

# Section 3. Set Up Your Business

*Content and references that were presented under the “Key Points” and “Challenge” tabs.*

## 1. Establish the Business

### Steps to Establish Your Business

To establish your business as a legal entity with a commercial identity (Venturize, 2018)...

1. Select your business name and register as a business entity at the federal and state level. State requirements vary. When you register the owner, be sure to consider the opportunities available for women-owned businesses (more than half owned and managed by one or more women).
2. Select a domain name for your website.
3. To make sure existing patents will not block your business idea, conduct a freedom to operate ([FTO](#)) search. You may want to hire a [patent](#) attorney.
4. Obtain federal and state tax IDs. Get an Employer Identification Number ([EIN](#)) through the IRS. An EIN is needed to pay taxes, obtain licenses and permits, hire employees, and open a business bank account. Registration takes up to the next business day. State tax IDs vary.
5. Obtain a [trademark](#) through the US Patent and Trademark Office if you want one.

Reference

Venturize. [How to Turn Your Small Business into a Legal Entity](#). Venturize.org. September 8, 2018.

### Licensing Your Invention If You Work at a University

If you developed your [intellectual property](#) (IP) while working at a university, the IP belongs to the institution. You must license the IP from them to use it in your business, usually for some

financial compensation (Chitale et al., 2022). You must disclose to the university the value of your company, the role you will play, and the time you will commit to the business. Your business's attorney will negotiate the details of the license with the university's [technology transfer office](#) (TTO), including a conflict management plan and milestones your business must meet to maintain the university's support of your business.

#### Reference

Chitale S, Lawler C, Klausner A. [So you want to start a biotech company](#). *Nat Biotechnol*. March 2022;40(3):296–300. [doi:10.1038/s41587-022-01239-9](https://doi.org/10.1038/s41587-022-01239-9).

### **Tip from *Establish the Business***

Select the domain name for your new business's website (URL) and business name simultaneously because one may affect the other. The availability of your ideal business name or domain name is not guaranteed.

## Challenge from *Establish the Business*

A (fictional) startup business is being established and needs a name. The business will produce a device that takes a new approach to using robotics to do physical therapy. To learn some of the challenges in finding a name for a business, select the name that you think will work the best from the following list of potential names. Then review what was determined by thorough research about each name.

- Robotherapy
- AutoWorkOut
- PTRoboticSolutions

### Feedback:

- The name Robotherapy is already in use for a form of psychological counseling. Please choose another name.
- In market testing, AutoWorkOut made people think the product is for exercising without any effort or that the service is automobile repair. Please choose another name.
- This name is not in use, not similar to existing names, not frequently misunderstood, and available as a domain name for the company website. It may be a good choice.

## 2. Registrations Required for Government Funding

### Business Registrations Required for SBIR/STTR Grants

Before you can apply for government funding to start your business, including [SBIR/STTR](#) grants, you must complete several additional registrations beyond establishing your business as a legal entity.

The four business registrations required to get [NIH](#) grants are. . .

1. **System for Award Management (SAM)** – Registration is required to do business with the government through SAM.gov, including getting a federal grant. It can take two to six weeks to process and must be renewed annually.
  - **Unique Entity Identifier (UEI)** – This 12-digit number identifies your organization for doing business with the US government. It is obtained while getting your SAM registration.
2. **Grants.gov** – Registration is needed to access and apply for federal funding. You will need to have completed your SAM and UEI registrations. This registration takes several days to five weeks to process for organizations and two days for individuals.
3. **Electronic Research Administration (eRA) Commons** – eRA is the NIH’s online research administration website used to submit and review grants. Start registration at least six weeks before grant submission. Registration with login.gov is also required.
4. **Small Business Administration (SBA) Company Registry** – Registration is needed to log in with SBIR.gov and takes only one business day. Your UEI, email, and [EIN](#) are required. Apply before submitting a grant application.

Reference

NIH. [Required Company Registrations](#). SEED.gov. Accessed March 6, 2023.

### Tip from *Registrations Required for Government Funding*

- Start your business registrations long before your grant submission deadline. Some take six weeks or more to process.
- Read up on what information is needed for each registration at the outset so that you are prepared.

### Challenge from *Registrations Required for Government Funding*

Test your knowledge. Select from the following list the business registrations required by all applicants to get SBIR/STTR funding:

- Small Business Administration Company (SBC) Registry
- CAP-Accreditation
- System for Award Management (SAM)
- Electronic Research Administration (eRA) Commons
- FDA Registration
- 8(a) Business Development Program
- Grants.gov

CHECK ANSWERS

#### Feedback:

The four registrations required to get an SBIR or STTR grant (or any NIH funding) are...

