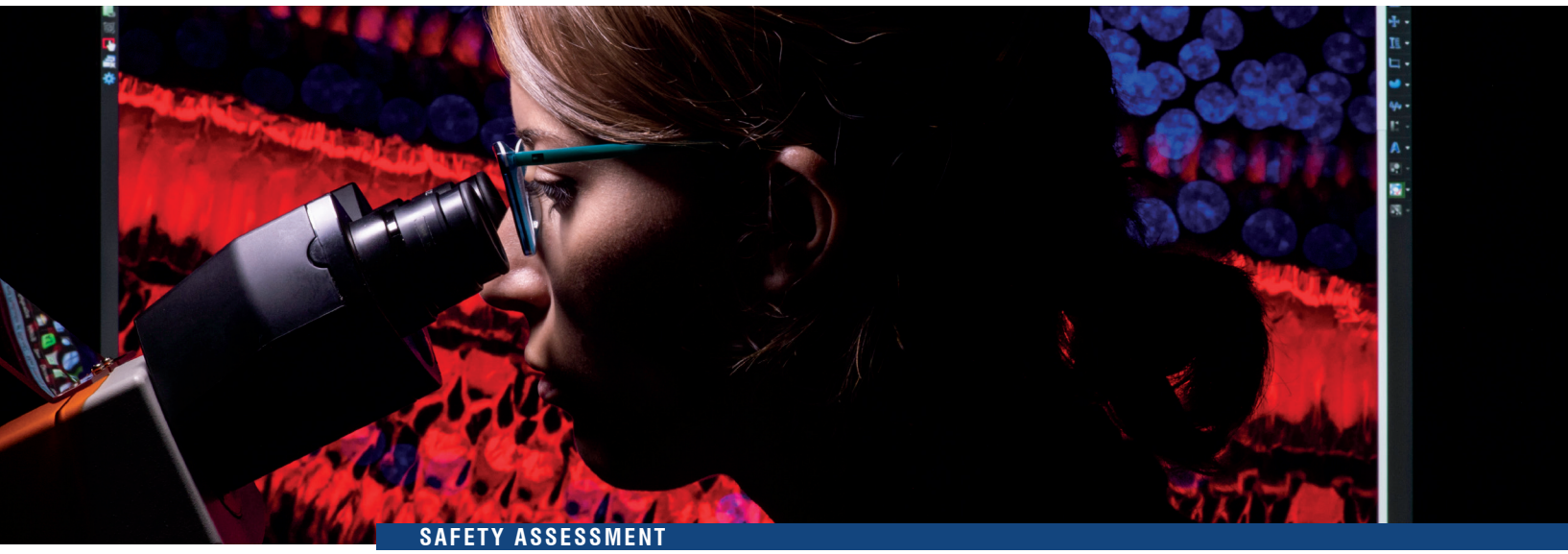
charles river



SAFETY ASSESSMENT

Safety Assessment

Click here to start your Safety Assessment program.

Charles River is committed to providing exactly what clients need with flexible solutions, accelerated timelines, and people who care about making a difference. From complete registration programs to stand-alone studies, our Safety Assessment team provides a full range of *in vivo* and *in vitro* testing services and regulatory support to comply with worldwide regulatory requirements for the nonclinical development of pharmaceuticals, medical devices and animal health products as well as chemicals, agrochemicals, and biocides. Our 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. 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 development. We have a large portfolio of laboratory sciences services in support of our pharmaceutical, agrochemical and chemical safety testing. 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.

Areas of expertise:

- Toxicology
- Safety Pharmacology
- Environmental Impact Assessment of Human Pharmaceuticals
- Genetic Toxicology
- Pathology
- Scientific Advisory Services
- SEND
- IND-enabling Programs
- Regulatory Advisory Services
- Laboratory Sciences

EVERY STEP OF THE WAY

Click here to start your Safety Assessment program.

Toxicology

For more than 40 years, our exceptional global team of scientists, including board-certified toxicologists and veterinary pathologists, veterinary surgeons, regulatory specialists, and support personnel 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 support all the standard routes of administration, including infusion and inhalation toxicology. Our team leads 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.

Laboratory Sciences

Over the years, our focus has always been to consistently deliver quality data for clients to make well informed decisions. Significant investments in highly-trained scientific and technical staff, plus state-of-the-art instrumentation combined with strong regulatory knowledge enables us to rapidly produce reliable data for many types of analyses using networked, validated data management systems. Quality laboratory data is vital to your discovery, nonclinical and clinical programs and as you advance your molecule through the drug development process we are there to develop the most relevant, efficient and accurate methods to support your program. We offer a full range of advanced testing including formulation and product chemistry, bioanalysis, immunology testing, biomarker testing, molecular biology and DMPK ADME studies.

