PRIME MINISTER'S COUNCIL FOR SCIENCE AND TECHNOLOGY

Engineering biology: opportunities for the UK economy and national goals

Summary

- Engineering biology describes the application of rigorous engineering principles to biology, enabling the construction of new or redesigned biological systems, such as cells or proteins, with applications across numerous sectors, including food, materials, and health.

- This transformative platform technology will provide innovative solutions across the economy. It offers more sustainable routes to existing products, as well as totally new bioproducts and processes with novel qualities and capabilities that will disrupt whole industry sectors. Engineering biology techniques allowed the rapid development of COVID-19 messenger RNA (mRNA) and viral vector vaccines.

- The UK's strong life sciences base, encompassing both health and non-health-related bioscience and biotechnology, offers a window of opportunity to establish technological leadership and capture economic and societal value from engineering biology. The UK is among the global leaders in engineering biology research, second only to the US in research investment and excellence[1].

- In the UK, engineering biology is approaching a tipping point in terms of commercialisation and the scale up of related technologies. Substantial scale up of existing infrastructure, skills and the availability of business finance will be needed to fully exploit the potential, focussed on building capacity at higher technology readiness levels. There is a pressing need for strategic investment to create a continuum of innovation facilities. This should build on early-stage support provided by UK biofoundries and provide support for commercial process development that is accessible to smaller companies.

- The UK's advanced position within this field is not guaranteed in the long term. Since 2016, the proportion of UK publication outputs on engineering biology has slowed, with decreases in average grant size. Other countries have invested heavily and are beginning to benefit economically and socially from innovations within the field. The US has pledged to spend $2 billion to launch the Biotechnology and Biomanufacturing Initiative[2].

- The challenge will be to rapidly strengthen and translate current research capabilities, help promising start-ups to grow, and scale up emerging applications into significant economic and social impact. The government should act now to accelerate the commercialisation of research within the field, or risk losing momentum and UK knowledge and talent to international competitors. The government has a critical role to help build business, investor, and consumer confidence.

[1] Royal Academy of Engineering. Engineering Biology: a priority for growth. 2019. https://raeng.org.uk/publications/reports/engineering-biology-a-priority-for-growth
[2] United States White House Briefing Room. The United States Announces New Investments and Resources to Advance President Biden's National Biotechnology and Biomanufacturing Initiative. 2022. https://www.whitehouse.gov/briefing-room/statements-releases/2022/09/14/fact-sheet-the-united-states-announces-new-investments-and-resources-to-advance-president-bidens-national-biotechnology-and-biomanufacturing-initiative/

- Government should communicate the level of UK ambition and match this with investment in national innovation programmes and infrastructure, create market incentives to pull through solutions for national goals, modernise regulatory frameworks and encourage standards for responsible innovation.

Scope of CST work:

1. To inform CST advice on engineering biology, we spoke with more than 40 experts from academia and industry to understand the opportunities and barriers to building UK capability, with a focus on what is needed to translate research into economic and social impact.

2. Our advice focuses on the following question:

   What action does government need to take to capitalise on the investment the UK has already made in engineering biology and to create a long-term, stable environment in which UK researchers, innovators and companies in engineering biology can establish and scale up their activity?

3. This advice aims to build on recent reviews such as the 'Building Back Better' report[3] from the Engineering Biology Leadership Council and the Royal Academy of Engineering's report: 'Engineering Biology: a priority for growth'.

4. The UK has a strong standing in life sciences and an internationally competitive research base. Urgent action would help harness this activity, establish technological leadership and promote engineering biology's full economic and societal potential for the UK.

5. We have considered where action is critical to sustain existing strengths and for the UK to be at the forefront of commercial developments in the future. We offer recommendations in three broad areas:

   a. Act now to build on and extend the UK's existing strengths in foundational capabilities;

   Recommendation one: The government should work with industry and public sector funders to establish centres for programming biology, forming a national institute working across disciplines to advance research within the field and accelerate its scaled up application.

   Recommendation two: The government should seek to become a world leader in measuring complex biological systems. The Department for Science, Innovation and Technology (DSIT) should convene the relevant national standards bodies to establish a bio-sector measurement standards and metrology board.

   b. Demonstrate leadership, define ambitions to signal direction and focus effort, and take strategic action:

   Recommendation three: DSIT should lead development of a cross-government engineering biology strategy to communicate government's vision and long-term

[3] UK Engineering Biology Leadership Council. Engineering Biology for the UK – A Resource to help Build Back Better. 2021. https://ktn-uk.org/wp-content/uploads/2021/07/EBLC-Building-back-better-with-Engineering-Biology_upload.pdf

ambitions for maintaining and extending UK capabilities, and harness engineering biology for solutions to the UK's national goals and challenges.

c. Lay the groundwork to support the scale up of engineering biology-based solutions and businesses;

Recommendation four: The government should work with industry and UKRI to establish multidisciplinary Biomanufacturing Innovation Centres, for testing, scale up, and commercialisation of non-health engineering biology applications, including materials and fuels. These integrated scale up hubs should be in locations with a relevant industry base, and link to universities with strong engineering biology capability and technical skills infrastructure.

