

# The nuts and bolts of startups

You have received funding for your startup, now you have to find and equip a functional home for your business, say Jeffrey Kiplinger and Kurt Last.

For many founders of scientific enterprises, the arrival of either grant funding or initial investment capital can be enabling and overwhelming, generating a new sense of urgency. Suddenly, what was once promise must be turned into profit: someone provided the money, and that same someone will expect a return. The successful execution of a business plan requires not only money but also—and

equally importantly—people, space, and equipment. And welding these components together into a workable whole requires attention to timing, cost, permits, and regulations. To integrate these elements smoothly requires the luck of a lottery winner, and no one navigates the complex process without hitting roadblocks and crises, or experiencing unforeseen and

dramatic shifts in direction.

Scientists and engineers—the “idea people” behind new ventures—often come to startups from positions in universities and larger companies. Therefore, they are inexperienced in the various facets of setting up a business: for example, how to start up a laboratory, design facilities, or handle regulatory affairs. Many venture capital organizations recognize that the inexperience of many scientist-entrepreneurs—and often an underlying lack of interest—in the more bureaucratic aspects of building a business, can hamper the progress of the venture. As a result, there is now a trend among biotechnology venture capitalists to place experi-

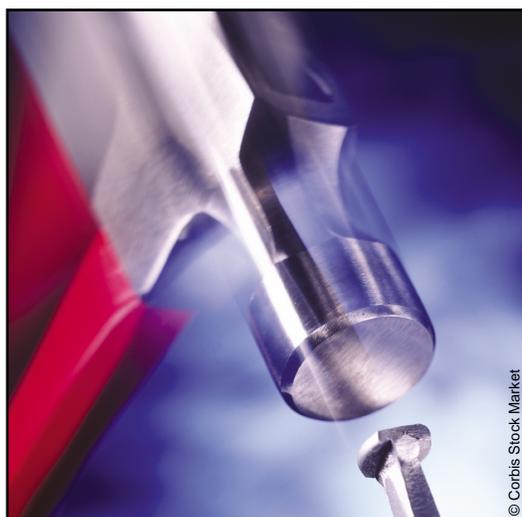
enced business managers in part-time, temporary roles within their portfolio companies, helping to build the startup's infrastructure while the scientists concentrate on the science<sup>1</sup>.

However, gaps frequently remain in the startup's experience in designing, equipping, and setting up a research facility. If they start up their new venture in, for example, La Jolla or Boston—areas in which biotechnology clusters are well established—a scientist-entrepreneur (henceforth called a bioentrepreneur) can readily tap an environment rich in experience—both executive and scientific<sup>2</sup>. Help in finding empty laboratory space or dealing with local regulations is just a phone call away. Being able to access this experience, often through colleagues and friends, is one reason why bioentrepreneurs gravitate to these areas. However, not everyone has the option of choosing to relocate a growing company to a biotechnology cluster. What can a bioentrepreneur expect if he or she starts up a company in, say, the Midwest?

## The pillars of business

The novice bioentrepreneur needs to appreciate that his or her company must be constructed on four fronts simultaneously:

- **Infrastructure:** A facility must be secured, designed, and configured for the specific research or manufacturing purpose, and all the appropriate local permits must be granted. The facility must then be able to run smoothly and continuously.
- **Sourcing:** No company can hope to carry out all functions internally from the start, and it may be more cost effective to contract out some functions to external suppliers on a permanent basis. However, it will be necessary to evaluate all prospective providers and ascertain their qualifications, negotiate contracts, and monitor and control performance.
- **Expertise:** In a small company, all employees wear multiple hats even though most are hired for their expertise in a single area. Over



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time, a company and its management must build, monitor, and maintain the expertise, allowing it to continue to operate efficiently. Small oversights can lead to major headaches: for example, an assistant might leave a company, taking along the password needed to access the only available records of the use and disposal of radioactive reagents.

• **Research:** Goals must be set, expertise acquired, and milestones achieved.

Failure to build on any of these fronts will result in delays in the research timeline, which in turn delay the financial returns expected by investors. A holistic approach to building a healthy company balances effort among these four fronts, yet scientists frequently neglect the functional details of startup in favor of research. Here we focus on finding and developing the laboratories and facilities to maximize the chances of research success.