Genetic Toxicology

Genetic toxicology testing is required for all classes of chemicals and drugs, but its conduct can differ from compound to compound to account for regulatory requirements and choice and design of assays. Our Genetic Toxicology team works to conduct studies assessing the potential for genetic mutations or chromosomal damage. We can run the appropriate assays to meet the unique requirements of your specific chemicals or drugs. Determination genotoxicity is essential to completing the safety assessment for new products (e.g., pharmaceutical ingredients and impurities, unique human metabolites, industrial chemicals, agrochemicals, cosmetics, etc.).

We work closely with other Safety Assessment groups to improve study results and integrity with supplementary services, such as formulation and analytical chemistry, pathology, and bioanalysis. We can also support studies by evaluating genetic toxicology biomarkers and determining mechanism of action (MOA) identification via in situ hybridization, flow cytometry, and determining apoptosis, if applicable.

Safety Pharmacology

Safety pharmacology furthers drug development by investigating the potential undesirable effects of a compound on physiological functions in relation to exposure in the therapeutic range and above. Charles River provides 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, including ICH S7B tests, hERG, and related early safety screening. This comprehensive approach combines safety pharmacology endpoints within repeat dose toxicology studies and integrates assays *in vitro* through *in vivo* for cardiovascular, respiratory, and central nervous system assessments. Our multidisciplinary scientific expertise allows for real time communication throughout various points in your safety pharmacology evaluations to bridge *in vitro* and *in vivo* studies and ultimately meet your timelines and regulatory requirements.

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Pathology

Our senior veterinary pathologists have actively participated in formal quality assessment and peer review programs since 1982. With over 170 pathologists, Charles River's Pathology laboratory employs the largest assembly of pathologists in the contract research industry, offering multidisciplinary expertise for all types of drugs, biologics, chemicals, and devices. We perform a wide array of routine and specialized pathology services either in support of *in vivo* studies performed at our sites or as a standalone pathology service. Our anatomic and clinical pathologists are recognized experts in toxicologic pathology, from investigative to regulatory studies for pharma, agrochemical and animal health, carcinogenesis research and testing, and diagnostic pathology. Learn more about our digital primary and peer review capabilities and how they enable you to interact virtually with our team, and consultant pathologists.

Environmental and Ecotoxicology

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 registration requirements of industrial chemicals, agrochemicals, biocides, cosmetics, personal care and household product ingredients as well as the Environmental Risk Assessment (ERA) needs of both human and veterinary pharmaceuticals. Our expert staff have a complete understanding of both European and North American regulatory requirements, and have the breadth and depth of knowledge to guide clients through the regulatory maze. Our dedicated environmental testing facilities provide modern, flexible laboratories that can accommodate all possible test scenarios. Services include physiochemical testing, as well as a full portfolio of environmental fate, terrestrial and aquatic ecotoxicology studies. Charles River also offers a comprehensive portfolio of endocrine disruptor studies and consultancy, combining excellent project communication and support from our dedicated team of experts.

Scientific Advisory Services

Charles River has built a unique team of Scientific Advisors whose expertise spans various therapeutics areas and stages in the drug development process. The mission of the Scientific Advisory Service (SAS) team is to guide clients, every step of the way. With decades of industry experience and proven abilities to navigate the complex and changing regulatory landscape, the SAS team can design and manage lean and robust preclinical programs. The team provides flexible, responsive, and personalized support, and each client's project is managed with the same dedication and attention as if it were our own. With access to the industry's most comprehensive portfolio – from early discovery to market support – our team is uniquely qualified to map your journey through drug development.

Regulatory Advisory Services

Our Regulatory Advisory Services (RAS) team will strategize, guide, and support your journey to a sustainable state of compliance and ensure you successfully meet business objectives and global regulatory and compliance requirements.

Our regulatory consulting team can help you keep track of the ever-changing regulations in various regions of the world, provide advice on legal requirements, develop a regulatory strategy for your product's lifecycle, help interface with the relevant regulatory agencies, and assist in the preparation of required registration documents for market approval. Our experts have experience in the pharmaceutical, biotech, food, dietary supplement, and medical device industries throughout all stages of the product lifecycle.

Data & SEND

SEND is an implementation of the CDISC Study Data Tabulation Model (SDTM) that provides a framework for the standardized, electronic representation of individual animal study data. SEND is intended to increase the effectiveness and efficiency of data review for regulatory submissions. Biotechnology and Pharmaceutical partners are responsible for providing the FDA with respective SEND datasets in accordance with the guidelines. Charles River SEND experts have experience working with all report types, even if reports come from other vendors. It is important to understand if your vendor is SEND compliant and can provide the necessary datasets for submission.

Please contact us for any of your Safety Assessment needs or to discuss your program with our advisors.

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