

Chapter 2

What Makes a Biotech Entrepreneur?

Biotechnology products arise from successful biotech companies. These companies are built by talented individuals in possession of a scientific breakthrough that is translated into a product or service idea, which is ultimately brought into commercialization. At the heart of this effort is the biotech entrepreneur, who forms the company with a vision they believe will benefit the lives and health of countless individuals. Entrepreneurs start biotechnology companies for various reasons, but creating revolutionary products and tools that impact the lives of potentially millions of people is one of the fundamental reasons why all entrepreneurs start biotechnology companies. Certainly, biotech entrepreneurs hope to make truckloads of money by building successful companies with billions in revenue. But most biotech entrepreneurs have an altruistic streak fueling their persistence, that keeps them going through the hardships and challenges that would stop cold those just looking to make a quick buck.

As the biotech entrepreneur and the start-up team begin a journey down what may be one of the most exciting and rewarding experiences of their entire career, they live out an opportunity to impact the world by developing medical products that combat some of the most challenging and deadly diseases that plague humanity. The sentiment heard universally from experienced biotech entrepreneurs is, that starting a biotechnology company is exciting, stimulating, and frightening – all at the same time. This chapter reviews the background of the biotech entrepreneur, as well as some of the most important personal characteristics of these individuals. Whether they live in Boston or Beijing, San Francisco or Singapore, Dublin or Denver – the characteristics of biotech entrepreneurs are all the same.

A Different Breed

The biotech entrepreneur is unique from all other entrepreneurs. Do not think this a patronizing statement, rather one of the cautionary relevance. Yes, the biotech entrepreneur must still possess the same attributes all other entrepreneurs do; those being independence, confidence, a desire to take the road less traveled, a passion for their work, the ability to work long hours, unrelenting persistence, and willingness to take risks. In addition, the biotech entrepreneur is usually an accomplished scientist,

bioengineer, physician, or businessperson. Most often, but not always, they have a PhD, MD, MBA, or combination of these educational backgrounds. These individuals usually have well-paying and secure positions, and are already experiencing some degree of success in their current position. A biotech entrepreneur voluntarily leaves their comfortable world, and steps into an industry that carries uncertainties and risks unique to any other business.

I am convinced that only true entrepreneurs can start a life science company. Any other personality type would be too cautious, too analytical and too practical, and conclude that it is futile to even begin. This is because biotech entrepreneurs do not just see problems, they envision an endless number of solutions to any given situation (never mind that many of these require resources not available, or it may have never been done before). Do not for a moment think that the biotech entrepreneur is cavalier – they just arrive in this world with a heavy dose of eternal optimism. A biotech entrepreneur recognizes problems, but does not focus on them for long. This is a strength of the biotech entrepreneur – but it can also be their downfall if not moderated.

Know the Challenges: Count the Costs

There are many challenges that await the entrepreneur. A biotechnology company is a melding of business and science, and thus it creates a business of scientific uncertainty. The product development process contains unpredictable biological and technical risks. These risks arise from a core technology based upon promising yet unproven science. Entrepreneurs must be prepared for an extraordinarily long product development timeframe. The average time to reach commercialization for biologics, drugs, and other types of therapeutics can take upwards of 15 years to reach the market. Diagnostics, medical devices, and molecular tests can range from 3 to 7 years. There are extraordinary financial risks. To develop a biotechnology product, one must secure exorbitant amounts of capital over many years, even decades, to complete development. Depending upon the type of product to be developed, the amount of money required may range from as little as \$50 million, to hundreds of millions of dollar. There are regulatory risks as well. A company cannot just produce a product and sell it as in many other high technology businesses – in the US one must first get approval from a \$2 billion dollar governmental agency called the FDA, standing between their product and commercialization. During this regulatory review, clinical testing results may be scrutinized for years – most likely within a changing regulatory environment. There are also new market risks. After a product receives approval, a biotech company then faces an untested and unproven market for a product that most likely never existed before. For the biotech entrepreneur, these risks are in addition to ones all entrepreneurs in any business face, such as over-stretched operational capacities, new market development issues, and challenges recruiting quality people, to name a few. By stepping into the shoes of a biotech entrepreneur, the magnitude and number of obstacles surpass those all other entrepreneurs face. *Welcome to the exciting world of the biotech entrepreneur!*

Do You Have What It Takes?

Before undertaking a start-up biotechnology company, one should count the costs because the stakes are exceedingly high. By understanding the challenges before beginning, one will be better prepared to handle them when they arise. Many individuals seek to accomplish lofty goals, but when things get tough, their desire wanes. Accomplishing anything of great value requires a significant amount of time and effort. The amount of time and effort is proportional to the significance of the endeavor.

