PBL Pacific BioLabs
The Service Leader in Bioscience Testing

GLP/GMP Drug Development and Device CRO

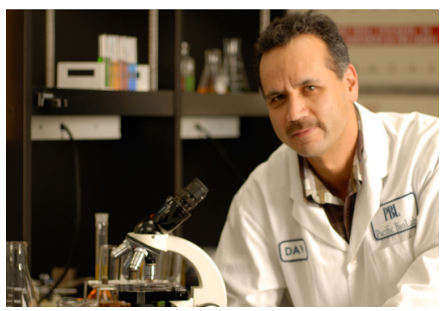
Since 1982, Pacific BioLabs has provided biological and analytical testing designed to support both growing and established medical device, pharmaceutical, and biotech companies.

Our aim is to provide our clients with a combination of expertise, rigor in our quality systems, and personalized attention that is unique among CROs.

Services and Capabilities

Pacific BioLabs provides services that support a number of key areas in life sciences product development and manufacturing.

- Medical Device Biocompatibility and Material Characterization
- Sterility, Sterilization Validations, and Device Re-use Studies
- Pharmaceutical PK, ADME, and Bioanalysis
- GLP Preclinical Toxicology
- Microbiology and Environmental Monitoring
- GMP Lot Release Testing
- Stability Studies
- Analytical Chemistry



Facility and Location

Pacific BioLabs is housed in a 32,000 square foot facility in Hercules, CA. This state-of-the-art laboratory/vivarium allows us to offer top quality testing services to our clients throughout the world.

Commissioned in 2000, all major building systems and equipment have been validated to cGMP and GLP standards. A generator supplies back-up electrical service for all critical utilities and equipment. A Rees monitoring system provides 24-hour alerts of any deviations, outages, or other problems.

PBL is FDA registered and ISO 9001:2008 and ISO 13485:2003 certified by Intertek.
Our animal science operations are accredited by AAALAC.

For more information about Pacific BioLabs services, please contact us or visit our website.

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www.PacificBioLabs.com
551 Linus Pauling Dr, Hercules, CA

PBL

TESTING SERVICES

Pharmaceutical and Biologic Development Support

- *In Vivo* Toxicology (GLP / non-GLP)
- Pharmacokinetics / Toxicokinetics
- Radiolabeled ADME (C-14, Tritium)
- Cytotoxicity
- Immunogenicity
- Biosimilars
- Stability Studies

Pharmaceutical and Biologic QC and Microbiology

- *In Vivo* Potency Bioassays
- Safety Tests (CFR/USP/JP)
- Microbial Limits
- AET / Time Kill Analysis
- Sterility Testing
- LAL / Pyrogen Testing
- Bacterial Identification
- Environmental Monitoring

Analytical Chemistry and Bioanalytical Services

- Method Development and Validation
- Characterization of New Chemical Entities
- Biomarker Discovery and Analysis
- Karl Fischer Water Analysis
- PK Bioanalysis
- ICP-MS Metals and Elemental Analysis
- GC, GC/MS, LC/MS/MS, HPLC, ICP-MS

Medical Device and Delivery Device Development and Manufacturing Support

- Biocompatibility / Material Characterization
- Extractables and Leachables
- Reusable Device Studies
- USP Class Plastics
- Shelf-Life / Accelerated Aging
- LAL / Bacterial Endotoxins / Pyrogens
- Sterility Testing
- Sterilization Validations

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