

# Closing Critical Commercial Skill Gaps

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**Successful business transformations don't just happen. They require planning and foresight. Product launch is too important to leave anything to chance.**

**T**he biotechnology industry is undergoing a significant evolution. The massive investments in drug discovery and development that have occurred during the past 10–15 years are bearing fruit as many emerging biotechs are maturing into product companies. As companies evolve through their business lifecycles—from R&D to clinical development to commercialization—they must change, adapt, and evolve their businesses by building the additional capabilities required of a commercial operation.

Successful business transformations contain three essential dimensions.

- **People.** New organizations, capabilities, and skill-sets are needed as part of the transition so critical functions required of a commercial company are effective.
- **Processes.** New and redesigned business processes are required to manage commercial products in a compliant, scalable, and efficient way.
- **Technology.** New and improved information systems are needed to manage the new transactions, data, and metrics associated with a commercial company.

The strong thread running through all of those dimensions is the urgent need to close the critical skill gaps between an R&D/clinical-oriented company and a product focused company. Many companies are falling short in building an effective commercial team, especially in areas of the country where the pool of qualified candidates is small or where competition for resources is fierce. Companies must look well beyond traditional employment tactics and adopt new planning, recruiting, and management practices to grow their commercial skill base.

## **GAPS AND MORE GAPS**

The typical emerging biotech company has built a strong scientific team, with expertise in research and clinical development. Companies also will likely have some precommercial manufacturing process, quality, and regulatory experience. The management team is typically science oriented and the general business experience is usually concentrated on strategic business development (licensing, partnerships, and so forth) and fund raising (either venture or public markets). Until this point, the focus was on building an organization with scientific and clinical capabilities, and backing it with sustainable financing.

As clinical development work proceeds, there is an increased urgency to begin looking at commercial business, yet the typical emerging biotech company is ill suited to perform such a task. Too many pieces are missing.

**Product supply.** Product supply issues begin surfacing early in commercial planning because of the long lead time required for manufacturing or sourcing capacity decisions. Whether vertically integrated or a virtual manufacturer,

biotech companies must develop reliable and scalable sources of supply for their products. Critical skills gaps exist in:

- procurement and materials management—in strategic sourcing of GMP materials at commercial scale;
- manufacturing—in ramping a validated production facility or negotiating supply agreements with contract manufacturing organizations;
- quality assurance—in establishing the proper commercial quality systems; and
- supply chain management—in developing the overall product supply, logistics, and distribution strategy and related business processes.

- human resources, including planning and sourcing candidates and professional development; and
- information technology, including business processes and software applications (versus infrastructure) needed to operate a commercial company.

#### **Commercial management team.**

Often, the management team itself has gaps in skills and experience that must be augmented. Furthermore, even an experienced commercial management team may have suitable individual experience, but recently hired individual members have not worked together to launch a product.

Faced with the need to increase the organization's skills, biotech companies work very hard to try to attract

the industry suffers from high turnover rates, salary escalation, and too many unfilled positions. In several areas of the country, serious staffing shortages exist and will only worsen unless new methods are employed.

Often, the assumption is to “hire experienced people and let them go to work.” What results, however, in too many cases, is a clash of style, approach, or varying opinions as to the best way to proceed. Although experience is necessary, it is not sufficient to ensure an effective transition of the company or successful product launch. Typically, there is a lack of professional and management team development.

#### **NEW AND DIFFERENT**

Despite all the challenges of transforming a company, establishing a systematic approach to planning for and acquiring the necessary skills for commercial success is possible. Important considerations include the following.

**Develop a commercial launch strategy, roadmap, and plan.** Companies should develop their commercialization strategy and roadmap 24-36 months before their expected launch, outlining the capabilities they will need to acquire or build to become a commercial entity. From there, a more detailed, multiyear plan can be developed to identify staffing and other critical investments.

**Take a layered approach to candidate evaluation.** Many highly talented people would like to break into the biotech industry. Companies should take a more holistic approach toward candidate sourcing and evaluation, segmenting them into four distinct categories.

