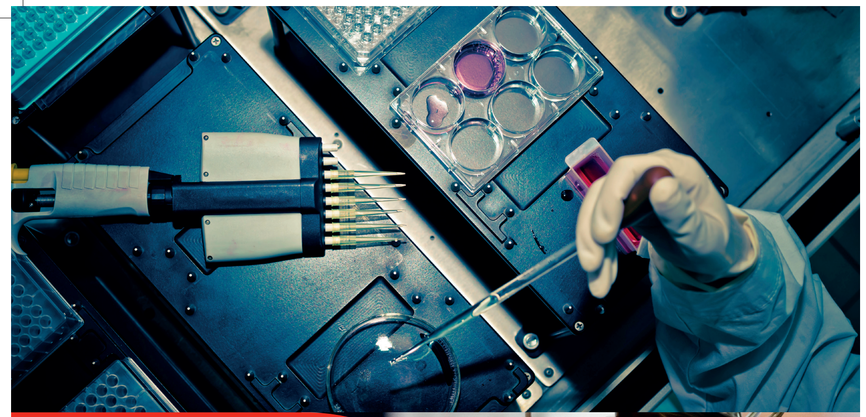

In any new technology there are uncertainties, and it is inevitable that there will be pressure for government to intervene at some point in future

Recommendations

It would be fair to say the primary objective of the project is to enable computer aided design, manufacture, and verification using digital biological information.

- BSI should work with UK synthetic biology stakeholders and develop an insight into where framework standards would be critical in establishing UK leadership in the principles and expectations of the industry.
- BSI should lead the creation of an international Synthetic Biology Standards hub, a collaboration of all the leading industrial and academic innovators in synthetic biology, with the intention of creating a broad consensus in priority areas.
- BSI should develop guidance on a systematic approach to the development of manufacturing processes that use digital biological information. This would enable organizations looking to develop commercial processes to achieve their goals using digital biological information more quickly than would otherwise be the case.

As new standards emerge and the industry evolves, the design guide would need to be updated periodically.

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By Royal Charter

UK Superbrands 2015

Executive Summary

The ascent of digital biomanufacturing

creating a new manufacturing industry through the development of synthetic biology standards

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Innovate UK – the new name for the Technology Strategy Board – is the UK's innovation agency. Our aim is simple – to accelerate economic growth by stimulating and supporting business-led innovation. For more information about Innovate UK please see: www.innovateuk.gov.uk or contact: support@innovateuk.gov.uk.

Timely, consensus-based use of standards plays a vital role in ensuring that the knowledge created in the UK's research base is commercialized and brought to market as well as playing an important role in driving innovation. Innovate UK is working with BSI, Research Councils and Catapults to establish new standards earlier in the development of new technologies and services.

We are collaborating in four emerging areas to define standards that will accelerate the development of those technologies and services; and provide UK businesses with a competitive "first mover advantage":

- Synthetic biology
- Cell therapies
- Assisted living
- Offshore renewable energy

The four technologies are at different stages of development and face different challenges in their commercialization. All four technologies are internationally competitive areas, and it is important that the UK creates successful capabilities quickly.

BSI is the UK National Standards Body, and is responsible for developing British Standards and related publications that serve the interest of a wide range of stakeholders, including Government, business and society. BSI represents the UK view on standards in Europe, and internationally (ISO and IEC), and has a globally recognized reputation for independence, integrity and innovation, ensuring standards are useful, relevant and authoritative.

Innovate UK
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Introduction

Synthetic biology has the potential to achieve great advances in terms of wealth creation and developing new products for new markets. For example, the biopharmaceuticals and industrial biotechnology markets are likely to benefit from the use of synthetic biology, with the main impact of the technology being felt through the creation of digital biomanufacturing industries, which will enable products to be brought to market more quickly and in greater number than before, thus bringing significant economic value to the UK. However, there are a number of challenges to the successful development and deployment of synthetic biology in the UK, including the poor data quality and lack of compatibility between data used and generated at the different production stages, designing extensible manufacturing processes and aligning the behaviour of market actors and traditions.