Sometimes we want what other people have, without going through what other people went through to achieve it. A man with a broken arm was in a cast for 8 weeks. He subsequently went back to his doctor to have his cast removed, and asked “Will I be able to play the piano when this cast comes off?” His doctor said “Of course you will!” The man smiled with joy, and said “that’s wonderful, because I couldn’t play the piano before I broke my arm!” Be sure that you are committed to do whatever it takes to be successful *before* you start your company.

A good way to know if someone possesses the ability to accomplish things of significance is to examine their past experiences. The entrepreneur should inventory their past to see if they stuck it out when things got tough. Did they find creative solutions to solve problems? Did they demonstrate patience and persistence when faced with a difficult situation? Did they persevere to the finish?

Personal Costs

It is equally important to recognize the personal and family costs before starting down this path. The biotech entrepreneur should have a strong support system of family and close friends because their work will also impact these individuals. A support system is vital, because there will be times when their understanding, encouragement, and help (possibly even their money) is needed.

I recently met a first-time entrepreneur, who asked me to evaluate his technology and assist him with technical and market advice in applying RFID to an agriculture application. He was finishing his Ph.D., and simultaneously preparing to get married while starting his new technology business. He was very excited about the prospect of his new technology opportunity and had received some early financing interest from potential investors and industry partners. After advising him on the business aspects, I then encouraged him, if he had not already done so, to sit down with his future spouse and have a discussion about what this new endeavor will potentially require in time and financial commitment, and to be sure that she was in favor of him doing this. He said he had not thought about that, but would do so. Subsequently, months after their wedding, and many months into his business development, he came back to thank me for bringing this to his attention because it helped him tremendously. He said they did discuss these issues and considered

the time and financial commitment, and then they both agreed it was the right thing to do. With that, he had her support and understanding. As the business began to consume more of his working and free time, she was committed to his efforts which enabled him to continue with confidence and support.

Four Backgrounds of Biotech Entrepreneurs

The typical biotech entrepreneur who starts a company usually comes from one of four background types. Although individuals from any background can start a biotechnology company – so long as they have the ideas, skills, and motivation. Unfortunately, the odds for success are heavily weighed against anyone not from one of these categories. Each of these backgrounds comes with their own strengths and weaknesses. The four most common backgrounds of life science entrepreneurs include the following:

1. The ***Scientist/Physician/Bioengineer*** who comes from an academic institution (University, Research Foundation, Non-profit Research Institute)
2. The ***Scientist/Physician/Bioengineer*** who comes from within the life science industry such as another biotechnology company
3. A ***Businessperson***, such as a former executive in the life science, pharmaceutical or venture capital industry, who is not a Scientist/Physician/Bioengineer
4. A ***Core Group of Individuals*** that are spun off from another life science organization within the industry

Most biotech entrepreneurs and founders can be classified into one of these four categories. There can also be fundraising effects associated with each category of biotech entrepreneur, which we will term “Founder Effects.” These are discussed in Chapter 8.

For the Scientist: Things vs. People

The largest majority of biotech entrepreneurs come from a scientific background, and this influences the things to which they gravitate. Fundamentally, a large percentage of scientists become scientists because they either enjoy or are more comfortable working with “things” (experiments) rather than “people.” This does not imply that scientists do not like people; it is just that they find the challenges and rewards of research more fulfilling, compared to the challenges and rewards of predominantly working with people. Ironically, a significant part of a biotech entrepreneur’s job requires that they work more with people rather than with experiments and science. As with any job there are skills that must be acquired in order to do what needs to be done whether one enjoys it or not. Many scientist

entrepreneurs find they need help with their people skills because these may not have been honed to the same degree as their scientific skills. For the physician entrepreneur, this may not be an issue because they usually have clinical experience, and if they have been in clinical practice for any length of time, they may have developed reasonably good people skills. For the businessperson entrepreneur, if they have been successful at a business previously, working with people and dealing with these issues are where they usually excel.

Good scientists are capable of becoming good CEOs. An accomplished scientist and early employee of Genentech was David Goeddel. He was a significant force in the establishment of Genentech and an exceptional hands-on bench scientist. Goeddel was instrumental in successfully cloning many of Genentech's early products that are now on the market. Goeddel later went on to cofound Tularik, another biotechnology company in South San Francisco, with Robert Tjian and Steven McKnight, and eventually became CEO. In a transcribed interview, he openly admitted that he was not a people person at first, but out of the need and desire to do things well, he adapted to the requirements of a good CEO, which he found were different from the skills of a good scientist.¹ Acquiring new skills can only be accomplished if the entrepreneur first recognizes and acknowledges that they have shortcomings in a particular area. Individuals who are successful in one area sometimes have a hard time admitting they are mediocre, or down-right terrible, in another area. All good scientists have the potential to acquire other skills because they understand the learning process and the importance of training to gain proficiency. A scientist desiring to be a good CEO, can do so if they set their mind to it, avail themselves to good learning tools, and persist in learning.