Recommendation five: DSIT should work with policy teams across government and the engineering biology community to review the critical uncertainties around future demand for engineering biology, explore scenarios for future changes to UK supply chains, and identify policy and regulatory implications.

Recommendation six: DSIT and the Office for Science and Technology Strategy (OSTS) should work with the Regulatory Horizons Council (RHC) to establish a 'Regulatory Observatory', bringing together insights on engineering biology applications for regulators across sectors, and advising on improvements to support the sector and provide consumer engagement and reassurance.

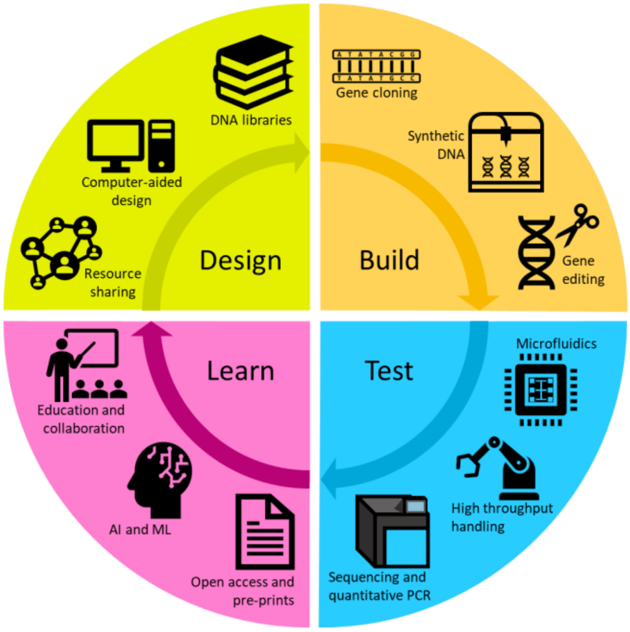
What is engineering biology and why is it transformational?

6. Engineering biology harnesses the capabilities of organisms, processes and mechanisms that exist in nature and combines this with advances in areas such as gene manipulation, processing power and machine learning. It can enable the development of breakthrough solutions to a wide range of complex problems across multiple industry sectors, contributing to more sustainable and resource-efficient solutions to the societal challenges faced in food, chemicals, materials, water, energy, human and animal health and environmental protection. Examples include plastic-free packaging, improved fibres for sports clothing, new green fuels, and life-saving therapies, many of which use manufacturing by-products, renewable resources or generate less CO_2 compared to conventional manufacturing processes.

7. Engineering biology sits at the convergence of genomics, data science and other disciplines. Through the convergence of these disciplines and the emergence of more computing power, it is now possible for designers and engineers to use biological components as the building materials for new innovations, meaning biology can be designed. The deployment of gene-editing technologies, like CRISPR-Cas9, has generated scientific breakthroughs with the potential to completely reimagine manufacturing processes across multiple sectors, reducing the dependence on fossil fuels, simplifying supply chains, and the design of new product functionality.

8. Engineering biology applies principles from the iterative design-build-test-learn cycle (Table 1), in which learning from systems analyses is used to inform subsequent rounds of design. This cycle builds on capabilities across a wide range of disciplines such as automated analysis and metrology, artificial intelligence (AI), and machine learning (ML) and modelling.

Table 1: Examples of key capabilities underpinning engineering biology	
Design	Understanding biological systems, genetic sequencing, DNA/RNA/protein function, molecular structures/folding, data science including artificial intelligence
Build	DNA synthesis, gene editing, post-transcription modification, assembly and delivery systems, artificial cells
Test	High throughput robotics, automated systems, sensors and analytical chemistry, sequencing, quality control and metrology
Learn	Data collection and analysis, machine learning



9. It is important that UK companies have ready access to skills, equipment, and facilities across these foundational capabilities to enable them to harness the potential of engineering biology.

Engineering biology has significant economic potential.

10. Biological applications are estimated to unlock $2-4 trillion in annual direct global economic impact by 2030-2040[4]. The McKinsey Global Institute also recently assessed several end-use applications of engineering biology that could be commercialised in the next 10–20 years and has estimated that they could attribute a combined global economic impact of up to $4 trillion[5].

11. Though the potential for engineering biology in the health sector is currently well-recognised (for example in personalised medicine), the diverse range of applications which fall beyond health are likely to have a similar or even greater impact on society. By some estimates, as much as 60% of the physical inputs to the global economy could, in principle, be derived from biological systems and living factories. Whoever leads in this field will be at the forefront of transformational changes across society, with strategic advantage in matters of security, health and supply chains. Spillovers from a strong health sector may support non-health biotechnology, and vice versa, as many of the

[4] Department of Business, Energy and Industrial Strategy. UK Innovation Strategy: leading the future by creating it. 2021. https://www.gov.uk/government/publications/uk-innovation-strategy-leading-the-future-by-creating-it
[5] Mckinsey & Company. The Bio Revolution: Innovations transforming economies, societies, and our lives. 2020. https://www.mckinsey.com/industries/life-sciences/our-insights/the-bio-revolution-innovations-transforming-economies-societies-and-our-lives

foundational services, machinery, and equipment can be deployed for both health and non-health applications.

