

**BioVolutions is a Contract Research Organization servicing clients whose interests range from preformulation to GMP supplies. BioVolutions' mission is to save time and money required to obtain tox supplies and clinical trial material.**

**BioVolutions was founded in November 2007 by Maurizio Cattaneo, PhD** to offer services originating from his many years of expertise in formulation development, drug delivery and analytical development. Dr. Cattaneo obtained his PhD at McGill University under the direction of **Dr. Thomas W Chang, the pioneer of microencapsulation for medical applications**. Dr. Cattaneo contribution to bioanalytical development centered on the development of new analytical assays based on amperometry and chemiluminescence.

## Value Proposition

BioVolutions is one single service provider that built a specific expertise and capabilities to develop a compelling offering by optimizing time and costs to obtain Clinical Trial Material (CTM). **BioVolutions is the ideal partner to outsource formulation developments by reducing costs, accelerating product development and complementing customers' expertise**. BioVolutions has the experience and expertise for successful technology transfer in the context of GMP. BioVolutions is responsible for releasing or rejecting each batch of Clinical Trial Material based on a cumulative review of completed manufacturing records and other relevant information.

## Why BioVolutions ?

You are a **drug discovery company** and you need to accelerate your go-to-market as well as minimizing the risks and costs associated to the formulation. Reduction of time-to-market is a critical success factor, since delays in product introduction of only a few months may translate to tens of millions of dollars in lost revenue. Minimizing time to market means minimizing false starts and excessive trial-and-error experiments in developing optimum formulation and processing conditions.

You are **pharmaceutical company** with first in class product and you need to protect your market share against generic product or competition by creating a new product via reformulation of your current drug product. Or you need to improve the efficiency of your product to acquire new market share by becoming first in class. Drug Delivery technologies are the least expensive and most reliable way to diversify a product by expanding market penetration capabilities.

You are **dermatology or cosmetic company** and have a challenging API in terms of solubility or skin permeability as determined by Preformulation studies. The BioVolutions' team has over a decade of experience in formulation development of challenging topical formulations. Our topical expertise covers both standard topical formulations such as creams and gels as well as liposomal and nanoparticulate formulations that can target specific skin components such as hair follicles.

## Case Studies

**Ask about our case studies to understand how BioVolutions had a dramatic impact on the product development life cycle of its customer.**



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## Offering

BioVolutions offers a complete range of product development services, analytical services and in-vitro assays.

Offering	Services	Comment
Product Development	Concept	Review of historical data, freedom to operate and conduct theoretical optimization.  Generate several bench prototypes.
	Qualification	Qualify active ingredients (e.g. solubility, particle size, etc.)  Characterize equipment (e.g. mixers, heaters , etc.)
	Formulation	Perform formulation development work under GLP (CFR 21 part 58) and GMP (CFR 21 part 211).  Manufacture laboratory pilot batches.
	Packaging	Qualify suitable packaging and closure.
Analytical Services	HPLC Testing	A type of column chromatography used to identify, quantify and separate chemical compounds.
	Particle Size Analysis	An automated laser diffraction analysis instrument used for measuring the size of particles in low-turbidity media (emulsions, suspensions and powders).
	Drug Dissolution/In Vitro Release	An automated dissolution test for measuring the release of the drug substance from the drug product.
In-Vitro Assays	Skin Absorption OECD428	In Vitro permeability and toxicity across human skin is measured to estimate the absorption of a test substance into human skin.
	Caco-2 Cell Intestinal Absorption	In vitro permeability and toxicity of a test substance across differentiated monolayers of CaCO-2 cells is measured to estimate human intestinal permeability.
	Ocular Absorption	This human tissue model is useful in determining permeability and irritation/inflammation of a test substance.

## Research and Development

After 10 years of research on liposomal delivery the existing solutions are still lacking product performance. Current delivery systems present a number of disadvantages such as poor specificity, high toxicity, poor stability and non-biodegradability. **BioVolutions is developing a liposomal delivery system for the targeted delivery of therapeutic agents. This novel approach may help customers achieve a higher therapeutic index.** BioVolutions targeted delivery system, **NTrap™**, provides a unique capability for efficiently and specifically delivering therapeutic agents to refractory tumors.

**NTrap™** is based on our US Patent Application No. 12/259,148 and is now undergoing review by the United States Patent And TradeMark Office. The Patent application is available under a CDA.