For the Businessperson: Communication with Scientists

The entrepreneur with an entirely business background has a different challenge to wrestle with than does the scientist. Individuals with business backgrounds have a difficult time appreciating the technical challenges of the science, and typically have trouble understanding why technology development takes so long. This gap can be disastrous for planning. Most businesspersons do not have the background to readily understand the limitations of a technology; as a result, they may be surprised by "unplanned" scientific problems, resulting in product development delays that translate into financial shortfalls. To them, it may not seem obvious why a scientist cannot just run an experiment once, get the results, and move on.

Frequently, tensions arise between the businessperson and the scientist. This happens when the businessperson may erroneously promise things the technology just cannot perform, or the scientists may become frustrated with the businessperson

¹David V. Goeddel, Ph.D., "Scientist at Genentech, CEO at Tularik," an oral history conducted in 2001 and 2002 by Sally Smith Hughes for the Regional Oral History Office, The Bancroft Library, University of California, Berkeley, 2003.

because they do not appreciate the technical difficulty, and why things take so long. Businesspersons need to develop frequent and good communication channels (not superficial) with the scientists. They should practice having shared understanding of goals and objectives, and identify the challenges for both the business and the science. It is critical that the businessperson learn as much as possible about scientific issues by asking questions of the scientists to gain appreciation of the technology and its limitations. By understanding the scientific limitations and then sharing the market needs, the businessperson may influence the scientific development in a way that better meets the market needs, while simultaneously engaging the scientists to help solve the market problems. Businesspeople may be surprised by the solutions scientists can come up with, once they understand the business and market issues.

First Time Entrepreneur, First Time in Business

Alternatives to Consider Before Taking the Leadership Role

If a professor, physician, scientist, or bioengineer from an academic background is contemplating starting a biotechnology company, but unsure about the decision to lead the company, they may want to consider a few alternatives. There are several ways to participate in the entrepreneurial process without carrying the responsibility for the entire organization and its outcome. Each of these alternatives still provides valuable experience for participating in the entrepreneurial process and equips you better for a future entrepreneurial opportunity. Options include:

1. Take the position of Chief Scientific Officer or Chief Medical Officer in the new company and allow someone else more experienced to shoulder the major business and financing responsibilities for the organization.
2. Participate as a cofounder in getting the company started and then return to research or medical practice, while contributing in a role as a Scientific Advisory Board Member or Board Member.
3. Be the scientific founder, help establish the company, and possibly work to get seed funding with the idea of later recruiting an experienced CEO. Find out how well you do before deciding whether or not to continue in this role, or turn it over to someone with more experience.

Young scientists or young businesspersons with minimal business experience may want to consider supportive roles such as these, or consider a transition role in the company rather than taking responsibility for the entire organization. In this way, they can learn by observing and participating, rather than being solely responsible for the outcome of the company. By doing this, they can gain valuable experience and apply it to the next opportunity, where they can lead with more experience and an understanding of the process and issues faced.

Although I had about 10 years of entrepreneurial industry experience when a group of four individuals cofounded a biotechnology start-up, I filled the role of VP of R&D, while the businessperson with a marketing background appropriately filled the CEO role. In my role at this company, I was still actively involved in the growth and development of the organization and participated in the fundraising and in the IPO road show process. As the company grew, I later took on the additional role of Chief Operating Officer and gained more insight into the running of a biotech business. These experiences better prepared me for the responsibilities at my subsequent biotechnology start-up, where I did assume the role of CEO. Just because the entrepreneur is not leading the organization, does not mean they will not participate in shaping its future.

An academic scientist's background and experience can sometimes be a help or a hindrance when raising money. The more practical business experience a scientist gains, the more confidence potential investors will have in that person's ability to successfully lead a company. Biotechnology investors invest in people they trust – not just in technologies alone. Unfortunately, sometimes stereotyping of scientists can occur. On one rare occasion I heard an unconventional venture capital investor angrily declare “I would never invest in a company where a scientist was the CEO”. Too bad, that investor would *not* have invested early in Amgen nor invested in Genentech today because a scientist *is* the CEO. This concern should not be the sole reason for a decision whether to lead a company or not, but it is a factor that one should at least be aware of early on. Those that are good at working with people, and can communicate well the value of the organization to investors, and have a strong desire to build and lead a biotechnology company, really will not be satisfied unless they do.