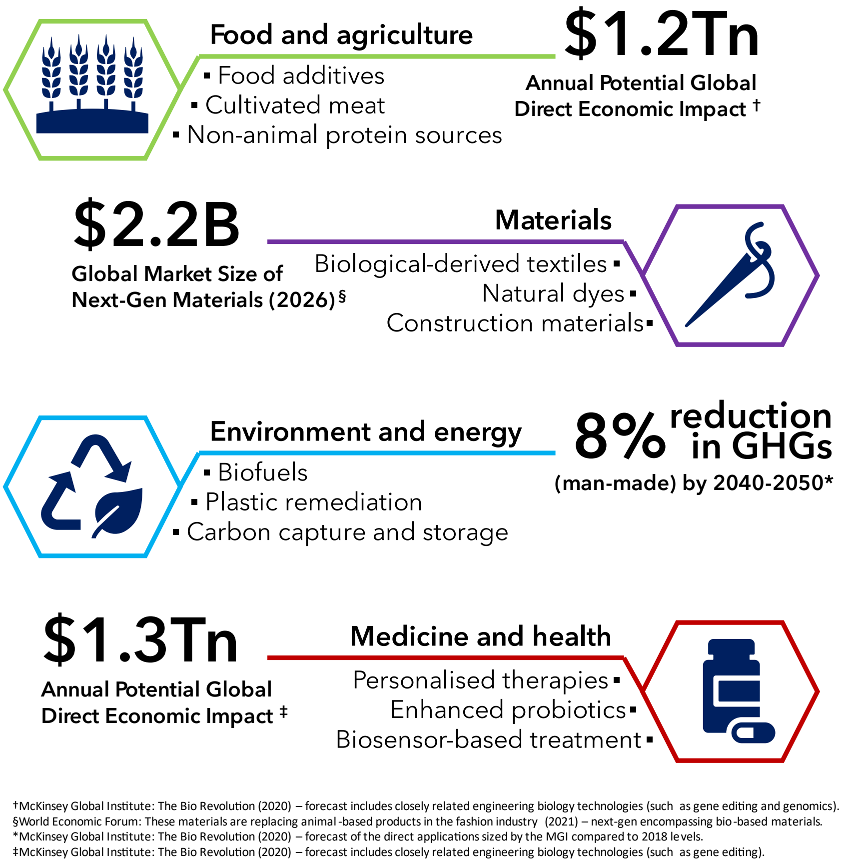


Figure 1: Example end-uses of engineering biology and their potential global economic and environmental impacts.

12. One major area of commercialisation is in modern industrial biotechnology (defined as non-health life sciences, including the bio-based manufacturing of chemicals, additives, and materials). In the UK there are over 1,800 businesses undertaking modern industrial biotechnology-related activity. These companies already employ 14,000 individuals, generate £3.7bn in revenue and contribute £1.2bn in gross value added[6].

13. The adoption of engineering biology across sectors can also help reach net zero[7]. By engineering the metabolic pathways of microbes and plants, renewable products and novel biomaterials can be generated from waste products or by utilising atmospheric carbon. This could be particularly impactful for the biofuels sector, as engineering biology provides a viable alternative to fossil fuels and could supplement or improve conventional renewable fuel production methods (see **Annex A**).

14. The introduction of novel materials has the potential to support a more sustainable future across a variety of industries, by reducing waste and CO_2 emissions associated with the life-cycle of their manufacture, as well as improving product functionality (see **Annex B**).

[6] Royal Academy of Engineering. Engineering Biology: a priority for growth. 2019. https://raeng.org.uk/publications/reports/engineering-biology-a-priority-for-growth
[7] Department for Energy Security and Net Zero and Department for Business, Energy & Industrial Strategy. Net Zero Strategy: Build Back Greener. 2021. https://www.gov.uk/government/publications/net-zero-strategy

15. Engineering biology is also important in the food sector. The metabolic re-engineering of microbes such as fungi and bacteria will enable precision fermentation, the production of novel food additives and other alternative proteins. Similar methods are also likely to play a key part in the maturation of the cultivated meat sector (**Annex C**).

16. Engineering biology is a platform technology which has the potential to expand into new areas beyond the current boundaries of the bioeconomy. For instance, DNA data storage creates innovative solutions to deal with the global increase in demand for storage solutions (**Annex D**).

The UK has a strong research base.

17. The UK's Synthetic Biology for Growth programme (SBfG) was established as part of the advice[8] from the Synthetic Biology Leadership Council (now the Engineering Biology Leadership Council). The programme represented £102 million of investment, to create six multidisciplinary research centres, foundries, and training programmes across the UK. This has helped enable the UK research base to support the production of over 9000 UK engineering biology research publications and over 23000 UK engineering biology patents (from 2010 – 2021)[9].

