

Product Safety Labs

over 40 years of service



Medical Device

The biological evaluation of medical devices is an important step in development. With over 40 years of experience, Product Safety Labs (PSL) is able to offer a comprehensive list of supporting tests. Whether your need is biocompatibility testing according to ISO 10993 or microbiological testing within development, production and finished product testing, we will support you with individual testing strategies and study designs to fulfill your needs. In addition, we offer chemical characterization of materials for extractables and leachables according to ISO 10993-18.

Our Services for Medical Device Testing Include:

- Biological Safety Testing including Biocompatibility Tests
- Microbiological Safety Testing
- Physicochemical Evaluation
- Extractable and Leachable Testing

Biocompatibility Testing

PSL offers biological studies according to the matrix of ISO 10993-1 and can also create individual customized testing strategies. Evaluation depends on the category of the medical device in accordance with the nature of the devices' use pattern and the duration of contact. We offer biocompatibility tests that fall within the following categories:

- Cytotoxicity
- Irritation
- Toxicity
- Genetic Toxicology
- Hemocompatibility
- Functional Implantation
- Local Tolerance

Extractable and Leachable Testing

As part of the evaluation of medical devices, it is important to assess the potential for various chemicals to migrate from the container, container closure system or other materials used for a device. We have experience detecting the full range of leachable substances of concern. No matter what the geometry, material or consistency of your medical device, PSL can assist in assuring that your product will be in full compliance with ISO 10993-18.

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Toxicology

As a leader in toxicology research and testing, PSL has provided over 40 years of services to the industry. We partner with our clients to provide data to support a variety of needs, including product discovery and development, pre-clinical safety

evaluations, product registration, product stewardship, regulatory compliance and risk assessment.

Since 1972, PSL has developed an outstanding reputation for providing excellent service and superior value. Our scientific data is of the highest quality and our reports enjoy a distinguished acceptance record with the regulatory agencies, facilitating product registration and approval. We serve a broad range of clients from global Fortune 500 enterprises to small start-up companies, in the U.S. and abroad. PSL is AAALAC accredited, GLP compliant and USDA registered. Our record of regulatory facility and data audits is outstanding.

PSL conducts toxicology studies in accordance with national and international regulatory guidelines and GLP standards. PSL also has a staff of experts with extensive experience designing customized studies to meet the specific needs of our clients. These include non-GLP screening studies which can be utilized to cost-effectively evaluate prototypes.



Analytical Chemistry

PSL has been one of the leading laboratories for analytical chemistry testing services in the industry. At PSL we pride ourselves on using some of the most sophisticated instrumentation, such as the HPLC, GC, MS, and ICP. We also have a highly experienced staff including several Ph. D. –

level chemists. PSL offers a wide variety of analytical test services to address all of your specific objectives. The vast majority of PSL's analytical studies are conducted in full compliance with U.S. and international GLP standards. Non-GLP services are also available upon request.

Genetic Toxicology

PSL also provides the full range of GLP genetic toxicology studies conducted in accordance with GLP standards and regulatory guidelines (FDA, EPA, OECD, ICH). Studies are regularly conducted on pharmaceuticals, chemicals, dietary ingredients and pesticides. Based upon many years of experience, we can advise you on the most suitable protocols to meet your regulatory needs.

Our Services Include:

- 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

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.

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