Clinical Pathology and Biomarkers

Sequani is a UK based CRO with its heritage dating back over 40 years. We are positioned at the forefront of pharmaceutical and biotechnology product developments and chemical safety testing. We thrive upon joining our clients upon their mission to achieve high quality data derived by undertaking each project to the highest regulatory standard. Our flexibility, adaptability, strategic programme management and scientific rigour guarantees our customer satisfaction.

Bursting with experience, excellence and expertise, we take pride in offering superior value for money, greater flexibility and speed of response- turning data into decisions and defining the way forward.

INSTRUMENTATION

• ACL Elite Pro • Advia 120 Haematology Analyser • BD FACSVerse flow cytometer • Clinitek Advantus • DS2 platforms • Roche Modular EVO (P800) Clinical Chemistry Analyser • Siemens Immulite 1000 immunoassay automated analyser • Spectra Max Plus

Led and staffed by highly experienced scientists, our specialist clinical pathology team is adept in the routine assays required to support our toxicology studies and also in development and implementation of novel and less routinely used assays and biomarkers. Our depth of scientific understanding allows for expert interpretation of findings and recommendations for follow-up evaluations.

Our laboratory is equipped with all the necessary instrumentation and autoanalysers required to support regulatory toxicology studies of all types, specifically designed to analyse blood, plasma, serum and urine samples from different species used in non-clinical studies.

Parameters routinely measured include but are not limited to:

CLINICAL CHEMISTRY

• Albumin • ALT • ALP • AST • Bicarbonate • Bilirubin • Calcium • Chloride • Cholesterol • Creatinine • Creatine kinase • GGT • Glucose • LDL/HDL Cholesterol • Phosphate • Potassium • Sodium • Total Protein • Triglycerides • Troponins • Urea

HAEMATOLOGY AND COAGULATION

• APTT • Cell morphology • Fibrinogen • Hb • Lymphocyte subsets • MCH • MCHC • MCV • PCV • Platelets • Prothrombin time • RBC • RDW • Reticulocytes • WBC • White cell differentials

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sequani NON CLINICAL
great people, great work, real results

Clinical Pathology and Biomarkers

There are many different ways in which analysis of specific biomarkers for toxicity and/or efficacy can add value to a non-clinical development programme. Biomarker analysis can also aid in safety assessment of chemicals and crop-protection products.

Sequani's experienced biomarker scientists are able to offer specialist advice to assist our clients in identifying suitable biomarkers or panels of biomarkers and developing and validating the methodology for analysis.

We offer a bespoke service, designed in conjunction with our clients, to form an integral part of a non-clinical de-risking strategy. Our biomarkers team is able to cover a wide range of target systems including, but by no means limited to:

- Bone • Cardiac • CNS • Endocrine Disruption • Hepatic • Immunophenotyping • Inflammation • Ocular
- Oxidative Stress • Renal • Reproductive Hormones • Vascular

PLATFORMS

Extensive technical expertise enables the application of multiplex platforms and other techniques to the development of biomarkers for use in non-clinical species. Technologies include:

- ELISA techniques, including robotically assisted platforms • Flow cytometry • Immunohistochemistry
- Siemens Immulite automated Immunoassays

DEVELOPMENT STRATEGY

The inclusion of biomarkers in a non-clinical development programme must also take account of the practical and scientific implications of collecting additional samples during the course of a study that may be submitted for regulatory review. Our scientific and technical specialists work closely with the biomarker group to ensure the design of scientifically sound, technically feasible and, where appropriate, regulatory compliant studies. Sequani can also work with you to develop programme specific assays utilising any of the above platforms.

STEP WISE APPROACH

Proposals to include novel biomarkers in a programme will normally involve a step-wise approach to the evaluation of potential methodology. Typically, this would involve:

- An initial evaluation to establish the feasibility of applying a commercially available assay to a non-clinical programme
- Application of the assay to the serial analysis of multiple samples collected over the course of a non-clinical study
- "Fit-for-purpose" validation, conducted to establish satisfactory performance during repeated use of the assay, prior to its introduction into a research setting
- GLP-compliant validation

ADDING BIOMARKERS TO YOUR STUDY

Whilst it is possible to add biomarker analysis to a study currently running or in the later stages of planning, we encourage our clients to speak with us as early as possible for the best and most comprehensive study design.

Sequani can offer bespoke packages at competitive prices to suit your needs.
For further information, please contact: **business.development@sequani.com**

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