

## REGULATORY COMPLIANCE

Biogenero Labs has made a commitment to provide world class ingredients with gobal regulartory 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 excellent.

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 |
| Complementary Medicine  | (Botanical and non-botanical)                   |
| Functional foods        | Natural Health Product Dossier                  |
| Food Supplements        | Proprietary Ingredient application (PI)         |
| Novel food              | Nutritional Analysis (Nutrutional Labeling      |
| Cosmetics               | Education Act of 1990)                          |

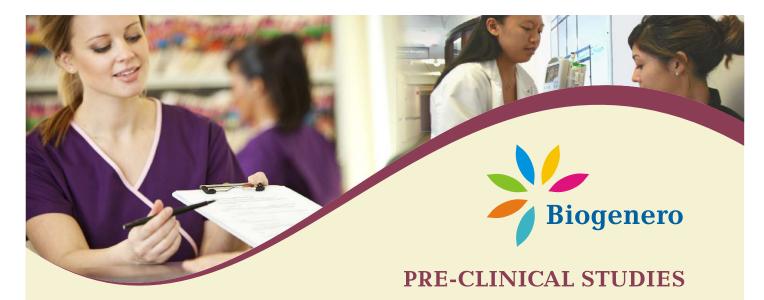
The services are based on extensive global regulatory knowledge and decades of practical experience in dealing with wide range of international regulations.

If you are looking to develop formuations and use ingredients with a pedigree you should talk to us. Dont risk to be found on the other side of the regulatory compliance law.

\* DISCLAIMER

\*\*OISCLAIMER\*\*
NOTHING IN THIS PUBLICATION MUST BE CONSTRUED AS A REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, OF FITNESS OF A PARTICULAR SOLUTION FOR A PARTICULAR PURPOSE. Any data or results given are based on controlled or laboratory work and must be confirmed by the Buyer by testing under its own conditions. Under no circumstances will Biogenero Labs be liable for any damages arising from reliance on the statements contained herein which are intended for general guidance only.

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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
- Absoulte 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
- Diabetis 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.



# 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 ingredinent. Biogenero's scientifc 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 negligeable 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 maintaning 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 it's 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.