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LimboTox™: A cornea in a culture dish, as an animal-free engineered solution for industrial and pre-clinical toxicity testing [Abstract]

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12) LimboTox™: A Cornea In A Culture Dish, As An Animal-Free Engineered Solution For Industrial And Pre-clinical Toxicity Testing

S.L. Wilson

Academic Ophthalmology, Division of Neuroscience, University of Nottingham, Queen's Medical Centre Campus, NG7 2UH, Samantha.wilson@nottingham.ac.uk

LimboTox™ is a pipeline technology currently under development at the University of Nottingham, working in partnership with Aeon Astron Europe (<http://www.aeonastron.com/>). The intention is to bring together innovative cellular and biomaterial technologies to develop a biomimetic human cornea, as a realistic platform for toxicology and pharmacology purposes. This venture has recently been supported by a University of Nottingham Hermes innovation grant.

Changing European directives and a global drive to limit the use of animals for toxicology testing has created a crucial need for reliable *in vitro* corneal alternatives. To date, due to the complexity of the tissue, there is no such realistic and validated substitute, thus creating a unique commercial and economic opportunity.

Once complete, Limbotox™ will provide a reliable, animal-free biomimetic cornea, available for toxicology testing purposes, for use by toxicology testing facilities and academic research institutions. It is expected to be capable of providing superior, quantifiable data, in comparison to existing *in vivo* and *ex vivo* animal testing protocols. Limbotox™ will be developed as a standardised, *in vitro* manufactured, multicellular, cornea-mimetic collagen construct. The gross morphology and histology will be similar to that of a complete natural cornea, resulting in similar gene expression wound healing responses when compared to *in vivo* human responses.

Since Limbotox™ will contain both human epithelial and stromal cells it has greater potential when compared to existing corneal epithelial toxicity models at distinguishing and classifying a wide spectrum of ocular irritants, ranging from non-irritating to severely irritating. Limbotox™ will also facilitate a broad range of toxicology testing capabilities, including multiple endpoints, concentrations, exposure methods *etc.* whilst allowing for reproducible and quantifiable data to be generated. It is also envisioned that Limbotox™ will allow for a mechanistic understanding of drug and chemical induced toxicity at a molecular level for use as part of an intelligent tiered-testing strategy, which incorporates scientifically-based decision triggers, to supply sufficient data to support regulatory decisions.