Acquiring Additional Business Skills

Scientists or physicians without a business background may want to consider supplemental training in business either before, or during, their involvement with a start-up company. Even the businessperson may want to consider additional training because they are not necessarily endowed naturally with the capabilities to lead a company simply because they have a career in some aspect of business. There are a variety of options for gaining further business skills and knowledge, and these helps are offered by some of the best business schools in the country. Most all business schools offer short courses that cover such topics as Finance for Executives, Health Care Strategies, and Biotechnology Business Issues, all the way to traditional MBA and Executive MBA programs. If you are considering a major commitment to formal business school education, and you can manage the costs and time commitment, an Executive MBA program is a great way to go. This is not an endeavor for the faint of heart as it is an intense time commitment, is also costly, and can run well over \$120,000 for tuition during the two years of a program. However, it provides an opportunity for a mid-career person to gain the skills and knowledge they may want without quitting your their job and taking two years off

to complete a traditional program; it is also an excellent experience that will sharpen your skills as a business executive and add broad-based knowledge to your decision making. The choice of school is critical, as it will shape your learning experience and your view of business in the future. If you go this route, choose a business school that incorporates your values, and offers high-caliber instruction in a collaborative environment.

I was in the biotech industry for 19 years when making a decision go to business school. I chose an Executive MBA program to learn with peers of equivalent career experience and working business knowledge. I sought a school with a strong core curriculum and also with high ethics and leadership training, which are qualities that are needed in the business world today. The way I personally chose a business school was by attending class lectures at different institutions before making my decision to apply. The Executive MBA program turned out to be a challenging and time-intensive two years (studying an additional 20–25 hours per week on top of a full-time job, not including class time); however, it is a decision I would make all over again. Having completed an MBA, I can honestly say I make better business decisions based on the knowledge and insight gained from my professors and peers through this training. There are many excellent business schools world-wide, so if you are interested in pursuing this avenue as an investment in your future, it may be well worth the time and effort.

For the Young MBA

For the young MBA student or graduate contemplating starting a biotechnology company, they should consider acquiring some type of training in the sciences, although a formal science degree is usually not necessary. Many good business schools have biotech courses available, and some even have dual Master's degree programs in Biotechnology and Business. Whatever your scientific interest, you should avail yourself to as many good educational resources as you can find.

Be a Life-Long Learner

In reality, most entrepreneurs do not have the time to pursue a formal business education. However, they can still acquire additional business skills by developing a practice of reading good business books to expand their knowledge about business issues. During my scientific career, I constantly read books on business practices, project management, and leadership, along with biographies of successful CEOs. Another option is to take advantage of half-day seminars or short presentations to help where you may be lacking, be it finance, marketing, negotiations, strategic alliances, business development, or scientific and technical areas. One can also gain additional business knowledge by meeting with successful business leaders or other biotech entrepreneurs, who can provide practical insights about making wise

business decisions. As you do this, you will find yourself thinking about business problems differently. By learning new skills and business concepts, you are acquiring the tools to help solve business problems. As the saying goes, “If you are a hammer, everything looks like a nail.” Work to increase the tools in your tool box and you will be able to make better decisions. Maintain a life-long learning mindset, and it will ensure that you will not always have to learn lessons the hard way.

Essentials of a Biotech Entrepreneur

Passion and Vision

The most successful biotech entrepreneurs all possess these two components – they have a *vision* and *passion* about what they are doing. Entrepreneurial passion is not an emotional characteristic, but a driving desire to accomplish something they firmly believe in, and will do, no matter how difficult the challenge. Being a visionary is about:

1. Seeing something others don't see
2. Communicating what they see in a way that inspires others to follow

Entrepreneurs should be sure they possess these characteristics if they are going to start a biotech company, because they will need them when they face the many challenges during company development. Also, potential investors will be looking for these characteristics because they know that they are essential to building a successful company.

Assess Your Strengths and Weaknesses

The more successful an individual becomes in one particular area, the more blind spots they tend to accumulate in other areas. As a result, most people do not have a good appreciation of their real strengths and weaknesses. The best way to know one's weaknesses is to ask those who are closest, to tell you what they are; however, the problem with this is that others are rarely comfortable telling someone the truth about their weaknesses. Another way to assess your strengths and weaknesses, is to complete a personality or work behavior profile such as a Myers-Briggs, DISC, or other self-assessment test. Many times these assessments are available with an interpreter or coach to assist in the translation and discussion of the results. Completing such a test is not a requirement for starting a biotechnology company, but it will be worth the time and money to complete it sometime during your biotech career. I highly recommend that you do it sooner rather than later, because it will help you objectively learn your weaknesses. By knowing these, you can

work to improve them, and later balance them by hiring staff with complementary strengths in your areas of greatest weakness.

