Accelerating progress in chemical safety testing with the latest animal-free science

CellR8 is a GLP accredited laboratory located at Sci-Tech Daresbury in Cheshire. Established in 2008, our mission is to accelerate the world's transition to 100% animal-free testing, through our scientifically advanced and ethical approach. We provide in *vitro* safety and efficacy tests for global cosmetics brands, chemical companies and ingredient manufacturers.

The replacement of animal testing isn't only an ethical issue, but very much a scientific one. By using the latest cell culture and tissue engineering technologies, we are creating test models with much higher relevance to humans in everyday use scenarios. Along with peers across the global scientific community, we're playing our part in bringing product safety testing up to date, while creating future-fit scientific careers here in the northwest. Our work was recently featured on the BBC series <u>Inside The Factory</u>, where we explained how we use our animal-free tests to provide safety data to cosmetics company, Lush.

Our latest ground-breaking acute toxicity research

Over the last few years, one of our key research areas has been acute toxicity - the adverse effects caused by shortterm chemical exposure by mouth, inhalation, or dermal absorption. Acute toxicity data is commonly required for regulatory submissions, and it's currently the only human health endpoint in REACH Annex VII with no validated nonanimal approach. As many cosmetic ingredients are imported into the EU at 1-10 tonnes per year, they fall into Annex VII, and a requirement to generate test data presents regulatory and ethical conflicts around animal testing. Across all sectors combined, more than 80,000 animals are used every year in acute toxicity testing in the EU alone, and millions worldwide. For almost 100 years, acute toxicity has been tested using "LD50" type animal tests - identifying the dose that's lethal to 50% of the animals - even though the methods have been widely discredited, both ethically and scientifically.

However, more robust and human-relevant science is on its way. Regulators - including ECHA in Europe and the EPA and NTP in the US - encourage the use of in vitro methods, combined with computer modelling *(in silico)*, as a first step which can sometimes avoid the requirement to do an animal test. Previously, there was no validated in *vitro* test with human relevance. With funding from Innovate UK and Animal Aid, we developed **"AcutoX"**, a human cell-based screen that predicts oral acute toxicity. The test uses a fully human test system, incorporates metabolism, and has been validated by XCelIR8 using 68 cross-sector chemicals. The resulting prediction model can classify chemicals in a binary fashion (toxic / non-toxic) as well as designating toxic class for both GHS and EPA classification systems. We launched the test at the Society of Toxicology (SOT) conference last year and our peer-reviewed paper will be published soon in the ALTEX journal. It's already being used by some leading companies, and crucially, regulators are interested in incorporating the test into their recommended programmes.

While we're thrilled with the progress being achieved through AcutoX, we're only at the tip of the iceberg, and our talented scientific team are moving on to next steps. We're now expanding our work to make AcutoX relevant to a much wider range of chemicals used across a variety of industries, from cosmetics and household cleaning products to automotive, aerospace, agriculture and healthcare. The next steps will massively increase the impact of the test and add further weight to our conversations with global companies and regulators. More companies will start using AcutoX instead of animals, with an immediate and direct impact on replacing animal testing with up-to-date, human-relevant science.

We are currently crowdfunding to raise £100,000 to enable this crucial work to continue and are looking for corporate sponsors to help keep up the momentum for this globally impactful work. Find out more <u>here</u>.

We'd love to hear from companies who are interested in using AcutoX or becoming a corporate sponsor for our animal-free testing and research.

For further details please contact info@x-cellr8.com / 01925 607 134.

Dr Carol Treasure Founder and CEO, XCellR8

Background Image - human fibroblasts used in the AcuTox test

