

## Medicilon Non-clinical Toxicology Studies Services (GLP and non-GLP)

Medicilon offers comprehensive toxicology study services designed to assess the safety profile and potential risks of pharmaceutical compounds. Our expert team collaborates closely with clients to tailor studies according to regulatory requirements and project-specific needs.

Our state-of-the-art facilities, advanced platform, experienced scientists, and commitment to quality ensure that clients receive high quality, reliable, and regulatory-compliant GLP toxicology data to support the development of safe and effective pharmaceutical products.

**As of the end of 2025, Medicilon has proudly served over 2000 clients worldwide, contributing to the successful approval of 651 IND applications, demonstrating our commitment to providing high-quality services and supporting the global advancement of pharmaceutical development.**

### Species:



NPH



Dog



Rabbit



Rodent



Mini-Pig

### Toxicology studies scope

#### Non-GLP & GLP Toxicology Studies



- Single/multiple dose
- Reproductive toxicity
- Genotoxicity
- Toxicokinetics
- Safety pharmacology
- Immunogenicity
- Local toxicity
- Carcinogenicity

## Histopathology

- Single/multiple dose
- Carcinogenicity
- Irritation study on blood vessel, muscle and eyes
- Pharmacodynamics
- Reproduction Toxicity
- Tissue cross reaction

## Clinical Pathology

- Blood biochemistry, hematology, coagulation, & urine analysis
- Bone marrow smear reading
- Lymphocyte
- *In vitro* hemolysis

## Bioanalysis services for small molecules

Our bioanalysis services for small molecules, including peptide and oligonucleotide, support every phase of drug development from discovery to market. With over 20 years of regulatory experience and most advanced technologies and strategies, we deliver precise, on-time and high-quality data for PK, TK, PD, biodistribution, and biomarker assays. We specialize in developing and validating robust bioanalytical methods for the quantification of API and metabolites in various biological matrices, using LC-MS/MS with HPLC, UPLC etc.

## Bioanalysis services for large molecules

Our bioanalytical lab specializes in large molecule bioanalysis, offering comprehensive services including PK, TK, immunogenicity testing, and biomarker discovery. We have developed and validated 500+ bioanalytical methods for macromolecules including protein, antibody, ADC, peptide, CAR-T, CAR-NK, Lytic virus, etc. We also provide customized bioanalytical solutions, developing and validating unique methods to address specific large molecule research challenges.

## SEND Data Submission

Medicilon's preclinical pharmacology and toxicology unit features a professional SEND format conversion team and a fully developed SEND data conversion platform (submit™ platform) encompassing software, technology, specifications, and quality control. This ensures accurate data conversion and facilitates seamless electronic data submission to the FDA.



### MEDICILON

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