18. Engineering biology was identified in the government's 2023 Science and Technology Framework as one of the five critical technologies the UK should focus on to build strategic advantage[10]. UKRI is working closely with the Defence Science Technology Laboratory (Dstl) to establish a new National Engineering Biology Programme (NEBP) to build on existing foundations and to develop momentum and bridging capability.

Global sector comparisons

19. The UK is amongst the global leaders in engineering biology research, both in quantity, breadth of capabilities and quality, second only to the US in recorded grant research investment globally. The UK maintains a strong R&D base with six major research hubs in addition to the UK's National Industrial Translation Centre for Synthetic Biology (SynbiCITE). **Annex E** provides more detail on UK strengths in foundational capabilities for engineering biology.

20. Internationally, engineering biology companies are predominately based in the US, China, and Europe, with specialisations ranging from nucleic acid synthesis to the development of bio-inspired textile dyes (see Figure 2 for examples). However, countries such as Israel and Singapore, who have significant support, leadership, and investment from their respective governments, are also strong and successful hotspots of activity.

21. As one of the global leaders in engineering biology research and many of the underpinning fundamental research capabilities, additional sector-specific focus, direction, and commitment from government could be pivotal towards translating our national research strengths into mature and successful industrial applications, creating economic benefits over the coming years.

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[8] Innovate UK KTN. A Strategic Roadmap for Synthetic Biology in the UK. 2012. https://ktn-uk.org/perspectives/a-strategic-roadmap-for-synthetic-biology-in-the-uk-2012/
[9] GO-Science TSI Science Power Index. November 2022.
[10] UK government. UK Science and Technology Framework. 2023. https://www.gov.uk/government/publications/uk-science-and-technology-framework

Figure 2: Examples of the breadth of companies operating internationally in the engineering biology sector.

ISSUES AND RECOMMENDATIONS

Act now to build on and extend the UK's existing strengths in foundational capabilities

22. The National Engineering Biology Programme (NEBP), its predecessor programmes, and the broader public sector investment in life sciences have helped to ensure the UK's outstanding strength, breadth and depth in the capabilities that underpin engineering biology. The UK has many promising start-up companies applying engineering biology across a range of sectors beyond health, including in materials and manufacturing, transport, agri-food, environment, and waste.

23. To be competitive in this space, the UK will need to make sustained investment in developing the fundamental capabilities that underpin product design, and support commercial process development and deployment. It will become increasingly important to build international partnerships that support access to capabilities for mutual benefit. Support for development and implementation of engineering biology applications at scale should not be at the expense of fundamental research, but in addition to it.

Support a step change in UK capability development

24. The foundational capabilities underpinning engineering biology are still being developed and there is much we do not yet know. We do not yet know how to comprehensively write DNA sequences in order to predictably engineer biology beyond simple bacteria or yeasts. We need to learn how to rapidly build the DNA of organisms, and how to write DNA sequences that produce any desired function (reliable programmable design). Addressing these challenges will make biology truly engineerable, and thereby drive engineering biology innovation and company growth across many different sectors and applications.

25. The Human Genome Project was a publicly funded project to undertake the first full sequence of a human genome. With support from the Medical Research Council and the Wellcome Trust, it encouraged international cooperation in biological science and set standards in techniques and technologies across the globe which influenced future medical research.

26. Thirty years on, the UK has the opportunity to be at the heart of the next revolution, combining the development of DNA synthesis, DNA assembly and genome synthesis, with AI, to solve the problem of how to write DNA sequences for organisms and how to design molecules, assemblies, and organisms that do what we want, and what we expect them to do. This technological development has the potential for extensive industrial applications and economic growth.

Recommendation one: The government should work with industry and public sector funders to establish centres for programming biology, forming a national institute working across disciplines to advance research within the field and accelerate its scaled up application. These centres should nucleate into a national hub with the following functions:

a. a UK-based capacity for rapid and cost-effective DNA synthesis (see recommendation five);
b. scalable technologies for rapidly building DNA genomes across microbial factories, plants, and animals; and
c. knowledge and AI based solutions for predicting and discovering which DNA sequences make organisms with the desired properties.

27. This hub should be connected to spokes focussed on technology transfer, industrial use and company formation and growth. Feedback between users and the technology development hub will directly accelerate useful and focussed development of foundational advances and the cadre of skills needed to underpin this. This should build on the work of existing laboratories across the UK.

Build capability in standardisation and measurement of complex biological systems

28. Technological standards create a common framework for accelerated innovation and product commercialisation. Standardisation is an important mechanism for the successful integration of product and process development in biotechnology[11]:

    a. Improved standardisation in biometrology and data, and its subsequent adoption, can help to bring a community of innovators together, establish a common language, and foster collaboration. This will support innovation in foundational areas and the development of novel applications into industry scale processes and products.

    b. Standardisation and technical frameworks, combined with the ability to measure complex biological systems, will be essential for the assurance of commercial-scale engineering biology delivery systems and end uses, to be able to compare applications against existing solutions, fostering trust and driving up investment.

    c. Engagement in international standardisation can project UK thought leadership and protect the interests of British consumers and businesses.