1. Small Business Administration Company (SBC) Registry – Required to get an SBIR grant. Provides access to SBIR.gov.

2. System for Award Management (SAM) – Required to get an SBIR grant. Register with SAM to do business with the government through SAM.gov. This registration will also generate your 12-digit unique entity identifier (UEI) number, which identifies your organization for doing business with the government.
3. Electronic Research Administration (eRA) Commons – Required to get an SBIR grant. eRA is the NIH online research administration used to submit grants and grant reviews. Also requires registration with login.gov.
4. Grants.gov – Required to get an SBIR grant. Register to access and apply for federal funding.

The following are not required by all grant applicants but may be helpful or needed at some point by a biotech business:

1. CAP-Accreditation – CAP is a laboratory accreditation program.
2. FDA Registration – You may need to obtain FDA registration during the development of your product if the FDA regulates your product.
3. 8(a) Business Development Program – This program assists small disadvantaged businesses.

#### Reference

NIH. [Required Company Registrations](#). SEED.gov. Accessed March 6, 2023.

## 3. Biotech/Biomed Industry Unique Requirements

### Learn the Requirements of Your Industry Sector

Industries have their own requirements you must follow in addition to the basic requirements for any business. For example, in the biomedical industry, many products must gain [FDA](#) approval.

#### US Food and Drug Administration (FDA) Regulation

- The FDA regulates. . .
  - Medical devices
  - Radiological health
  - Over-the-counter and prescription drugs
  - Biological therapeutics and products, including some human cell and tissue products, medical test kits, and drugs
  - Products with color additives and new food additives
- Start learning about FDA approval early in your business planning. The FDA sponsors workshops, conferences, and trainings. Some [NIH](#) institutes, such as the NCI, offer support for communications between small businesses and the FDA.
- New drugs go through three phases of clinical trials. If the data shows the therapy is effective and safe, you submit a new drug application to the FDA.

(Registrar Corp, 2023)

#### Health Insurance Reimbursement

- If your product is a biomedical treatment or device, make sure health insurance companies will provide reimbursement for its use.
- If a medical procedure is involved, you may need to secure a new procedural code to permit billing for it.

(ULP, 2022)

#### References

Registrar Corp. [How to Get FDA Approval](#). Registrar. 2023.

University Lab Partners. [Reimbursement for MedTech and Biotech Startups](#). October 17, 2022.

## Planning Your Research Environment

### Location for Life Science Research and Biotech/Biomedical Businesses

Consider locating your business near a center for life science research and biotechnology—such as Boston, San Francisco, San Diego, or the Research Triangle in North Carolina—because it will facilitate hiring, networking, and collaborations. A lab location that all key personnel can access facilitates communication and productivity (Chitale et al., 2022).

### Planning Your Lab

The following cost- and time-saving options can help expedite getting your research started (Chitale et al., 2022; Manbachi, 2018):

- Renting bench space in an established lab during their off hours.
- Renting lab space in an [incubator](#), an organization that supports the growth and success of startups by providing physical workspace, shared facilities, guidance, and some funding.
- Engaging a lab or a contract research organization to conduct all or part of the research for you.
- University employees or students may be allowed to conduct sponsored research in their university lab (at some negotiated cost and with conflict of interest details worked out), which saves the cost and effort of setting up a separate lab.



## References

Chitale S, Lawler C, Klausner A. [So you want to start a biotech company](#). *Nat Biotechnol*. March 2022;40(3):296–300. [doi:10.1038/s41587-022-01239-9](https://doi.org/10.1038/s41587-022-01239-9).

Manbachi A, Kremer-Tonin K, Walch P, et al. [Starting a Medical Technology Venture as a Young Academic Innovator or Student Entrepreneur](#). *Ann Biomed Eng*. January 1, 2018;46(1):1–13. [doi:10.1007/s10439-017-1938-x](https://doi.org/10.1007/s10439-017-1938-x).

## Tips from *Biotech/Biomed Industry Unique Requirements*

- If your product needs FDA approval, seek help from attorneys and other expert consultants familiar with the process.
- Show that you understand the regulatory pathway in your grant proposals.
- Be sure to collect all the data you will need for FDA approval or to support insurance reimbursement when you have the chance to collect it.
- Determine whether medical products fit within existing clinic protocols or whether a change would be needed for your product to be adopted.