I personally have all my senior staff take a work behavior profile test and have the results explained so that our team can understand each others communication styles, and how each naturally responds to their environment. Years ago I would have discounted this exercise as fluff, and say, “we just need to get the work done.” I have since learned that a fair portion of problems arise from miscommunications, differing communication styles, and different reference points, rather than from true disagreements. Having a good understanding amongst team members results in open and honest communications. However, when team members do not trust each other, the company does not move in the most straightforward path. When team member problems occur, a typical approach is to force everyone to work together whether they like it or not. This can lead to a situation where individuals begin looking out for only themselves instead of the goals of the organization. This generates artificial problems and is counter-productive – realize there are enough real problems in starting a biotech company, without generating more. Be sure your team is equipped with good communication tools, and help them learn useful interaction skills early on. By doing this, it will minimize artificial problems later and the team will become a more productive group.

Learn New Skills Quickly

Regardless of how accomplished someone may be in their present career, they should not be fooled into believing this guarantees success as a biotech entrepreneur. Entrepreneurs need to learn new skills quickly or they will not be successful. The reality television show “The Apprentice” is a successful television series in which creator Mark Burnett brings accomplished individuals from various areas of enterprise to vie for a spot as the winner of Donald Trump’s next apprentice. The latest modification to this show, featured a twist in the casting, where famous and successful individuals from various walks of life were cast for the “Celebrity Apprentice.” During this particular season, 18 hugely successful individuals included: world heavyweight boxing champions, Olympic gold medal athletes, rock stars, TV stars, a super model, and successful personalities. The object was to win at the business tasks as a team: Whereas, the losing team faces Donald Trump in the Board Room, and the least successful person on that team will hear the words “you’re fired!” Interestingly, two of the first three “terminated” celebrities were accomplished gold medal Olympians: Jennie Finch, the 3-time USA gold medal softball pitcher, and Nadia Comaneci, the 5-time Olympic gold medal winner in gymnastics. These two are fiercely competitive athletes, who keenly know what it takes to be successful competitors. Both athletes experienced victory because they devoted their life to self-discipline, focus, planning, and execution, to achieve Olympic Gold Medal success. However, excellence and accomplishment in one field, no matter how great, does not immediately endow one with superior business

skills. There is no doubt that these athletes, with proper business training, could quickly excel and become superior business competitors, but without time and training in business, all individuals begin at remedial levels. The Biotech Entrepreneur must adopt the mindset of being a quick learner because it will serve them well as they establish and grow their business. If one quickly recognizes what they do not know – and learns what they need to know – they can avoid the pitfalls encountered by less successful individuals.

Good Business Sense

Most good business decisions are really just common sense. The problem is that common sense is not always “common.” Having common sense allows one to make good business decisions *if* they understand the issues. However, if an entrepreneur has trouble understanding business issues, they will also have trouble making good business decisions. For the scientist, a good way to become exposed to business issues is to read business journals and newspapers such as the Harvard Business Review and the Wall Street Journal. If the entrepreneur finds that nothing in these publications interest them, they may not yet have an appreciation for business issues. This does not mean they cannot start or run a biotechnology company. However, someone who does not enjoy the business aspect of running a company should consider some of the alternatives to leading the business, as discussed at the beginning of this chapter.

Have the Ability to Speak Two Languages: Be a Multi-Disciplined Translator

A significant universal barrier to achieving success for a biotechnology company is the absence of a “multi-disciplined translator”. A multi-disciplined translator is a person who understands the marketing, financial, and business issues, but also understands the technical and scientific issues – and speaks both languages well. One of two scenarios is usually played out in biotech start-up organizations: The first, is where the entrepreneur without a technical background, cannot or does not want to understand the scientific issues and limitations. In this situation, the entrepreneur operates in a pseudo-environment where they believe the science operates in a certain way, but in reality it does not. The second situation is where the entrepreneur is a scientist who cannot, or will not, learn to communicate scientific issues in a way that the business and financial persons and investors can understand. They tend to go headlong into a discourse on issues that are of no interest to anyone except those with a technical mind. The scientist, in this case, does not attempt to translate, but speaks to businesspeople, investors, and Board members in scientific jargon, and approaches them using the scientific method. Neither of

these situations accomplishes true communication. As a result, transmission of critical information necessary for effectiveness does not occur.

All scientists are trained to be skeptical when analyzing data. Scientists are good at looking for problems, seeing issues of misinterpretation, and identifying incorrect conclusions – these are great skills for performing quality research. However, these qualities are terrible communication tools for speaking with business and financial partners. For the scientist to be an effective leader, they must have a “split brain.” This does not translate to “schizophrenic.” It means having a strong right brain that understands the more abstract things such as market forces, branding issues, consumer psychology, and other business development issues, *and* having a left brain that understands the science and technical issues. Whether the biotech entrepreneur has a background as a scientist or businessperson, each must speak to the other group of individuals using *their* terminology and vernacular. I do not advocate memorizing business and scientific lexicons; however, it is essential that the entrepreneur understand the concepts that drive both business and scientific decisions, and possesses a working knowledge of these terms.