29. To provide a strong framework for innovation, we suggest a focus on two major enabling areas:

    a. Biometrology: tools and methods for the physical and digital characterisation of biological processes and/or products, which would allow manufacturers to measure, compare and improve processes and products in a shared language as the industry scales up and diversifies. Consolidating metrological standards in engineering biology is a challenge, partly due to the technical complexity and diversity of bioprocesses and end products, and partly because entirely new biological/bio-inspired production methods are still being developed. Government should build on existing leadership and good practice from the LGC and the National Physical Laboratory.

    b. Data standards and sharing: for the formatting, language, and description of biological data, including the storage and management of this data. There is currently a lack of a standardised data format for engineering biology applications, which may eventually result in challenges as the sector begins to adopt AI and ML on a more significant scale. Standardisation of data is important for the design and engineering of new biological products and processes. It is also vital for supporting knowledge sharing and enabling the use of data-based analysis and design tools including AI and ML in process and product design. From our engagement we note that these areas are under-recognised and under-funded. The UK has an opportunity to sustain a leading position in digital design, by supporting good practice in the development, implementation, testing and appropriate deployment of product data standards and design.

[11] Lorenz, A and others. The role of standardization at the interface of product and process development in biotechnology. The journal of Technology Transfer 2019: volume 44, pages 1097–1133. https://doi.org/10.1007/s10961-017-9644-2

Recommendation two: The government should seek to become a world leader in measuring complex biological systems. The Department for Science, Innovation and Technology (DSIT) should convene the relevant national standards bodies to establish a bio-sector measurement standards and metrology board.

30. The UK should establish a national consortium for standardisation in engineering biology, with membership including the British Standards Institute, National Physical Laboratory, LGC, and National Institute for Biological Standards and Control. The UK should also support the development of international partnerships (e.g., with the U.S. National Institute of Standards and Technology) in order to develop international industry-led standards**.** The aim should be to develop a UK-centric roadmap on standards and metrology for biomanufacturing, with a focus on supporting the needs of start-ups, SMEs and industry. This capability would support commercialisation of engineering biology applications, underpin UK commercial innovation across the life sciences, and provide a focal point for international collaboration.

Demonstrate leadership, define ambitions to signal direction and focus effort, and take strategic action

<u>Leadership and strategic actions</u>

31. The government's Life Sciences Vision outlines how the sector might contribute to a range of healthcare missions. There is an opportunity for an ambitious strategy for engineering biology to encourage development of transformational applications in other national goals and support the growth of new businesses. From cleaner, greener industries and more sustainable fuels to radically new products and services, engineering biology applications are relevant to policy goals across many government departments. While there is some coordination of these workstreams across government, there is a lack of a clear strategy, buy-in and coordinated action across relevant departments.

32. Engineering biology is at a tipping point in terms of commercialisation and the scale up of key technologies. To harness the opportunity presented by engineering biology the government needs a clear, long-term, and well-communicated strategy to signal a sustained commitment, provide business and investor confidence, and create a focal point for international engagement. Substantial scale up of the UK's existing infrastructure, skills, and the availability of business finance will be required, with a focus on building capacity at higher technology and manufacturing readiness levels. Experience from previous programmes suggests that for every £1 invested in manufacturing research, £63 will be returned to the UK economy[12].

Recommendation three: DSIT should lead development of a cross-government engineering biology strategy to communicate the government's vision and long-term ambitions for maintaining and extending UK capabilities, and harness engineering biology for solutions to the UK's national goals and challenges.

33. This strategy is needed urgently and should be delivered at pace to provide direction and focus for government action to champion research, support business growth and incentivise private sector investment. The output should be made public.

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[12] UKRI. Manufacturing: the key to unlocking UK innovation. 2023. https://www.ukri.org/blog/manufacturing-the-key-to-unlocking-uk-innovation/

34. Key elements of government support for an ambitious strategy should include:

a. Support for collaboration – engineering biology is a highly interdisciplinary field. Scaling up applications will involve bringing a wide range of disciplines together to solve complex challenges. Innovation in biomanufacturing will require the synchronised development of process engineering, novel engineering techniques, AI, and the application of new knowledge in materials, feedstocks, and biological processes.

b. Infrastructure – engineering biology is a field where specialised innovation infrastructure for testing, experimentation and scaling is essential, including large-scale scientific equipment, specialised testbeds, and measurement and testing capabilities. The cost of accessing these facilities is a major barrier for SMEs. The goal should be the creation of a distributed network of state-of-the-art, industry-facing innovation hubs which companies can access and afford, to provide the infrastructure, facilities, process development and skills to enable the pull through of promising applications to market.

c. Funding – UKRI and the Defence Science and Technology Laboratory (Dstl) have recently allocated £20.6 million to fund innovative engineering biology projects through the NEBP[13], but we note from our engagement the need for more support for development, deployment and scale up of engineering biology applications. Now is the time for the NEBP to evolve to have a more explicit focus on applied R&D, innovation, and commercialisation to deliver impact across multiple sectors. The National Quantum Technologies Programme[14] could offer a model for driving innovation in engineering biology across a range of sectors.

