



Building Your Biotech – Four Keys to Sustainable Growth



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Contents

The Building Blocks of Sustainable Growth	2
1. Organizational and Development Strategy.	2
2. Organizational Structure.	2
3. Processes and Systems.	2
4. Implementation.	3
5. Recalibration.	3
Case in Point.....	3
• Assessment.	3
• Project Management.	3
• Process Development.	4
• System Implementation.	4
Conclusion	4

Overview

In their early days, many biotech startups operate with what can best be described as “organized chaos.” These companies often have a core team of employees who are stretched thin—not only managing trials but also selecting CROs, working with sites and writing protocols. Lean, mean, and highly committed to the company’s success, this core team will do just about anything required to get the job done in clinical development.

At first, that approach works well: It’s nimble. It’s focused. It’s the right fit for that phase of the company’s evolution. Over time, however, organized chaos can give way to a chaotic organization. A lack of strategy and structure can cause confusion, anxiety, and stress for newly hired employees—while constraining the company’s ability to achieve clinical and commercial success.

In working with biotech startups, Pharmica Consulting has observed that many reach this tipping point after hiring a new senior executive— VP of Research & Development, COO or even CEO. As these new executives settle in, they notice:

- Inefficient teams
- Lack of project management resources and/or lack of emphasis on formal project management processes
- Chaos among new hires
- Missed timelines
- Excessive CRO spend
- Overwhelmed HR team
- IT team challenged to understand business needs
- IT resources overwhelmed with basic infrastructure needs
- Lack of cross-functional collaboration at both the VP and team levels

Often these executives recognize the need for a more formal approach, including greater discipline in implementing and maintaining core functions. By assessing the organization, leaders can determine which functions are strong, which are weak and which are non-existent.

In prior projects, Pharmica Consulting has identified the following patterns of functional maturity within growing biotechs:

Overheard in Your Halls?

“I don’t know what’s expected of me.”

“I don’t know how to do my job here.”

“What’s the company strategy, and how does my function fit within it?”

“Doing everything in spreadsheets just isn’t working.”

“I don’t know where to find information or who to ask...”

“This company seems to lack a strong culture.”

“We need to recruit and retain great talent. What’s our value proposition to employees?”

“Are our CRO partnerships expensive or inefficient?”

Functional Area	Functional Comments
Clinical—including Clinical Operations, Data Management, Statistics, and Writing	Study teams typically not defined or effective. Lack of processes, data, and organization.
Commercial—including Sales and Medical Affairs	Need to ramp up quickly. Often need specialty experience and lack experience on market access. May need systems for approved content for MSL/sales people.
Finance	Immature functional and project budgets. Poor accrual forecasting. Often do not trust numbers from Clinical.
IT	Often lack strategy and clear articulation of IT services that will/will not be provided. Unable to increase user adoption of systems.
Medical/Clinical	May be reluctant to give up control and decision making.
Procurement	Completed by resources who lack experience. Inadequate or non-existent procurement standards.
Project Management	Function either does not exist or is too tactical. Not viewed as the “business” leader with the project leader as the “science” leader. Services are undefined. Lack respect within the organization.
Regulatory Affairs	Lack regulatory strategy and ability to guide teams on program strategy. Struggle with eCTD.

The Building Blocks of Sustainable Growth

To transform many of these growing pains into a sustainable growth plan, Pharmica Consulting recommends that biotech focus on five areas:

1. **Organizational and Development Strategy.** How many compounds do you foresee in your company’s pipeline? Will you purchase the assets? Which indications do you target? How many trials? What countries should you file in? Will the trials be fully outsourced? Or, will monitoring be outsourced but data management kept in-house?
2. **Organizational Structure.** With a development strategy in hand, the next order of business is crafting a rough organizational structure. Will you invest in study managers or a project management group? Will you invest in a strong team culture? Do you invest in employees or use contractors? What services will each organization perform?
3. **Processes and Systems.** Develop processes and systems that align to your organizational structure and goals. This area is where many companies become chaotic and inefficient. Often, biotechs have

more software and hardware than they really need—particularly if a company plans to outsource all trials. CRO partners should be able to access SharePoint in the cloud to share work completed on trials or to manage an electronic trial master file (eTMF). Meanwhile, employees should be managing the electronic common technical document (eCTD) in the cloud.