When communicating, all entrepreneurs should learn to use the language of their listener. A scientist talking with a businessperson should not speak with multisyllabic words having Latin derivatives. The word “bacteria” works just fine for “bacteroides melaninogenicus,” and the single-syllable word “gene” suffices for “single nucleotide polymorphism.” A businessperson talking to a scientist should not go into a lengthy discourse about “discounted cash flows” when asked “how much is the company worth?” Learn the language of the listener, and if necessary, digress to “translate” any technical concepts into words the audience will then understand. Verbal communication is simply a means of faithful transmission of thoughts and concepts to another person. Use words that best transmit these concepts to the listener. When verbal communication is an impediment, the listener never knows if the communicator’s thoughts are worthy of consideration, or whether they are in disagreement, or they just do not understand. This problem is worse than communicating with someone in an unfamiliar foreign language. In the former situation, listeners comprehend the words, yet they really do not understand the context. Often they think they understand what is being said, but conclude that the communicator does not know the real issues. Practice is important to becoming a multi-disciplined translator. When communicating, ask for feedback from listeners and see if you are understood, and ask them if they can paraphrase what they heard. Most people will be patient if they know you are trying to communicate more clearly.

Successful multi-disciplined translators *think* about issues in other disciplines. Individuals who have mastered a foreign language, routinely say that they think in that language once they have become proficient. The businessperson should practice thinking about the problems scientists do. The scientist should practice thinking about the problems a businessperson faces. For those that do not know where to begin, explain the problem to a proficient businessperson or scientist and get their help. Scientists and businesspeople approach problems differently – learn to follow their thinking process, not just the end result.

Beware of the Unknown Unknowns

The biotech entrepreneur will encounter two types of “unknowns.” The first is the known-unknowns. These are things easily recognized as important but you also understand your knowledge is limited in these areas. Although you would like to have knowledge in these areas, you can compensate for this by hiring a consultant or by seeking advice from those that are experts in these areas. The trickier problem for the biotech entrepreneur is the unknown-unknowns. These are things you do not know – that you do not know. The reason for this problem is you *think* you understand the issue, but you do not realize there are other hidden issues.

Unknown-unknowns are challenging to recognize because by definition one does not know that they do not know these issues. Always seek guidance and help from others, even if you think you already know the answers, because you can either learn something new or confirm your assumptions. If you practice learning from everyone, you will avoid mistakes and circumvent unknown problems. For this reason, the biotech entrepreneur needs help from experienced consultants, Advisory Board members, Board members, and experienced venture capital partners. Venture capitalists focused in the life science industry are usually familiar with most issues a biotechnology company will face, so it is wise to seek and utilize them for more than just financial reasons (more on this subject in Chapter 8). Having partnerships with larger organizations that have experience in your life science arena also assist in uncovering the unknown-unknowns. Just remember, listening to everyone is not the same as accepting advice from everyone, for truly, many individuals give advice that do not know or understand the issues you face nor do they understand the ramifications of each decision. Grow in discernment because everyone you talk with will have an opinion, but not everyone will know what is best for your situation – seek experienced opinions.

Gain Knowledge and Wisdom

Entrepreneurs are guaranteed problems and challenges, but having knowledge is not enough to resolve them. Knowledge is simply the acquisition of information. In addition to knowledge, one needs wisdom, which is the proper application of selected pieces of knowledge at the right time. A good example of wisdom applied to a difficult situation is exemplified in the Old Testament, where King Solomon was presented with the problem of two women, each claiming that a particular infant child was their own after one of the mothers’ infants died in their sleep (DNA testing certainly would have helped). In this situation, one woman who was always envious of the other, accidentally rolled over and suffocated her own baby while it slept near her. The jealous woman did not want the other woman to have a baby since she lost hers, so she switched her dead one for the live one while the other woman slept. The disagreement appeared irresolvable. King Solomon wisely said

that because they both claimed the baby, the only way to solve the problem was to split the baby and give half to each mother. He instructed the palace guard to draw his sword and split the remaining baby in two. The first women said “yes!” but the second women instinctively cried “give my baby to the other women for I would rather see my son live than die!” King Solomon immediately instructed the palace guard to give the baby to the second women, for she was the rightful mother.

Although this problem is not one an entrepreneur would expect to face during the start-up of a life science company, however, similar types of uncertainty can be expected. Decisions such as, which development route to take, which candidate employee will be the best hire for the organization, which venture group to go with, what is the best strategy to the market – each require a Solomon type of wisdom. Many times, additional information is found by those who will spend the time to ponder more than just the straight facts of the situation. Decisions should never be whimsical nor should they be made irrespective of the facts, but always seek as much additional information as possible before drawing conclusions and making critical decisions.