d. Access to finance – for both early-stage development and the scaling up of commercial activity. The physical facilities and digital infrastructure needed for engineering biology are capital intensive. Marketable products take time to develop, and businesses report challenges in accessing knowledgeable investors who can understand the potential of the technology, and who are willing to give companies time to develop commercial presence (particularly in sectors outside of health where there are long development times). Previous CST advice on finance for innovative companies offers recommendations on government action to unlock scale up finance[15].

e. Skills development for innovation and commercial growth – there is a lack of technically skilled individuals at both technician and PhD-level within the UK engineering biology sector. The interdisciplinary nature of this field means that individuals with expertise spanning a wide range of subjects, at all levels, will be required to support innovation. There are very few taught degrees focused solely on engineering biology or biotechnology, and no vocational courses (e.g., BTECs, T-levels) centred on technical support roles. An ambitious strategy should bring together businesses with higher and further education institutions to develop people with new combinations of disciplinary knowledge and skills, as well as attracting talent from overseas.

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[13] UKRI. UK Engineering Biology receives £20.6 million funding boost. 2022. https://www.ukri.org/news/uk-engineering-biology-receives-20-6-million-funding-boost/
[14] UK National Quantum Technologies Programme. https://uknqt.ukri.org/
[15] 'Increasing the availability of scale-up investment for domestic innovative science and technology companies' CST letter to the Prime Minister. October 2022. https://www.gov.uk/government/publications/letter-to-the-prime-minister-on-investment-in-innovative-science-and-technology-companies

f. Missions and procurement – to support engineering biology applications that benefit the nation and public services. To develop the strategic capabilities required to support and underpin commercial innovation long-term, government departments will need to collaborate with UKRI, industry and academia to identify areas where UK capabilities for biomanufacturing need to be supported or strengthened. There will need to be stable long-term support for emerging solutions relevant to policy goals, such as early-stage feasibility studies, industrial stage research, and experimental development grants. A major candidate area for this is providing incentives for bio-based alternatives to petrochemical-based product.

35. To develop and implement the strategy, DSIT should bring together cross-government stakeholders working on engineering biology in order to develop a formal focal point for sector leadership with industry and academia, and for working in partnership with funding bodies such as UKRI and the Advanced Research and Invention Agency. This body needs to be representative of the diversity of the sectors, and of UK industry strengths. Given the breadth of the sector and pace of change, this would benefit from open and transparent engagement. The body should also explore and build awareness of current and future applications, inform understanding across government on the policy implications of these, and identify specific applications on the cusp of commercial use that would benefit from targeted, sustained mission-led support.

Lay the groundwork to support the scale up of engineering biology-based solutions and businesses

<u>Gap in physical infrastructure facilities and skills for scale up</u>

36. The innovation infrastructure needs for engineering biology are dependent on the intended application and the technology and manufacturing readiness level.

37. Building on research strengths in academic labs, the network of UK biofoundries provides important facilities and expertise for early stage industrial translation of research as well as being a channel for work on standardisation and international engagement. The current UK biofoundry facilities tend to focus on high throughput, small volumes (up to a few litres).

38. Innovators then need support for manufacturing process development as they move to technical and economic viability testing. However, we heard from businesses on the challenge of accessing pilot scale (300 – 1000 L) facilities. There is a need for accessible pilot scale facilities in the UK to support businesses scaling up innovation, from testing through to commercialisation.

39. At later stages in manufacturing innovation, the Centre for Process Innovation provides important industry-facing support for design, development, optimisation and demonstration of manufacturing processes. This includes facilities relevant to engineering biology but is not tailored to biomanufacturing for specific applications. We heard from stakeholders that these facilities can be expensive to access for UK SMEs.

40. Application-specific facilities (representative of commercial production environment) are critical to support innovations moving towards end-stage development. Businesses seeking to develop commercial-scale fermentation of novel proteins will have different facilities needs to those involved in biofuels.

41. Other countries are investing to support this pipeline. Notable recent national investments include Estonia (Novo Nordisk) and Finland (Synbio Powerlabs)[17]. We heard from UK companies who are transitioning to use scale up facilities in continental Europe and then investing to build their business there.

42. The health-centred applications of engineering biology appear to be well supported by existing catapults and infrastructures, for example the Medicines Manufacturing Innovation Centre in Renfrewshire. These facilities provide infrastructure for scale up, in addition to resources specific to pharmaceutical applications, for example Good Manufacturing Practice-compliant facilities. They also support businesses to scale up through targeted training and support. The non-health applications of engineering biology will need to receive similar focus and support as they develop, particularly as they begin to integrate into existing key markets, such as fuels. These infrastructures have an important role in providing expertise, support and advice to businesses as they develop.

43. In the longer-term, an ambitious vision for UK engineering biology should anticipate that the demand for facilities along the continuum of scale (i.e., from bench to large scale) is likely to increase substantially.

