



## REGULATORY COMPLIANCE

Biogenero Labs has made a commitment to provide world class ingredients with global regulatory compliance. To augment our expertise and reputation as a leading supplier and developer of high end dietary ingredients and provide comprehensive world wide regulatory support services we draw upon labs, clinicals and scientific data collection centers of excellence.

Our regulatory expertise includes reputed professionals and scientists who have extensive experience in dealing with **U.S, EU, Canadian, Japanese and Australian regulations.**

Our experts provide a wide range of regulatory consulting support for developing and implementing worldwide regulatory compliance strategies for new and existing Dietary Ingredients/Supplements, Natural Cosmetic Ingredients, Functional foods and Nutraceuticals.

Our regulatory and technical professionals are ready to meet and satisfy your regulatory requirements. Testing, if required, is carried out at our laboratories, conforming to international regulatory standards.

Our Services Target	Key Areas of Expertise
Dietary Ingredients	Common Technical Document (CTD)
Dietary Supplements	New Dietary Ingredient (NDI)
Natural Health Products	Standardized Information on Dietary Ingredients (Botanical and non-botanical)
Complementary Medicine	Natural Health Product Dossier
Functional foods	Proprietary Ingredient application (PI)
Food Supplements	Nutritional Analysis (Nutritional Labeling Education Act of 1990)
Novel food	
Cosmetics	

The services are based on extensive global regulatory knowledge and decades of practical experience in dealing with wide range of international regulations.

If you are looking to develop formulations and use ingredients with a pedigree you should talk to us. Don't risk to be found on the other side of the regulatory compliance law.

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## PRE-CLINICAL STUDIES

Biogenero's strategic alliance with reputed pre-clinical laboratories is the reason we are able to provide an entire range of animal studies in the area of toxicology and pharmacology. Our range of studies include Pharmacokinetics, Efficacy Studies and Toxicological studies. The type of compounds tested are Dietary Ingredients / Supplements, Pharmaceuticals, Biologicals / Biomarkers and Agrochemicals. We adhere to guidelines prescribed by ICH, OECD, EPA, IP, BP, USP and Schedule Y to name a few.

### Services offered

#### Drug metabolism and Pharmacokinetic (DMPK)

- Studies in rats and mice
- Single Dose pk
- Dose proportionality studies
- Absolute Bioavailability
- Multiple Dose Pharmacokinetics
- Multiple route of administration: Intravenous, oral, subcutaneous, intramuscular, intraperitoneal and dermal
- Tissue distribution

#### Efficacy models

- Acute efficacy screening models
- Chronic efficacy screening models
- Development of new animal models
- Diabetes models,
- Obesity models
- Acute Eye irritation
- Ocular Toxicity
- Acute Dermal irritation or corrosion
- Skin sensitization or corrosion
- Carcinogenicity
- Reproductive toxicity - Segement I, II, III & Multi-Generation
- Developmental toxicity
- Dermal toxicity
- Genetic toxicity - AMES, Micronucleus & CAT
- Ecotoxicity
- Teratology studies

**We don't test our ingredients on animals for cosmetic purposes.**

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## FORMULATION DEVELOPMENT (Dietary Supplements)

The natural products industry and dietary supplements in particular pose unusual challenges when it comes to formulating a finished product. To accomplish a finished product in solid dose or aqueous base one needs to start from choosing the right type and grade of ingredient. Biogenero's scientific staff are masters in putting such hard to make formulations together. We provide expert guidance on formulation development and can even provide pilot batches for approval. This is especially useful at the initial stages of launch of your product when volumes could be negligible for you to reach out to a large scale contract manufacturer.

Our organization provides major outsourcing solutions through broad and integrated portfolio of services for new supplements identification and development of formulations with R&D process, providing cost effective solutions.

We offer excellent quality products at highly affordable prices and offer the following facilities under one roof:

- Tablets
- Capsules
- Oral Dry Powders
- Syrups & Liquid Orals
- Nutraceutical & Herbal preparations

We strive to meet your most stringent Quality and Statutory requirements and norms. Our Quality Policy is implemented by maintaining a Quality Management System that consistently meets the regulatory requirements to ensure the best Product Quality as per GMP Standards.

Biogenero's focus is to provide the best quality products to satisfy its clients needs and help them to make big brands by choosing us as their backbone support system. Our network design helps to get the best Man, Material & Services to meet all your formulation needs.

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