*Candidates who currently have the direct skills and experience desired.* These are the traditionally sought-after candidates and should be pursued vigorously. Just don't expect that there will be enough of these people to meet all your requirements.

*Candidates who have some of the direct skills and experience desired.* These candidates are close to ideal and, in many cases, can be brought to the level desired through on-the-job train-

Many talented individuals who could easily transition into the biotech industry are never seriously considered.

**Commercial operations.** An entirely new business development infrastructure is required to bring a product to market. Critical skill gaps exist in:

- marketing, which includes market strategy formulation and tactical marketing;
- sales and sales support, including a new sales force, sales operation and training, and medical science liaisons; and
- product management, which includes responsibility for managing the product through its entire life cycle.

**Business infrastructure.** As the company evolves, new business and information management capabilities will be needed to support the new cross-functional enterprise. Critical skill gaps exist in:

- finance, which includes revenue recognition, expense management, inventory accounting, and accounts receivable;

qualified candidates but many of their efforts fall short. Launching a company's first commercial product is often a make or break deal for a biotech company, yet many have not developed a multiyear launch plan or budget for the capital and people investment required. Biotech companies often rely on the annual budgeting process to determine next year's staffing. That approach, however, overlooks the fact that brand new capabilities must be added.

The typical biotech company spends most of its staffing efforts trying to recruit from its neighbors and many will ignore candidates who do not have the exact requirements needed, especially if they lack industry experience. In fact, biotech career fairs typically set a minimum requirement of two to four years of industry experience for a candidate to attend. With such approaches, many talented individuals who could easily transition into the biotech industry are never seriously considered. In the meantime,

ing, mentoring, or other professional development efforts.

*Candidates who have related skills and experience, and strong interest in the industry.* These candidates may have related skills and experience in other industries but lack specific biotech experience. If the underlying skill base is sound and they can demonstrate a solid aptitude for learning, these candidates can be very attractive and with early planning and modest investment, can be brought to the necessary skill level needed for commercial launch.

*Entry-level candidates who have talent and strong interest in the industry.* These candidates represent entry-level hires that will need training and support but could grow into superior staff members.

By segmenting candidates according to such criteria, companies can ensure they have a superior pipeline of people, while devising the appropriate development programs to ensure employee skills are at the level needed.

#### **Grow your own talent base.**

Continued pursuit of “perfect” candidates with all the experience desired is unsustainable. Biotech companies should think two to three years ahead about their staffing needs and invest in innovative programs for growing their own talent base. Such programs should include tactics designed to help employees and candidates expand their abilities and experience so they are ready to fill some of the upcoming skill gaps. A number of tactics should be considered.

- classroom, electronic, and on-the-job training
- mentoring programs that pair experienced personnel with new hires
- cooperative programs with undergraduate, graduate, and trade schools
- internships for people looking to break into the industry
- graduate fellowships, scholarships, or grants to lock in new graduates
- continuing education programs to enhance skills of current employees

**Invest in management team development.** Hiring experienced commercial managers is an appropriate strategy, but one that should be augmented with appropriate management development.

- create a unified team philosophy and management practices
- establish clear goals and roles/responsibilities of the team
- develop an integrated commercialization strategy and roadmap
- identify critical capability gaps and the mechanisms for closing them

Ultimately, the team must oversee the transformation into a commercial company, so it is essential that a consistent philosophy and cross-functional approach is established.

**Consider bringing in a COO.** Often, the CEO of an emerging biotech company is focused externally, may not be heavily involved in day-to-day operations, or even may not have the skills to lead the internal transformation of the company. In such cases, the company should consider recruiting a president/COO who would have responsibility for leading the transformation into a commercial company. Candidates should have solid operating experience across many functional areas and the people skills needed to lead the management team through the launch process.

The launch of a commercial product is a pivotal event for a biotech company. The industry and the street are watching, and will remember whether your first launch is a hit or a miss. So the margin of error is slim. Although there are myriad things to consider, developing mechanisms for closing critical skills gaps should have a high degree of urgency for biotech executives. By adopting a multiyear launch planning approach, innovative staffing and professional development programs, and enhanced management practices, emerging biotech companies can transform themselves into successful commercial entities. ~

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