Recommendation four: Government should work with industry and UKRI to establish multidisciplinary Biomanufacturing Innovation Centres, for testing, scale up, and commercialisation of non-health engineering biology applications, including materials and fuels. These integrated scale up hubs should be in locations with a relevant industry base, and link to universities with strong engineering biology capability and technical skills infrastructure.

43. Biomanufacturing Innovation Centres must be focussed on supporting industrial-led scale up, located close to regions of relevant business activity, connectivity and adjacent to academic centres of excellence[16]. This will help to ensure strategic alignment between the academic pipeline and industry. There are opportunities for regional hubs in Teesside, Humberside, Liverpool, Manchester, and Grangemouth in Central Scotland,.

44. Biomanufacturing Innovation Centres could provide similar functions to the established Catapult concept, but with a recognition of the earlier-stage maturity of engineering biology as a manufacturing sector (compared to the more established fields currently covered by the Catapult network).

45. A regular sector needs analysis will help to determine when the right time is to invest and establish each Centre, especially when business demand begins to outgrow or diversify away from the UK's existing infrastructures. The analysis should also identify the scale, quantity, location, and interest for each centre, as well as any potential specialisations needed to suit specific engineering biology applications. This process will help to establish a good long-term business plan for each centre, ensuring efficiency and survival.

46. The prospective functions of Biomanufacturing Innovation Centres should include:

*Provide affordable and accessible specialist **facilities** for commercial-scale activity:*

a. A suite of financially accessible infrastructures throughout the continuum of scale – from pilot (300 – 1,000L) to industrial (10,000 – 75,000L) capacity, to support the transition of small to medium enterprise, and to encourage collaboration with wider industry.

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[16] 'Levelling up: The role of science and technology' CST letter to the Prime Minister. September 2020. https://www.gov.uk/government/publications/the-contribution-of-science-and-technology-for-levelling-up-across-the-uk

b. A complementary suite of downstream bioprocessing infrastructures, including general equipment such as filtration and centrifugation systems, and specialist equipment such as food extrusion systems (as for alternative proteins), with specific infrastructure determined by outcomes of the user needs analysis.
c. Alongside downstream facilities, centres should also encompass upstream facilities in the form of biofoundries, comprising of integrated automation and analytics facilities for organism engineering, prototyping and pre-scale up research and development.
d. An important function will be bringing together and integrating technologies to allow simultaneous manufacture of materials, chemicals and energy carriers.
e. Access to the new centres should also be subsidised for SMEs – with discount offset by government and larger industry contributions.

*Support the development of the practical **skills** required in related businesses:*

f. The centres should encourage a skills and talent pipeline relevant to emerging engineering biology businesses, as well as a visible career pathway in the field. A focus should be placed on nurturing technical skills in the areas of bioprocessing, biological engineering, and process engineering with the inclusion of AI and ML, to complement the UK's existing strengths in the molecular sciences.
g. Centres should work closely with their local universities to support the development of industry-focussed qualifications in engineering biology. The Advanced Manufacturing Research Centre (AMRC) has an excellent approach to apprenticeships, including a dedicated training centre with state-of-the-art facilities where student training is funded directly by future industry employers. A similar approach would be beneficial for the proposed Biomanufacturing Innovation Centres.
h. Centres should support companies to develop a financially viable business plan, which will enable spin-out companies to grow, scale up and commercialise. The centres could have a role in engaging the investment community to highlight and explore investment opportunities within specific sectors of application.

<u>Remove barriers to scale up</u>

Take a system view on supply chains issues for scaling up commercial activity

47. Engineering biology applications have the potential to disrupt supply chains across the economy, creating risks to address and opportunities to exploit. Examples include:

a. Nucleic acid synthesis – the large-scale commercialisation of engineering biology applications will rely on the UK developing its nucleic acid synthesis capabilities or securing access from international partners to nucleic acid synthesis at scale and low cost. Supply chains (for equipment and reagents) are well-established but are based outside the UK and so vulnerable to supply chain issues, such as delayed shipping and resource shortages. Enhanced capability for large-scale, more complex DNA synthesis would be a major enabler to both research and technological advances. There are some companies currently looking to develop new approaches (mainly enzymatic synthesis, which allows longer sequences and faster manufacture) and a few have UK presence[17].
b. Feedstocks for new manufacturing processes – industrial biotechnology requires feedstocks for manufacturing. Waste from other industries could be one potential source, which would then make these wastes an important factor in the biomanufacturing process. If this occurs, then government should seek to ensure the availability and consistency of these waste streams.

[17] Examples include Camena Bioscience, Evonetix, Touchlight

48. The development of robust supply chains is critical to enabling the UK to lead in these sectors. Strategically investing into capabilities to support domestic supply chains can protect against future supply chain issues.

Recommendation five: DSIT should work with policy teams across government and the engineering biology community to review the critical uncertainties around future demand for engineering biology, explore scenarios for future changes to UK supply chains, and identify policy and regulatory implications.