Persistence

Many times the difference between success and failure is just holding on a little longer. Thomas Edison remarked, when asked about his numerous unsuccessful attempts to find the perfect filament for the light bulb, “I never failed once, it just happened to be a 2,000-step process.” For the biotech entrepreneur the saying, “success is 1% inspiration and 99% perspiration” is an important truth to remember when building a business. There will be times, when you find yourself in unfamiliar situations that are extremely challenging and have great consequence. During these times, the natural human instinct is to draw back and retreat. Retreat shows up in various ways such as shortening your work hours, avoiding decision-making, lack of confidence, apathy, shirking responsibilities, and limited communication with your team. These actions are exactly the opposite of what is needed from a leader. People do not look down on leaders who valiantly fight a battle but lose; however, they rightly fault and criticize those who shrink from their duties, when they hold positions of responsibility. During trying times, step up to face the challenge regardless of whether the answer is clear. Instead of retreating, redouble your efforts until a solution is found to overcome the situation. Investors, employees, and supporters are counting on the leader to have a plan. There is no easy route to success, and it requires commitment, dedication and just plain “hard work.”

Dealing with the FDA may qualify as one of these sustained challenges, especially when you are caught in the middle of a change in FDA policy that may have been completely unexpected. This is the situation I encountered while leading a company as we sought to bring a product to the market. The first product was a multi-gene test, performed in a clinical laboratory accredited by CLIA, having regulatory requirements that were in existence for decades. The FDA changed its policy

at the same time we completed our product development, which was contrary to our discussions five years previous and prior to the development of the product. In this situation, the FDA prohibited us from marketing this laboratory test without a pre-market approval, even though it was not previously required. The ensuing process, from device exemption approval, to completion of the requested studies, to the filing of a premarket application for marketing, took over 22 additional months and another \$3.5 million dollars. As a result of these regulatory changes, the company was on the verge of running out of capital, and I was constantly seeking additional funding, negotiating with vendors and suppliers, and working to maintain employee morale and implement a strategy that would ultimately result in the successful marketing of this product. During this time, it would have been easy to give up, and some well-respected individuals even encouraged me not to waste my career and future on this battle. Ultimately we gained the go-ahead to market our first product. There may be a time to call it quits, but encountering challenges and difficulties is not a good reason to give up. By quitting too soon your life will be guided along the path of least resistance, rather than one of your choosing. It is only through overcoming challenges and difficulties that one can accomplish anything of real value.

Having a Deep Sense of Responsibility

Successful companies are shepherded by great leaders who understand that leadership is not the same as friendliness or likeability. Though most good leaders also have those characteristics, they are much more than likeable people. Deep within, they have an innate sense of responsibility for what they have been entrusted. It is from this foundation of responsibility that they make decisions, rather than from a short-sighted view of pride, personal gain, or convenience. Although individuals start and lead companies for a diverse number of reasons, not all individuals have a “deep sense of responsibility,” which is essential when going through tough times if you hope to come out successful at other end. Without a deep sense of responsibility, individuals will run from difficulty or choose to ignore problems rather than deal with them when they are easier to handle. Without this sense of responsibility, uncertainty will surface in a team when the company encounters rough times because they do not have confidence that their leader will deal effectively with difficult situations.

Do not be fooled into believing that starting and building a business is all fun. Some of the most challenging times lay ahead of those who choose this business endeavor. However, some of the most rewarding and fulfilling times also await the ones that have a deep sense of responsibility, and persist through these situations rather than run from them. Entrepreneurs need to assess whether they have a deep sense of responsibility by examining how they have dealt with difficult situations in their past. If they find that they did not have this responsibility factor, all is not lost. Consciously be aware of this, and when encountering troubled times, work at doing the opposite of your natural inclination. When you make an effort to change and do something different, you will see different results. A good definition

of craziness is, “doing the same things over and over but expecting different results.” A deep sense of responsibility is one key component that supports other qualities commonly associated with outstanding leadership such as dedication, personal integrity, persistence, and vision.

Be a Negotiator

This may sound like an unusual topic for a biotech entrepreneur. Is not negotiation what one does when there are differences between groups of people and between organizations? Yes – but formal negotiation is only a very minor facet of negotiation. Whether we realize it or not, we negotiate many times each day, even outside of the work setting. Let us say we have plans for Saturday morning and our spouse says on Friday night, that both need to go shopping on Saturday morning for a Birthday present for a family member. One might instinctively say, “how about if I finish up what I had planned by 2:00 PM and we meet at the mall at 2:30 PM?” This is a negotiation. Let us say we rush to drop our clothes at the cleaners because we need a suit or dress cleaned for a dinner meeting tomorrow night, but the sign says “deadline for next day service at 8:00 AM”. You walk in at 8:15 AM and say (very nicely) something like “I know you have a 8:00 AM deadline, but I really need these by tomorrow but got tied up this morning, is there any way you could possibly get these cleaned by tomorrow? Some type of pleading dialogue may occur and you may arrive at an acceptable solution that accomplishes your needs, which allows them to also be supportive of the outcome even though it may not be what is routine. These are examples of everyday negotiations. In your start-up company, you will find yourself negotiating each day for deadlines, deliverables for projects, balancing workforce assignments, and personnel issues. To be a good negotiator, you must understand what are the essential and the nonessential issues and objectives, and learn to concede the nonessential ones.

