PACIFIC BIOLABS

The Service Leader in Life Science 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 several key areas in life sciences product development and manufacturing.

- Medical Device Biocompatibility and Material Characterization
- Sterility, Sterilization Validations, and Reusable Device Studies
- Pharmaceutical PK, ADME, and Bioanalysis
- GLP Preclinical Toxicology
- Microbiology and Environmental Monitoring
- GMP Lot Release Testing
- Stability Studies
- Drug/Device Combination Studies
- Analytical Chemistry
- *In Vitro*/Cell-Based Assays
  - Cellular Toxicity Assays
  - Transient Transfection/Reporter Assays
  - Proliferation Assays
  - *Ex Vivo* Hemolysis Assays

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.

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.

Vaisala monitoring system provides 24-hour alerts of any deviations, outages, or other problems.

- FDA registered and ISO/IEC 17025:2017 accredited by ANAB
- Animal science operations accredited by AAALAC

For more information about Pacific BioLabs services, please visit us at PacificBioLabs.com

PACIFIC BIOLABS

The Service Leader in Life Science Testing

TESTING SERVICES

PHARMACEUTICAL AND BIOPHARMA DEVELOPMENT SUPPORT

- *In Vivo* Toxicology (GLP/non-GLP)
- *In Vitro*/Cell-Based Assays
- Pharmacokinetics/Toxicokinetics
- Cytotoxicity
- Immunogenicity
- Biosimilars
- Stability Studies

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

PHARMACEUTICAL AND BIOPHARMA QC AND MICROBIOLOGY

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

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

PACIFIC BIOLABS
551 Linus Pauling Dr
Hercules, CA 94547

PacificBioLabs.com
510.964.9000
info@pacificbiolabs.com