### Home base

Emerging scientific enterprises may find access to incubator or other laboratory-

ready space in buildings subdivided for biotechnology tenants. Such facilities offer tenants the option to install hoods or other laboratory equipment and instrumentation, and the benefits of shared facilities for shipping/receiving and storage, and communal spaces and utilities. The availability and potential of such facilities varies widely, but they are becoming more common as developers and local governments realize that such facilities are a key to attracting biotechnology companies<sup>3</sup>. Tenants find incubators attractive because they provide assistance with the first three “pillars” mentioned above, so that the scientist can concentrate on the fourth—research. Unfortunately, many companies find that not all “lab-ready” facilities offer the features that they need to carry out specialized research and development (R&D) work (see Table 1).

The planned use of a laboratory should influence its design. Most scientists are familiar with some of the principles of ergonomic and safe laboratory design, but they may not be as knowledgeable about other aspects of

facility programming (designing and building a facility with operations in mind). A scientific company must evaluate several “underlying” issues when deciding on the suitability of a potential space for occupancy (see Table 1). Indeed, the ability of that space to match the necessary criteria should be the prime concern of any company. However, pressure to meet research milestones or the objectives of investors often forces bioentrepreneurs to compromise on features. Sometimes, companies can work around design problems (see “CytoTherapeutics’ solution”), but doing so requires foreknowledge and planning.

Certain aspects of facility build-out (renovation and construction) require skills that are best provided by contractors or vendors, for example, telecommunications and networking, specialized equipment (such as power supplies and transformers, or autoclaves), and instrumentation. Such specialists are best involved at the programming stage. The scientist–founder assuming responsibility for sourcing and coordinating these resources has a job as complex as that of a general contractor on a large construction project, and should not expect to contribute much to research programs during this time. An alternative is to find a project manager experienced with research facility programming and operations. A company that anticipates continuing expansion may choose to hire an experienced operations director; however, most young companies do not need full-time operations staff.

### Roles and responsibilities

It may be most desirable to hire a temporary or part-time project manager who assumes the role of operations director for as long as it takes to set up the company. The project manager may have many responsibilities, including the following:

- Provide continuing logistical support for the entire duration of the project, beginning with the evaluation of potential leases and finishing with the commissioning and switching on of equipment (the official “opening” of the new facility).
- Work with the design team and/or landlord on the building’s infrastructure and layout.
- Ensure that facility security or specialized areas (such as sterile or radioactive, i.e., “hot” laboratory areas) are worked into the design phase, as needed.
- Secure necessary permits and coordi-

**Table 1. Priority considerations for facilities that must be equipped for various common applications**

Application	Power requirements	Heating, ventilation, and air conditioning complexity	Risks	Regulatory issues
Light chemistry	Low	Moderate	Vapors Fire Waste	Waste Discharge Fire
Heavy chemistry	Moderate	High	Vapors Fire Waste Storage	Waste Discharge Fire Storage
Analytical chemistry	Clean	Moderate	Waste Solvent storage	Waste
Biologicals	Moderate	High	Exposure control Waste	Waste Pathogens
Radiologicals	Low	Moderate	Exposure control Waste Storage On-site decay	NRC Storage Waste
Animal care	Very high	Very high	Exposure control Waste Security Public relations	USDA (and others) Waste Discharge
Good Manufacturing Practice (GMP) manufacturing facilities	Very high	Very high	Production interruptions	FDA and the Canadian Public Health Board (PHB) Other regulatory bodies Discharges Waste

## CytoTherapeutics' solution

In 1991, the biotechnology company CytoTherapeutics expanded its operations into a 15,000 square foot facility on the fourth floor of an occupied office complex in Providence, Rhode Island. Although the requirements for chemistry and animal-care laboratories were smoothly accommodated by additional air handling from the nearby roof, access to the laboratories proved problematic. A single elevator served the building, and this had to transport chemicals, waste, and animals past the office floors and the ground-floor restaurant. During its tenancy, CytoTherapeutics worked around this problem by ruling that technical staff could only use the elevator for such purposes before 7:00 a.m. and after 11:00 p.m. Though less than ideal, this solution allowed the company to achieve operational goals in Providence faster and more cheaply than any other available option. Such solutions are unusual in a dedicated and established facility, but such problem solving is the norm among emerging and expanding scientific companies. *JK, KL*

nate regulatory filings necessary to begin operations. These can involve federal agencies (e.g., for permits for use of controlled substances, and manufacturing licenses), and local agencies (e.g., for permits for use of hazardous materials, waste management, or local zoning restrictions).