Smaller companies, in particular, should explore Microsoft Office 365—the cloud-based version of the popular business software suite. Not only is it inexpensive, but the cloud-based version also reduces the burden on an internal IT organization.

4. **Implementation.** Once processes and systems are designed, work with teams to implement them. After all, your teams are where work should happen—with the project leader and project manager helping team members through issue resolution. Too often, discord between project and functional leaders results in significant dysfunction among teams. Implementing processes at the study, program, and portfolio level—with clearly defined roles and responsibilities—will provide structure for how people should work at each phase of a study. Please note, however, that it's not just about *documenting* roles and responsibilities. Often what is needed first is a meaningful conversation with a third-party consultant who can listen and coach, helping ensure consistency of processes and systems across teams.
5. **Recalibration.** Since executives and organizations rarely achieve all of their goals on the first try, this step may be the most important. Strategy is about making a choice and applying resources to that choice. But strategy does not stop there. You also need a mechanism for asking this simple question: "How are we doing?" Every organization should address that question on an annual basis, with smaller recalibrations happening on a quarterly basis.

Case in Point

Frustrated by missed timelines, the COO of a 200-employee biotech company turned to Pharmica Consulting for project management help. From our experience with other growing firms, we quickly identified the likely culprits: a culture of dysfunctional teams, improper use of systems, too many assumptions, and too little documentation—along with project managers who were note takers, not leaders, and new hires who were ill informed about how to work effectively within the company.

Pharmica Consulting recommend the following remediation:

- **Assessment.** In the first phase, Pharmica conducted one-to-one and small-group interviews, immediately engaging employees in the change process. The findings of this critical phase also formed the basis for the go-forward plan. The key point here is prioritization. Typically companies fall so far behind that it is critical to determine which projects produce the most value in the shortest amount of time.
- **Project Management.** We recommended development of a project management organization characterized by project leaders who understand not just clinical development but also change management. Pharmica also helped develop tools for planning—including a simple, table-based Microsoft Word document in which teams had to concisely and consistently describe their

crossfunctional plans. One of the marketing team members actually did not know the primary indication for one of the firm’s compounds, and the planning document brought this to light. We also helped to develop standards around timelines and reporting, along with team roles and responsibilities. These tools helped team members as they interacted on a weekly basis. For growing biotechs, the key with project management is not to replicate “Big Pharma” tactics but rather to be nimble and practical— with a light cross-functional focus. Over time, build up this capability as your business evolves.

- **Process Development.** We helped the client to develop processes for how studies are planned and managed, including standards for CRO proposals. Such standards enable “apples-to-apples” comparisons—a capability that ultimately drove millions of dollars in savings for this client. Further, we recommended use of checklists to ensure clarity and recommended review and simplification of standard operating procedures (SOPs). Sharper SOPs are enabling the company to remain compliant while eliminating extra work, such as reviewing every trip report. Finally, we suggested program-level processes to guide both strategy and team leader interaction and to standardize how each team presents information.
- **System Implementation.** Pharmica recommended a review of the current portfolio of systems and their effectiveness. This company had licenses for a clinical trial management system (CTMS) but outsourced its entire portfolio—resulting in a major IT investment that was adding little value. Unfortunately, this scenario is not unusual. Pharmica’s answer: let each CRO use its own CTMS but provide a weekly “data dump” that feeds into a set of simple, effective and appropriate reports. This company used Microsoft SharePoint to store drafted, non-validated documents—with validated documents stored in a SharePoint environment in the cloud. This approach is keeping infrastructure light while still addressing document management needs. The client is also using SharePoint as a productivity and collaboration platform. And don’t overlook CRO oversight: Your systems should address this, or the FDA will address it for you.

Conclusion

While this paper has discussed biotech companies in broad strokes, it’s important to acknowledge that different-size companies have different needs. At Pharmica, we typically segment biotechs into those with up to 50, 50–250, 250–1,000, and 1,000+ employees—and we know there is no-one-solution-fits-all approach.

The imperative for leaders of any growing biotech is not to be complacent. Don’t wait too long to recognize when growth is occurring—or to address changes in employee attitudes and company culture. By taking a proactive approach, you can retain the best of your firm’s entrepreneurial spirit and energy while still supporting sustainable, profitable growth.

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