

Nexus SME Toolbox

Commercialising Regenerative Medicine

Speaker Biography

Mike Leek, Lab2Launch

Described by Prof. Chris Mason and Dr Stephen Minger (of the London Regenerative Medicine Network) as a 'true pioneer in the field of Regenerative Medicine', Michael was closely involved in establishing Smith and Nephew's joint venture with Advanced Tissue Sciences (1994) which resulted in one of the first commercially available cell therapeutic products – DermaGraft.

He was also jointly responsible for moving Intercytex from a pre-clinical research company to an AIM-listed biotech with several cell therapy products in the clinic.

- Michael has extensive experience spanning many areas of regenerative medicine, including: Translation of stem cell therapies from bench to bedside
- Design, build, commission and management of an FDA/EMEA licensed GMP production facility.
- Provision of logistic and supply solutions related to distribution of cell therapy product for a multinational phase III clinical trial.
- Management of CRO's to drive forward clinical trials of cell therapy products.
- Quality management and regulatory affairs related to autologous and allogeneic cell therapies.
- Business planning - worked directly with venture capitalists to secure funding in excess of £17m.
- Intellectual property management - obtained exclusive licenses to patents generated by Japan Science and Technology – this was the first time JST had granted a 12 year exclusive license to a non-Japanese company.
- Commercial negotiation - Secured an agreement with a leading hair transplant chain, providing them with an exclusive option to distribute cell therapeutic products for hair regeneration

Michael is also principle inventor of Vavelta – a novel facial rejuvenation product designed to enhance the skin's collagen support matrix, thus enabling the appearance of facial wrinkles and folds to be improved.

In 2006 Michael was involved in a BIA cross-industry working-party, providing input into the EU Advanced Therapy Directive which was implemented early 2009.