Synthetic biology contributing to wealth creation through manufacturing innovation

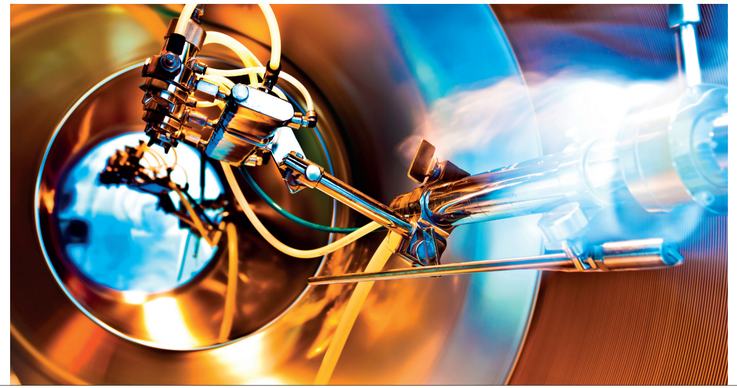
Just one example of the value of synthetic biology is the development of DNA synthesis and sequencing. Research shows the cost per base of DNA sequencing and synthesis is falling to a level where it will become routinely affordable. The developments in synthetic biology are driving towards increasing productivity of production processes, and adding value through greater outputs and lesser inputs, ensuring greater returns on R&D investment.

However, standardization efforts to increase the productivity of synthetic biology-inspired biomanufacturing processes will not guarantee success. There are uncertainties regarding the move from contained processes to non-contained ones and the associated risks and investments needing to be covered by the insurance and banking industries. Government legislation and regulation could guide the industry towards an outcome that is both economically successful and publicly acceptable.

Standards in synthetic biology

There are currently no formal standards specific to synthetic biology. However, there are many existing standards that are not specific to synthetic biology, but could be useful in some way, and a number of academic pioneers working in the field creating knowledge that could be turned into formal standards. There have already been a number of efforts internationally to start to address standardization in synthetic biology, and papers by Torrance & Kahl, and Kitney & Freemont describe these. The relevant existing standards can be broken down into the following categories.

Market Sector	Number of standards identified
Mathematics and Natural Sciences	870
Environment and Health Protection	8,863
Information Technology and Office Equipment	10,161
Food Technology	5,120
Chemical Technology	7,443
Petroleum and Related Technologies	1,708
Rubber & Plastics	5,302
Total	39,467



Conclusion

The evolution of the technology towards full automation through the development of standards is illustrated below.

The ascent of digital biomanufacturing – the evolution of synthetic biology through strategic development of standards 2014-2025.

	2014	2015-2017	2018-2020	2020-2025
	Generation 0	Generation 1	Generation 2	Generation 3
Automation	No automation other than robotically controlled individual machines			Fully automated processes on a global scale.
Repeatability	Not yet developed repeatable processes		Repeatable processes within a single machine.	Globally interoperable machines delivering repeatable processes.
Interoperability	Not yet achieved interoperability		Full global interoperability between all machines.	
Metrology	Understanding of biological systems not yet sufficient for development of industrial systems.	Consensus developed on what needs to be developed to enable repeatability.	Metrology to enable design verification of simulation modelling.	Metrology to enable feedback for machine learning.
Systems able to be digitally described	None	Genes	Genes and proteins	Genes, proteins and cells.
Standards required	Systematic design of manufacturing processes using digital biological engineering (0G).	Standards for: • Enabling flow of digital biological information between machines; • Digital description of genes; • Metrology for repeatable processes; • Systematic design guide (1G).	Standards for: • Digital description of proteins; • Metrology for verification of models; • Systematic design guide (2G).	Standards for: • Digital description of cells; • Systematic design guide (3G).
Framework standards	Framework standards to be developed in line with the consensus view of synthetic biology stakeholders.			

There are, as yet, no formal standards specific to synthetic biology

The standards that need to be developed to drive the industry towards full automation include:

- Standards that specify how digital biological information should be transferred between different machines;
- Standards that enable the digital description of genes, followed by standards that enable the digital description of proteins;
- A description of the consensus on measurement requirements for repeatable processes.