- Coordinate safety planning and training, and assist in establishing contracts with insurers, and reviews by fire district officials. Insurers and local fire districts require proof that the company can operate safely.
- Coordinate safety, transport, and facility-use procedures with other tenants in the building.
- Assist in tax planning: equipment installed in a facility is often subject to US property taxes.
- Source any equipment and instrumentation needed and coordinate its correct installation. Many emerging companies either lease equipment or purchase it used on the second-hand market or at auction.
- Hire experienced specialist subcontractors, acting as general contractor.
- Ensure continuity following project completion by fully documenting all facility modifications, equipment installation, subcontractor contact details, and any continuing contracts.

For startups in biotechnology clusters, the much-needed help and advice is often just a phone call away. For those that need to locate elsewhere, because of either cost or convenience, finding assistance requires only a little more effort. The key can be locating just one experienced and helpful person, who can act as a "point source" leading to contacts with other experienced people through a network. Suggestions for sources include the following:

- Managers of regional biotechnology incubators are experienced with every facet of laboratory operations and can provide advice even if they are not familiar with your locale. They have worked to accommodate

many specialized companies, and have helped them move out of incubator space into independent facilities. Most managers are genuinely dedicated to helping startups.

- While it is important to evaluate carefully architects experienced in the design of biotechnology laboratories to determine their level of expertise, a good architect can take over many of the functions of a project manager.
- Commercial real estate developers who manage laboratory space often offer some build-out allowance—a partial reimbursement of renovation expenses—as part of a lease, but tenants may be able to negotiate terms for additional assistance. In addition, real estate developers are often in contact with local, experienced subcontractors.
- University technology transfer or business development offices are often networked with experienced service providers, especially those that have had a history of cultivating scientific businesses successfully.
- Professional societies may be a good source of names of local companies or individuals, which can help begin the process of building a network.
- There are now specialized support companies offering project management and operations expertise on a contract basis. Larger consulting firms may offer such services, but must receive careful evaluation to determine their experience.

The role of the project manager in the building of the facility and starting up operations is primarily that of a risk manager. Although comprising multiple goals and timelines, one must manage the project with a single criterion for success in mind—that the startup's research capabilities are fully operational on schedule. All risk and change must be managed against this goal. In a large, mature company, such a project is generally one of many ongoing at any one time, a delay will have little impact on a company's overall operations; to an emerging company in its

fast-growth phase, the risks are much greater.

Things can, and do, go wrong. The damage wreaked by natural disasters, such as Hurricane Allison's flooding of university animal-care facilities in Houston, Texas, in the spring of 2001, cannot be anticipated. A wise company plans for the worst-case scenario. However, more frequently, oversights in routine day-to-day planning are an even greater danger and, in the authors' experience, are fairly common. Some examples include the following:

- In the final stages of construction of their new facility, a medicinal chemistry company failed to notice that their architect had neglected to include chemistry laboratories in the blueprint.
- An emerging pharmaceutical company neglected to carry out adequate commissioning of a new \$300,000 animal-care facility, only to find that backup systems were not wired properly. When an automatic temperature control failed, the company lost animals worth \$4 million overnight.
- A pharmaceutical contract laboratory constructed an animal-care facility for pigs, but the project contractor installed a cage washer to fit rodent cages.
- Faced with the need to treat pH-basic aqueous discharge, a medical device company engaged an architect who designed a lime-chip water treatment system, making the water even more basic. The local sewer authority forced them to close and redesign the facility.

These examples are not extreme, nor can one simply chalk them up to ignorance. However, they *are* one result of the very nature of today's emerging and rapidly expanding biotechnology startups, in which the importance of hitting research milestones distracts bioentrepreneurs from the complex and difficult job of setting up a smoothly operating company. The solution is not to disengage scientists from the exciting and challenging job of setting up the facility, replacing them—for example—with management brought in by investor groups. Instead, entrepreneurs must appreciate the importance and difficulty of the task, making an informed decision either to embrace it or to seek help from elsewhere. The successful handling of operations is an invisible component of a company's success; inadequate handling can result in a very visible failure to meet a company's goals.

1. Brickley, P. *The Scientist* 15, 38 (2001).
2. A.T. Kearney Executive Attribute Location Research Survey, August 2001, available at <http://www.atkearney.com>.
3. Special issue on entrepreneurs. *Chem. Eng. News*. November 13 (2001).