



## **Benchmark Biolabs Company Overview**

Benchmark provides our clients with a full range of scalable services; focused on the validation, development, licensure, and commercialization of their unique technologies. Collectively, our scientists are responsible for over 100 issued patents, 200+ USDA and FDA licensed products and establishments, and many groundbreaking technology introductions.

A company of around 30 people, several with prior experience from major animal health and pharmaceutical companies, we provide practical and cost efficient support in the form of industrial science. The key management personnel at Benchmark have held Director, Vice President, and President positions across the industry, and our regulatory personnel have a long and outstanding relationship with the government.

Benchmark is highly regarded within the animal health industry, and is the only company to provide such a breadth of services. We undertake contract research but also serve the industry through provision of laboratory services (both analytic and custom), regulatory consulting, QA/QC services, manufacturing, formulation, process development, and business consulting in addition to clinical trial support. In short, our role is to provide an extension of efforts to gain or maintain approvals and expand commercial opportunities for products.

Benchmark serves a number of established companies as well as universities, government agencies, and start up enterprises. These clients use us to manage internal resources, expand scientific capabilities, reduce management budgets, manage fixed costs, resolve technical bottlenecks, address conflicting priorities, and ultimately achieve technical and commercial success.

Benchmark provides these services via our state-of-the-art laboratory facilities in Lincoln, Nebraska. We also staff and manage 3 manufacturing sites for clients as well as a distribution management function for another. Over the past two decades Benchmark has taken several products from initial concept through to licensure, and has contributed to the licensure of numerous other products.

Benchmark personnel in various positions can be linked to the development of virtually every new biological technology over the past two decades.

### **From Concept to Commercialization**

***"The highest quality, most responsive and most adaptable service at any point on the path from concept to commercialization."***

BENCHMARK BIOLABS INC.

421 WEST INDUSTRIAL LAKE DRIVE LINCOLN, NE 68528

Phone 402-475-8104 Fax 402-475-8511

[WWW.BENCHMARKBIOLABS.COM](http://WWW.BENCHMARKBIOLABS.COM)



**Demographics:**

Privately held company based in Lincoln, NE

**Activities:**

- Conduct research and development on biological products for animal health (85% of business) and human health (15% of business) companies worldwide.
- Functional areas:
  - Bench science
  - Clinical science
  - Regulatory assistance
  - Product licensing plans
  - Manufacturing
  - Quality Assurance
  - Quality Control
  - Novel testing
  - Reference requalification
  - Delivery systems
  - Adjuvant technology
  - Financial Modeling
  - Business Development
  - More...
- Clients Include:
  - Leading multinational pharmaceutical companies
  - Start-up companies
  - Government entities
  - More...
- Projects include:
  - Injectable vaccines
  - Oral vaccines
  - Traditional vaccines
  - Biotech vaccines
  - DNA vaccines and gene delivery
  - Immunotherapeutics
  - Dermatologicals
  - Adjuvant technology
  - Unique platform support (adenovirus, insect cell, plant cell)
  - Current influenza antigens
  - Select agent
  - Probiotics
  - Nutraceuticals
  - Formulations
  - More...

**Results:**

- Have established at least one new licensed company/technology every 2 years for the past decade
- Licensed the world's first plant cell derived vaccine
- Licensed the world's first manufacturing plant for the production of plant cell derived vaccine (located in Lincoln, NE)
- Licensed the world's first oral delivery platform for fish
- Licensed the world's first in-vitro potency test for live parasites

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## **Benchmark Manufacturing Model**

Benchmark Biolabs (BBL) has developed a novel strategy for designing, constructing, licensing, and operating manufacturing establishments on behalf of our clients. This strategy enables our clients to take advantage of BBL expertise while being able to manage their costs and exposure when entering manufacturing under USDA regulation.

In addition to managing risk, the client gains the benefit of having ownership of the USDA license for both establishment and product.

Though there is flexibility in the model the following is a general guideline:

- BBL acquires a “shell” facility which it leases to the client
- Client funds construction and modifications (including utilities) to allow building to accommodate manufacture of the product(s)
- BBL personnel oversees and manages construction/remodeling including management of contractors, permits, etc
- Client purchases necessary manufacturing equipment
- BBL oversees acceptance and placement of equipment as well as any necessary or desired validation. BBL can assist as desired in identifying and locating equipment as well as assisting in negotiation with suppliers
- BBL oversees regulatory licensure of facility on behalf of client. BBL can communicate with regulators on behalf of client though client is required to name contact person who is a client employee.
- BBL prepares all documentation necessary for the transfer, production and record keeping of the product.
- BBL oversees transfer of materials to facility
- BBL provides all staff necessary for operation of facility—line manufacturing including fill/finish, regulatory, QA, administration, shipping/receiving, etc. BBL can do all activities other than sales and marketing.
- Client, at its sole discretion, retains right to acquire facility or utilize its own employees (as a component of the team or the entire team).
- In the event of transfer to client control, BBL can continue to conduct work on behalf of client to the degree that the client may desire.