ul style="list-style-type: none">• The Risk: Operating in a vacuum. A competitor may reach the market first or raise the bar for standard of care before the startup exits the clinic.• What to look for: Evidence of an ongoing competitive intelligence assessment framework that tracks rival pipelines and informs strategic pivots.

PHASE 2

Execution & Program Management

1	2	3
<p>Are there defined Stage-Gate Governance & Go/No-Go Criteria?</p> <ul style="list-style-type: none">• The Risk: "Zombie programs" that drain capital because founders are emotionally attached to failing science.• What to look for: Established, objective, data-driven criteria for advancing a compound or killing a program early.	<p>How realistic is the Resource Allocation and Budget?</p> <ul style="list-style-type: none">• The Risk: Running out of runway before hitting critical inflection points.• What to look for: A budget that directly maps to the development roadmap, with appropriate contingencies for scientific setbacks and CRO delays.	<p>Do they have a strategy for External Alliance & Vendor Management?</p> <ul style="list-style-type: none">• The Risk: Poor oversight of Contract Research Organizations (CROs) or CDMOs leads to slipped timelines and compromised data integrity.• What to look for: A structured approach for selecting, onboarding, and managing external partners and academic collaborators.

PHASE 3

Process Optimization & Infrastructure

1	2
<p>Is there a scalable Data Storage & Knowledge Management System?</p> <ul style="list-style-type: none">• The Risk: "Siloed" data living on individual researchers' laptops, making tech transfer or future regulatory submissions a nightmare.• What to look for: Standardized data storage, basic SOPs, and accessible knowledge management systems that protect intellectual property.	<p>Is a Risk Management Framework in place?</p> <ul style="list-style-type: none">• The Risk: Being blindsided by foreseeable manufacturing, regulatory, or scientific hurdles.• What to look for: A formalized risk register that identifies top operational/scientific risks alongside actionable mitigation strategies.

PHASE 4

Team, Leadership & Communications

1	2
<p>Are cross-functional roles and accountabilities defined?</p> <ul style="list-style-type: none">• The Risk: A fragmented team where everyone is doing everything, leading to dropped balls and burnout.• What to look for: A Team Charter or RACI (Responsible, Accountable, Consulted, Informed) matrix ensuring clear decision-making authority.	<p>Do they have a clear Scientific & Regulatory Communication Plan?</p> <ul style="list-style-type: none">• The Risk: An inability to translate complex science into an investor-ready narrative or a coherent regulatory strategy (e.g., Pre-IND meetings).• What to look for: A plan for engaging regulators early and a refined scientific narrative that aligns with commercial and investor expectations.

The Verdict: How Did You Score?

8–10 Points

Strong operational foundation.
The team is ready to deploy seed capital efficiently.

5–7 Points

Moderate risk. The science may be excellent, but the operational backbone needs immediate reinforcement post-investment.

0–4 Points

High risk. Proceed with caution. Significant operational buildout is required before capital is deployed.

Need to de-risk a potential investment or build out a portfolio company's operations?

Whether you need pre-investment due diligence, post-close operational buildouts, or fractional leadership (VP Ops / Program Head) for your portfolio companies, **BioVertex Consulting** brings the strategic rigor that moves programs forward.

 **Let's navigate the complexities of life sciences, together.**

[Book a Call](#)

[Email Us](#)

[Visit Website](#)