

# Bio-Concept

Laboratories, Inc.



CUSTOMIZING OUR SERVICES  
**FOR YOUR VISION**

## Welcome To Bio-Concept Laboratories

We offer a full range of formulation development, microbiology, analytical chemistry, process development, stability programs and aseptic clinical manufacturing in ophthalmic plastic bottles and parenteral serum glass vials.



## Ophthalmics

Bio-Concept Laboratories, Inc. is an FDA registered Contract Research Organization (CRO) and Contract Manufacturing Organization (CMO). Bio-Concept is also EU compliant. We offer a full range of product development services from pre-formulation through aseptic manufacturing and stability. Our clients are Biotechnology, Pharmaceutical and Ophthalmic companies at all stages of development from start-up to companies to industry leaders.

Our expertise in the development of ophthalmic formulations allows Bio-Concept to anticipate and address challenges that are unique to ophthalmic products. We offer specialized insight into preservative systems, ingredients, buffers, other excipients, aqueous solutions, emulsions and suspensions.

## Our Process

- Product Development
- Formulation Technology
- Microbiology
- Analytical Chemistry
- Aseptic Fills
- Stability
- Pre-Clinical Testing
- Process Research

## Liquid Injectables

Bio-Concept has over 20 years experience with injectables from small molecules to larger polymers and proteins. Our customized development process and hand-fill manufacturing promotes conservation of API during the early stage of development.



# About Bio-Concept

## About Bio-Concept Laboratories

**At Bio-Concept, we have the years of practical experience and expertise to get your ophthalmic and injectable products to clinical trial quickly. The staff at Bio-Concept has extensive expertise in formulation technology, microbiology, analytical chemistry, aseptic fills, product development, stability, process research, pilot scale-up, and manufacture.**

## Overview

### About Bio-Concept:

We offer a full range of formulation development, microbiology, analytical chemistry, process development, stability programs and aseptic clinical manufacturing Phase I-III in ophthalmic plastic bottles and parenteral serum glass vials. Our recent expansion into a 30,000 square foot facility in Salem, NH positions Bio-Concept for continued growth as we expand our services to address the needs of a diverse and growing client base with low volume commercial manufacturing.

### Experience, and Expertise:

At Bio-Concept, we have over 20 years of practical experience to get your product to clinical trial quickly. and we have particular experience with ophthalmics and injectables. The staff at Bio-Concept has extensive expertise in; formulation technology, microbiology, analytical chemistry, aseptic fills, product development, stability, process research, pilot scale-up, manufacture, and formulation science. Contact us today and see how we can help your company effectively expand its product base and realize your new product visions.

### Contact Us:

If you have questions about how Bio-Concept can help you, please contact us. Contact us today, and a program specialist will contact you.

### Headquarters:

Bio-Concept Laboratories, Inc.  
13 Industrial Way  
Salem, NH 03079  
info@BioConcept.com  
603-437-4990 x2001

# Bio-Concept

Laboratories, Inc.

## Our Services



### About Our Services

#### About Our Services:

Bio-Concept has an integrated product development program designed to bring your new product to market efficiently and effectively. The status, strategy and assumptions are routinely reviewed with the client and modified as appropriate. Each project is assigned a project coordinator to give you and your project the personal attention that both deserve.

#### Always Thinking Ahead:

Our experience allows us to identify, early on, the most challenging items that could potentially affect the success of the project. We also assess the validity of our approach. In this way, we can predict and overcome possible delays while minimizing your costs. Our product development process is divided into various overlapping stages.

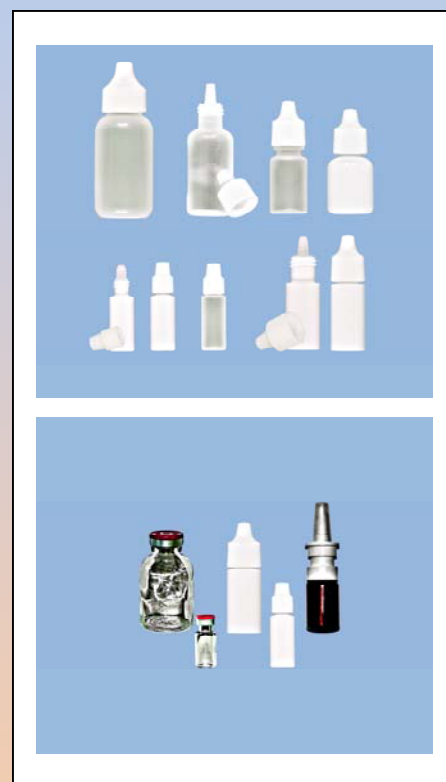
### Our Services

#### Ophthalmics:

Our expertise in the development of ophthalmic formulations allows Bio-Concept to anticipate and address challenges that are unique to ophthalmic products. We offer specialized insight into preservative systems, ingredients, buffers and other excipients. Aqueous solutions, emulsions, suspensions and gels are formulated and filled into plastic bottles with a dropper tip and cap. Our flexible hand-fill process allows us to customize manufacturing requirements to address a variety of fill volumes and container options.

#### Liquid Injectables:

Bio-Concept has over 20 years of experience with injectables from small molecules to larger polymers and proteins. Our customized development process and hand-fill manufacturing promotes conservation of API during the early stages of development. Parenterals are filled in small glass vials with rubber closures and aluminum crimp seals.



**Bio-Concept Laboratories, Inc**

13 Industrial Way

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President and CEO

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# Bio-Concept

Laboratories, Inc.

**Contract Manufacturing  
and Development**

## Demonstrated Expertise in Product Development and Manufacturing of:

- Ophthalmic products
- Injectables
- Nasal Spray
- Ear Drops

**FDA and EU Compliant  
Over 20 Years Experience  
New CRO & CMO Facility**

### Drug Discovery/ Feasibility

- API Selection and Pre-screening
- Assay Development
- Assay Qualification Type I
- API Solubility
- Comfort
- Preliminary Formulation

### Preclinical

- Formulation Optimization
- Assay Qualification Type II
- Process Development
- Preclinical/Toxicology Batches
- Stability Study
- Microbiology Testing

### Clinical

- Assay Qualification Type III
- Phase I through Phase III
- Aseptic and Non-aseptic Fill-Finish
- Stability Study
- ICH Study

### Commercial

- Small Volume Manufacturing
- FDA Registration Batches
- Early FDA Submission



**An Industry Leader in  
Quality, Delivery and Price**

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President and CEO Francis X. Smith

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