## Challenge from *Biotech/Biomed Industry Unique Requirements*

Which of the following products do you think are regulated by the U.S. Food and Drug Administration (FDA)? (Choose all that apply)

- New prescription drugs
- Medical devices
- A new color additive for food
- Biological products including medical test kits
- New food using previously approved food additives
- Over-the-counter drugs

[CHECK ANSWER](#)

### Feedback:

All of these items are regulated by the FDA, except a new food using a previously approved food additive. The FDA regulates. . .

1. Medical devices
2. Electronic products that emit radiation
3. Over-the-counter and prescription drugs
4. Medical biological therapeutics
5. Certain human cells and tissue products
6. Medical test kits
7. Cosmetics and tobacco products
8. New color additives and food additives

### Reference

Registrar Corp. [How to Get FDA Approval](#). Registrar. 2023.

## 4. Pitching Your Business

### When Do You Pitch Your Business?

Pitching your business, which is presenting information about it to interest groups (e.g., investors, customers, etc.), happens throughout the life cycle of your business. Besides potential investors and customers, you may pitch your business to an NIH program officer, the manager of an incubator, a potential new team member, industry news media, or a loan officer.

### Consider the Audience

Tailor your pitch to the interests of each audience. If they will not benefit directly from your business themselves, describe the benefits for a group they might care about.

Your audience may **include non-scientists**, so . . .

- Find common ground, such as caring about the problem your product solves. Emphasize this at the outset.
- Use language everyone can understand.
- Limit technical information to essentials and briefly explain key technical details for everyone.

(B-BIC Skills Development Center, 2015)

#### References

B-BIC Skills Development Center. [Presenting Your Science to a Diverse Audience](#) (Video). 2015.

B-BIC Skills Development Center. [How should scientists communicate science to investors?](#) (Video). Communication Skills Training Series (2015).

## Pitch Topics to Cover

1. The **need** for your product or service, including the problem that it will solve and who has that problem.
2. Your **solution** and its unique value.
3. The **target market**, who would benefit.
4. **Yourself**, including your training, achievements, where you have worked, projects you have worked on, leadership experience, and product lines produced. Also, describe your team.
5. The **business's profile and financial details**, including purpose, mission, history, regulatory issues such as [FDA](#) approval, business model, reimbursement strategy, funding raised to date and its yield, and future funding needs and plans.
6. Your **research**, including a summary of key findings, publications, grants, awards, remaining research questions, clinical trial status if relevant, and your vision for your research.
7. **Business achievements**, including patents/applications, prototypes, product stage of development, and progress toward regulatory approval.
8. **Risks**, risk mitigation, and alternatives.
9. The **competition**, including overlap and differences.
10. If pitching to potential investors, include...
  - A **timetable** for when they can leave with a profit.
  - **Milestones** associated with a change in the value of the business.
  - How much **money** you need and how you will spend it.

(Shimasaki, 2016; Koch, 2020)

### References

Koch K. [How to Create an Effective Biotech Pitch Deck](#). University Lab Partners. May 29, 2020.

Shimasaki C. [What to Put in a Biotech Investor Pitch Deck?](#) LinkedIn. June 25, 2016.

## How to Write Your Pitch

1. **Stay focused** on the most important parts. Get to the point quickly.
2. **Try using a template** (find some free ones online), which may come in the form of a series of slides called a **pitch deck**.
3. **Use a story arc** with a beginning, middle, and end to engage your audience.
  - Example 1: Start with the need for your product, describe how you discovered your solution, and then talk about the challenges you faced and how you solved them.
  - Example 2: Tell a story about someone with a personal need for your product and how your solution would impact their life.
4. **Develop different versions** of your pitch for different purposes: a brief, 30-second **elevator pitch**, a formal 5-minute slideshow introduction to your idea, and a longer, more detailed presentation for potential investors.
5. **Summarize data** and offer to supply details if requested.

(FSI, 2023)

Reference

Foundation for Shared Impact. [How to Pitch Your Business—All the Basics You Should Learn](#). Blog. Accessed March 9, 2023.

## Tips on Pitch Delivery from *Pitching Your Business*

- Be confident and well prepared.
- Display passion and enthusiasm for your product and work.

- Show leadership ability, including being able to think strategically, inspire, and execute.

### Challenge from *Pitching Your Business*

Rate Examples from Bonita's Pitch Deck (See [Story](#) Above)

How well do you think Bonita did with considering her audience and engaging them?

- Poor
- Fair
- Good
- Great

SUBMIT

VIEW RESULTS