

## **Getting Started in Biotechnology & Biodefense:**

So you are ready to do business with the federal government. We can help. For new businesses or established businesses that want to do business with the government you must do these steps first:

Steps:

- 1) Register for a [DUNS Number](#)
- 2) Register with [SAM \(System for Award Management\)](#)
- 3) If you are a small business with a 'set-aside' you must register with the [SBA](#)
- 4) Register for [matchforce.org](#) with NCMBC

### **Biotechnology is a Unique Sector:**

Biotechnology, which includes biodefense, is a unique sector within the federal government. Biotech is a broad term that can span across multiple industries such as medical products, defense related products, agricultural and wellness care. The one common factor unique to all biotech is that the [Food and Drug Administration \(FDA\)](#) and the [Environmental Protection Agency \(EPA\)](#) both have oversight on certain aspects of the industry.

To learn about which oversight body has purview on your service or product please review both websites on industry concerns:

[FDA for Industry](#)

[EPA for Industry](#)

*\*Please note that biocides and other decontaminating agents are covered by one or both agencies. Start with EPA and then learn about decontaminating agents in the FDA.*

### **Working with existing Biotechnology Companies:**

Like all business, the Biotechnology or Biodefense industry has two branches of operation to consider. First, each business relies on their day-to-day operations. For product providers that market support equipment, office supplies, janitorial services, and personnel management, these are often not sexy, but are essential to a well-run company. Most small businesses can win significant amounts of business by supporting a large company's daily and routine activities. If you have a set-aside provision for your business this is an ideal opportunity to build a performance history with your company.

### **Innovative & Disruptive Products/Services:**

New and advanced products and services can enhance the services that biotech related providers perform. If you have a new idea, product, or service that can disrupt the industry you should consider applying for [SBIR funding](#) to prove the capabilities of your product. Get to know your key markets, industry size, key players and *let them tell you* how much they think your product is worth. Before discussing any of these opportunities, be sure to have mutual [non-disclosure agreements](#) before revealing the amazing aspects of your technology or service.

**Have your paperwork ready:**

No matter which agency covers your product, the FDA or the EPA, ensure you have all the official letters and certifications necessary to sell your product or demonstrate and prove its claims and efficacy. No federal agency will contract with a biotechnology service provider or product manufacturer unless it has these certifications. If you are selling a chemical or compound, ensure you have the required [Material Safety Data Sheets \(MSDS\)](#) from the [Occupational Safety and Health Administration \(OSHA\)](#) , part of the Department of Labor.

**What matters most when competing for a government contract?**

Each federal government agency administers hundreds of projects each day. Getting your innovative idea, product or service a close look by the contracting representative comes down to a couple of factors. Make sure that you make a solid business case. Please refer to these resources for developing a strong and winning business case:

[University at Albany, Center for Technology in Government](#)

Other essential considerations:

- **TCO: Total Cost of Ownership:** Although contracting officers are happy that you're idea maybe "life saving," "ground-breaking," or "the best" those claims alone are not compelling for them to go with your idea or service. Of course your product is great, but if it costs 3 times as much as currently available technology it will face an uphill battle for adoption. You must be able to clearly and completely demonstrate a solid business case for lowered operational costs over the life of the project. If your product costs less to purchase but requires more maintenance time it will most likely be rejected. Be open, transparent and honest when discussing these details.
- **Burden of Proof:** Claims made by providers must be able to show that their product does what it claims. Sometimes "good enough" is better than newest or modern preferred provision. Just because your provision may be newer, meet certain federal goals, or be trendy, it must still actually do what you claim it does and do it reliably and consistently. Performance risk should be understood and your business must embrace the fact you will be audited, scrutinized, and analyzed with a critical eye over the lifetime of your product or service's claim.
- **History of Performance:** If you are new to the federal contracting world, be sure to have a list of references of your qualifications to perform both as an individual and as a company when possible. Biotech is a unique sector that does not always lend itself to having a long history of performance, especially in disruptive or new innovations. If you are not bringing a new product to market or have a

patent on your product, we highly recommend that you start by partnering and teaming on projects with other more established companies. Although it is possible, you are not likely to win a \$14 million dollar federal contract as a company with no reputation or federal contracting experience.

- Be Ready Before you Win: The good news is that you can and will win a federal government contract if you follow the rules and read the instructions. But, winning a contract is not the first step. You must have a system in place for detailed records keeping; accounting, recorded personnel certifications, safety training, EEO and other HR training, safety SOP and it must be well documented and updated regularly. Hiring practices, personnel policies, equipment procurement policies will be required for periodic review by federal auditors. Ensure you have a current system or a plan to have these internal systems in place before you compete and win a contract.

Please contact the NCMBC for further coordination and to help work through the process of registering and doing business with the government. We look forward to helping you compete, win, and grow to be fabulously successful in your business!