Q&A SESSION WITH KEITH FOSTER

KEITH FOSTER, Chief Scientific Officer, **Sutura Therapeutics** *and* Associate Professor in Translational Medicine, **University of Reading**

Keith is a translational biologist with 23 years' experience in developing gene, cell and pharmaceutical medicines for Duchenne muscular dystrophy (DMD) and metabolic diseases. He currently runs a state of the art research lab at the University of Reading that is able to facilitate medicine development and subsequent analyses in pre-clinical disease models.

Keith is the inventor of technologies to enhance the in vivo delivery of antisense oligonucleotide gene medicines; the technology can be applied to target any gene in any human tissue. The technology belongs to Sutura Therapeutics, with whom Keith acts the Chief Scientific Officer. Sutura Therapeutics' lead pipeline targets muscle and heart tissue.

What are the most exciting therapeutic developments in 2018/2019?

I think the most exciting development recently is, on one level, just the volume of studies coming through the clinics and arriving at market approval. Of particular interest is within the realms of antisense oligonucleotides because they have an ability to target any gene in your genome, and infectious genomes as well. I think as these new pipeline begin to emerge, it will have huge societal impacts.

What are going to be the crucial strategies in gene therapy development?

I think the most crucial strategies that we need for many gene medicines is the way that we effectively deliver cargo to the affected tissues, as many clinical trials fail because of toxicities associated with the medicine. I think with effective delivery strategies we'll be able to alter the 'cost vs benefit' ratio in favour of better therapeutic outcomes.

What do you think the key priorities are going to be in manufacturing?

The key priorities for manufacturers is perhaps standardizing the resource materials and how we can actually have reference-basing on where this material comes from which will generate cleaner data and lead to quicker pipeline developments, e.g. standardisation of viral vectors production and titres would be desirable. Because, between studies there is a lot of variability generated due to manufacturing standards that reduces the power of the studies.

What are the most important technologies impacting the cell and gene therapy landscape over the next five years?

So the most important technologies that will impact on the gene therapy market over the next five years, I still think are going to be effective delivery strategies because we know now what our genes of interest are, and now need to ensure effective delivery whether the gene medicine is delivered by a viral or non-viral delivery method. I think therapies to re-administer viruses or strategies to effectively deliver antisense cargoes or other gene medicine cargoes are actually going to be the most critical developments.

What will the regulatory landscape look like over the next five years?

I think the regulatory landscape will continue to evolve, particularly within the areas of rare disease. There have been great strides taken by the regulators, to help partner academics, startups and Big Pharma in how to evolve the clinical trial designs. I think there'll be more adaptive protocols for clinical translation programs where flexibilities can be used as the programs progress through the clinical trial. Rare disease is where I think we're going to have the biggest evolution.