Enlarge Your Circle of Influence

It is important for a biotech entrepreneur to build a circle of influence by including many people they trust – these will be individuals from whom they can later seek help, advice, and assistance. When encountering new problems, it is sometimes challenging to find a solution because we often do not have the necessary frame of reference to relate. The best suggestion is to find advisors who have gone through the building of life science companies successfully, and seek their advice. Get input from individuals who are trustworthy. Do not blindly operate on the advice of someone who has never been in a similar situation, nor dealt with a particular challenge in question, but seek the advice of many counselors.

On Creativity and Change

One of the strengths of a start-up biotechnology company (yes, they have strengths) is their ability to respond quickly to change. The biotech entrepreneur's ability to respond to change is critical to the future success of the organization. Always strategically assess the environment, the market, and the opportunity for changes. Large corporations cannot make changes quickly; they have too much infrastructure and too many reporting relationships to make changes happen quickly. Learn to monitor the changes in the business environment, and then appropriately adjust the business strategy or development plans or even the market strategy to take advantage of any new opportunities.

A former medical director of a previous start-up biotechnology company I cofounded, had left to join a very large company that was quite successful. About a year later, he called back to catch up on our progress. I heard him lament that he missed the daily meetings we had where we would have a great idea, and after discussing things, go out and adjust the business strategy that same day. He said, now they have major committee meeting and subcommittee meeting to discuss things but the inertia is so great that new ideas get pushed into more meetings and more subcommittees until it becomes very watered down, if it gets ever gets done, it is months later and not what it started out to be. Although it is never a good idea to have a new "five-year" plan each week, do not lose the ability to be creative and execute quickly on your developing ideas; this is a strength of a small company.

Leadership and Core Values

The foundation of a good leader is their core values. Any individual can be a leader, but having the right core values will lead an organization down the right path. Hitler, Lenin, and Marx were arguably examples of effective "leaders," since leadership is often defined as the ability to marshal resources, command respect, share a vision, execute a plan, and inspire others to follow. These individuals are negative example of good leadership because they were based on misguided core values. Good leadership must be placed in the context of proper core values to build a successful, sustaining organization. The leader's core values are the compass by which the organization will be directed. Be sure to examine core values, because these are the principles and beliefs one reaches into when they do not know what to do, and are faced with difficult decisions. There are many great books on leadership that would be helpful to the biotech entrepreneur. For those who do not know where to begin, I would recommend Jim Collins' book "Good to Great"² as a place to start.

²Jim Collins, 2001. "Good to Great: Why Some Companies Make the Leap...and Others Don't," Collins Business, New York, 300 pp.

Summary

Successful entrepreneurs possess a diverse list of characteristics that add significance at various stages of their biotech career. They are multi-taskers, or as one serial entrepreneur put it – they must have “rapidly adaptive, serial, single-pointed, focused attention.” First time entrepreneurs who have started and built companies will point out that the qualities described herein are ones they all wish they had a good dose of early in their tenure. A biotech entrepreneur may not initially possess every skill required to lead a talented and diverse team to build a successful business, however, as with any skill set, most can be learned if the entrepreneur is willing. Once these skill sets are acquired and proficiency is gained, these entrepreneurs generally go on to start many other biotech companies. These serial entrepreneurs successively build upon each previous learning experience and become proficient at their work and at recognizing the critical components of a successful business opportunity.

Whether someone seeks to start or join a company at any stage of development, a good analogy for building a biotech company is to realize that every great architectural structure we see today was first conceived in someone’s mind. The Eiffel Tower was just a concept – a grand idea that existed many years before the first steel girder was ever set in place. During its inception, the visionaries encountered seemingly insurmountable challenges, and were faced with many reasons to quit. Some of the naysayers of this project voiced that it costs too much, the design cannot support its weight, and the land where it is to be erected is not solid. Through the perseverance of the Tower’s visionaries and their ability to communicate the vision effectively to others – they recruited a team that later solved the engineering, construction, financing, and political challenges. As a result, this monumental piece of architecture stands today. What is your vision? Communicate it frequently to others, and before you know it you will see a company established and growing through the efforts of diverse individuals, all joined together to accomplish something far greater than anyone can accomplish alone.

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