49. We note that access to affordable, rapid, long sequence nucleic acid synthesis capability is likely to be a critical enabler for future biomanufacturing in the UK[18]. This would be a key component of a high-ambition long-term strategy for engineering biology. The focus should be on nurturing technologies underpinning synthesis capability, rather than supporting individual companies or products.

Adapt the regulatory system for engineering biology applications

50. We heard from researchers and innovators about the need for clearer frameworks for emerging applications, as well as challenges with the current regulations:
    a. The breadth of potential applications means some bioproducts or processes may sit across the remit of several regulatory agencies. Navigating such a complex regulatory landscape can be difficult and create a burden on companies' time and resources.
    b. Engineering biology is an increasingly creative and digitised process. Intellectual property and ownership rights are an important factor to get right at the research and design stage. We heard that the interpretation of broad international frameworks (such as the Nagoya protocol on genetic resources) can be challenging for researchers and small businesses to manage.
    c. There is also some uncertainty on regulatory principles. However, the Genetic Technology (Precision Breeding) Bill[19] is a welcome example of legislative reform which regulates products according to their end characteristics and function, as opposed to the processes used to generate them. Regulation must also consider consumer rights to transparency, whilst liability needs to be clearly defined for businesses and end-consumers.

51. Engineering biology is a rapidly developing area with companies bringing novel applications on to the market that will start to challenge existing regulatory frameworks across different sectors. Regulators need to be able to access, share and develop skills and knowledge on emerging applications to anticipate implications in their sector, including international approaches.

52. For an ambitious strategy supporting commercialisation, the UK needs a clearer framework and regulatory position on engineering biology applications, which facilitates responsible research, supports industry innovation, and stimulates public confidence in these practices.

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[18] Hoose, A. and others. DNA synthesis technologies to close the gene writing gap. Nature Reviews Chemistry 2023: volume 7, pages 144-161. https://doi.org/10.1038/s41570-022-00456-9.

[19] The bill aims to ensure that animals, plants and food products produced using precision breeding techniques can be more easily authorised and marketed, rather than restricted by overarching and generalised regulations applied to genetic modification.

Recommendation six: DSIT and the Office for Science and Technology Strategy (OSTS) should work with the Regulatory Horizons Council (RHC) to establish a 'Regulatory Observatory', bringing together insights on engineering biology applications for regulators across sectors, and advising on improvements to support the sector and provide consumer engagement and reassurance.

53. Functions should include:

a. A proactive approach to developing skills and knowledge amongst key regulators, including communication between academia and industry on emerging applications;
b. Coordination among regulators for horizon scanning activities, to identify emerging end-use applications and their implications. Regulatory agencies should also work together to update this information as the engineering biology landscape and technologies rapidly emerge and develop. As commercial applications come through, a regulatory sandbox approach may be helpful to explore innovative solutions in specific sectors.
c. Dialogue with biotechnology start-ups and SMEs to guide companies through the appropriate regulatory processes and requirements, with a focus on pulling through promising applications into practice and building a culture of evidence-based demonstration of efficacy and safety. Government should establish a clear mechanism for innovators to highlight 'fixable' issues that cut across sectors or regulators.
d. A focal point for international engagement with other nations on regulatory issues.

END

Acknowledgements

The Council for Science and Technology would like to thank the following individuals, companies, and organisations for the input and evidence that they provided during this work.

- Dr Michael Adeogun, National Physical Laboratory
- Professor Ramiro Alberio, University of Nottingham
- Dr Jonathan Appleby, Cell and Gene Therapy Catapult
- Dr Yvonne Armitage, Centre for Process Innovation (CPI)
- Professor Sharon Baurley, Royal College of Art
- Professor Ewan Birney, European Molecular Biology Laboratory (EMBL)
- Professor Patrick Yizhi Cai, University of Manchester
- Dr Michael Chen, Nuclera
- Professor Lionel Clarke, UK Engineering Biology Leadership Council (EBLC)
- Professor Tom Ellis, Imperial College London
- Professor Thomas Heinis, Imperial College London
- Dr Andrea Hodgson, Schmidt Futures
- Dr. Paul Hodgson, University of Cambridge
- The Industrial Biotechnology Innovation Centre (IBioIC)
- Seren Kell, The Good Food Institute
- Professor Richard Kitney, Imperial College London
- Dr Pushmeet Kohli, DeepMind
- Professor Natalio Krasnogor, Newcastle University
- LettUs Grow
- Professor John Love, University of Exeter
- Professor Nigel Minton, University of Nottingham
- Professor Anne Osbourn, John Innes Centre
- Dr Diego Oyarzún, University of Edinburgh
- Phycobloom Ltd
- Professor Saul Purton, University College London
- Professor Paul Race, University of Bristol
- Professor Alex Routh, University of Cambridge
- Professor Nigel Scrutton, University of Manchester
- Professor Jeremy Shears, Shell Research Ltd
- Dr Ben Sheridan, British Standards Institution
- Professor Guy-Bart Stan, Imperial College London
- Professor Joyce Tait, University of Edinburgh
- Professor Eriko Takano, University of Manchester
- Elena Walden, The Good Food Institute