charles river

SAFETY ASSESSMENT

# Safety Assessment

Charles River is committed to providing exactly what clients need with flexible solutions, accelerated timelines and people who care about making a difference. With continual improvement of our global research processes, exceptionally high standards for our scientific teams, and our state-of-the-art facilities, we're focused on expediting preclinical drug development. Our global network of facilities in Mainland Europe, the United Kingdom, Canada and the United States allows us to provide preclinical testing capabilities with a local touch.

Charles River scientific and regulatory staff work with clients to develop and execute individual studies or customized testing programs to ensure that safety and efficacy assessments are conducted in the most efficient manner. This allows us to consistently meet or exceed worldwide regulatory standards for quality and compliance, and to continually expand the company's scope and range of preclinical services to address the ever-changing demands of the industry and our clients.

### Areas of expertise:

- Toxicology
- Laboratory Sciences
- Genetic Toxicology
- Safety Pharmacology
- Pathology
- Environmental Impact Assessment of Human Pharmaceuticals
- Drug Metabolism & Pharmacokinetics
- Consulting Services

### Toxicology

For more than 40 years, our exceptional global team of scientists, have designed and performed safety programs ranging from acute through chronic toxicity and carcinogenicity studies. We offer a broad range of *in vitro* models as well as animal models and supports all the standard routes of administration, including infusion and inhalation toxicology. In addition, we lead the industry in the field of *in vitro* and *in vivo* specialty toxicological assessments for neurotoxicology, developmental, reproductive and juvenile toxicology, bone, ocular and cellular therapy research, immunotoxicology and phototoxicology.

EVERY STEP OF THE WAY

## Laboratory Sciences

Over the years, Charles River has made significant investments in highly-trained scientific, technical and support staff, excellent facilities and state-of-the-art instrumentation. Our Laboratory Sciences offerings include bioanalysis, immunology, immunogenicity, biomarkers, molecular biology, as well as formulations development, in-life study formulation support and analytical chemistry.

## Genetic Toxicology

For more than 30 years, Charles River has been helping clients to develop custom testing strategies and conduct appropriate assays to meet the unique requirements of their chemicals and drugs. Our ongoing involvement with regulatory working groups and international societies ensures that our clients have access to the latest developments in science and its and applications in the regulatory environment.

## Safety Pharmacology

Our safety pharmacology program can help further drug development by investigating the potential undesirable effects of a compound on physiological functions in relation to exposure in the therapeutic range and above. We provide a comprehensive, global, harmonized program to meet the ICH S7A core battery and supplementary safety tests that may be needed based on early observations or concerns. We offer ICH S7B tests, including hERG and related early safety screening.

## Pathology

A comprehensive assessment of pathologic changes is critical in the evaluation of toxicology and research studies, as well as for animal colony maintenance. As a world leader and the largest provider of contract toxicologic, clinical and specialty pathology services (e.g., musculoskeletal, neuropathology, ocular pathology, ultrastructural pathology, and image analysis), we have the resources and expertise to fully support the research and development needs of our clients.

## Environmental Impact Assessment of Human Pharmaceuticals

With extensive experience in the conduct of studies to assess the environmental impact of test articles, Charles River offers a full portfolio of services to support the Environmental Risk Assessment (ERA) requirement of a Marketing Authorisation Application (MAA). Our expert staff have a complete understanding of both European and North American legislation and have the breadth and depth of knowledge to guide clients through the regulatory maze. Our dedicated environmental testing facility provides modern, flexible laboratories that can accommodate all possible test scenarios. Services include physicochemical testing as well as a full portfolio of environmental fate and ecotoxicology studies.

## Drug Metabolism & Pharmacokinetics

Routine and specialized *in vitro* and *in vivo* metabolism and pharmacokinetic services are available for complete characterization of the absorption, distribution, metabolism and excretion (ADME) of test articles in rodent and nonrodent species. These include tissue distribution (tissue dissection or QWBA), micro-autoradiography, excretion/mass balance, absorption and bioavailability. We can also perform metabolite profiling and identification, protein binding, bioanalysis, radioanalysis, dosimetry and PK/TK studies.

## Consulting Services

Charles River has a team of scientific and regulatory advisors around the world with years of experience in the discovery and development of new chemical entities, biological products and medical devices. Acting as consultants, program manager, and outsourced program directors, our experts use their specialized knowledge to direct well-designed safety and efficacy programs that are fully compliant with international regulatory guidelines.

charles river

**askcharlesriver@criver.com • www.criver.com**