



“A key challenge is to establish how standards can accelerate innovation and increase the likelihood of advancement in synthetic biology and cell therapies”

## How we're developing biological manufacturing standards and supporting the UK's position as a world leader in synthetic biology and cell therapies

We are ideally placed to bring together innovation networks of stakeholders that are seeking to improve the quality and productivity of biological manufacturing processes.

Our work in this field includes developing a synthetic biology standards strategy and delivery plan, as well as seeking input from stakeholders to achieve consensus on the right way forward for cell therapy standardization.

Synthetic biology refers to the design and construction of biological parts, devices and systems. Cell therapies/regenerative medicine means replacing or regenerating human cells, tissues or organs to restore or establish normal function. A key challenge is to establish how standards can encourage innovation and advancement in both.

### Synthetic biology

In partnership with the Technology Strategy Board (TSB), we've been working with SynBiCite to develop a strategy for standards in synthetic biology to help create a digital biomanufacturing industry and to accelerate the rate of commercial success using the technology.

Based at Imperial College London and funded by the Engineering and Physical Sciences Research Council, Biotechnology and Biological Sciences Research Council and the TSB, SynBiCite is a new Innovation and Knowledge Centre created to improve the UK's ability to translate the emerging field of synthetic biology into application and provide a bridge between academia and industry.

The centre will become a national resource and involve researchers from 17 other UK universities and academic institutions, as well as 13 industrial partners, including the research arms of Microsoft, Shell and GlaxoSmithKline.

Standards developed in this area could play a key role in enabling various organizations to work in partnership, as well as ensure interoperability between synthetic biology technologies that are developed. Our strategy development work will enable the synthetic biology community in the UK to maintain its competitive edge by leading the development of international standards.

### Cell therapies

In recent years we've also been working with the UK research base, academia, regulatory bodies and other public and private sector organizations to better understand the challenges faced by those involved in cell therapies/regenerative medicine.

We've long been committed to finding ways to support UK stakeholders by providing guidance documents, codes of practice and formal standards. Examples include PAS 84:2012, developed to encourage use of common terms and definitions within regenerative medicine.

More recently, we've been working with the Cell Therapy Catapult, a London-based centre of excellence for regenerative medicine that was established by the TSB in 2012. It was created to build the UK's position as a global leader in the development, delivery and commercialization of cell therapies.

### Eight Great Technologies

Our unique capabilities for convening leading innovators, capturing best practice and making this available more widely will enable industry in the UK to innovate quicker. The Minister for Universities and Science, David Willetts, has identified synthetic biology and cell therapies/regenerative medicine as one of the "Eight Great Technologies" the UK needs to prioritize and in which the government is to invest more than £600m.

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