Dietary Supplements and Functional Foods

Supplements and functional foods are the fastest growing segment of the health products industry. Product Safety Labs (PSL) has been conducting the safety, efficacy and bioavailability studies needed to establish product success for the food and pharmaceutical industries for over 40 years and has been recognized in the CRO Quality Awards for 2014. PSL is a leading provider of toxicology, pharmacology and analytical services to the Food industry. PSL is GLP compliant, AAALAC accredited, offering the latest in scientific techniques and instrumentation.

Food Ingredient and Dietary Supplement Testing
Since 1972, PSL has been conducting toxicology studies on dietary supplement and food ingredients in accordance with national and international regulatory guidelines and GLP standards. Over this time, PSL has developed an outstanding reputation for quality, responsiveness and value. Studies are designed for NDI/GRAS notification submission to FDA, EFSA and other worldwide guidelines and include a successful record of publication in peer-reviewed journals. PSL’s services include:

General Toxicology
- Single and repeat dose studies in rodents (including 90-Day Subchronic Studies)
- Routes of exposure include oral and dietary administration
- Neurotoxicity assessments, including functional observation battery (FOB) and motor activity (MA)
- Immunotoxicology assessments
- Pathology peer reviews

Developmental and Reproductive Toxicology
- Range finding and definitive fertility studies
- Range finding and definitive teratology studies

Genotoxicity
- In vitro gene mutation (Ames) testing
- In vitro tests
  - Micronucleus Assay
  - Chromosome aberration
  - Mouse Lymphoma Assay
- In vivo tests
  - Micronucleus Assay
  - Chromosome aberration
  - Pig-a assay

*Additional testing available
In addition, PSL conducts the Protein Efficiency Ratio (PER) and the Protein Digestibility Corrected Amino Acid Score (PDCAAS) tests to support the growing need for in-vivo substantiation of protein quality for both internal client use and marketing purposes. Each study can be tailored to include specific dietary requirements (e.g. high lactose, low fat, high fiber), and PSL has experience working with a variety of food products ranging from powdered infant formulas to packaged microwaveable meals.

**Analytical Services**

Product Safety Labs (PSL) is a leading GLP laboratory for analytical services tailored to the identification and concentration of a wide range of food ingredients including active components of a natural product. At PSL we pride ourselves on using the most sophisticated technology, such as the HPLC, GC, MS, LC/MS, LC/UV, ELISA and ICP. The majority of the studies we conduct fall into the following categories:

- Formulation characterization
- Analytical support for GLP toxicology including; method development, dose analysis, homogeneity and stability
- Bioanalysis including toxicokinetics
- Custom analytical protocols also available

**Pharmacology**

Product Safety Labs (PSL) is a recognized world leader in pharmacology testing with experience conducting studies for determination of absorption and product comparison to market formulations. PSL also has extensive experience in conducting calcium, iron bioavailability studies and radionuclide exposure. Study designs include, but are not limited to, pharmacokinetic profiling, screening, bioavailability, tissue collection and metabolite collection/identification. PSL specializes in development of custom proof-of-concept protocols using applicable animal models for effective definition of clinical study parameters.

**Therapeutic Areas**

<table>
<thead>
<tr>
<th>Cardiovascular</th>
<th>Cardiac Profiling (ECG, Blood Pressure, Arterial gases), Heart Failure, Hypertension, Atherosclerosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal</td>
<td>IBD, Eating disorders, Diarrhea, Abdominal pain and Irritable bowel syndrome</td>
</tr>
<tr>
<td>Inflammation</td>
<td>Arthritis, Wound Healing</td>
</tr>
<tr>
<td>Metabolic Diseases</td>
<td>Dislypidemia, Diabetes; Obesity, Metabolic Syndrome</td>
</tr>
<tr>
<td>Central Nervous System</td>
<td>Pain (Acute, Visceral, Post-Surgical, Neuropathic, Inflammatory), Parkinsonism</td>
</tr>
</tbody>
</table>

**Clinical Trials**

PSL and Eurofins Optimed also provide more than 200 human clinical trials in the field of nutrition with experience in a wide range of areas. Our specialized services have the expert supervision of medical and scientific staff for nutritional monitoring and regulatory control of health claims and aim to fulfill your expectations by obtaining the evidence required to highlight the benefits of your products and their effects on health, respecting your timelines and adding value.

Call one of our experts at Product Safety Labs to help you design a study to meet your objectives.

**Product Safety Labs…Superior Service, Reliability and Results.**