UK BioIndustry Association

BIA submission: Engineering Biology call for evidence

About the BIA

The BioIndustry Association (BIA) is the voice of the innovative life sciences and biotech industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world-changing innovation.

Our members include start-ups, biotechnology and innovative life science companies, large pharmaceutical companies, universities, research centres, tech transfer offices, incubators and accelerators, and a wide range of life science service providers: investors, lawyers, IP consultants, and IR agencies. We promote an ecosystem that enables innovative life science companies to start and grow successfully and sustainably.

The responses to the below consultation questions have been shaped by insights from years of close consultation with our engineering biology membership and our expert Engineering Biology Advisory Committee (EBAC), which includes engineering biology-based start-ups and SMEs, research institutes, accelerators, and service providers. BIA has been promoting the UK's engineering biology sector for over a decade. Our expert committee has been active since May 2013, providing deep insights into engineering biology business and shaping our activities and publications, such as our 2018 Engineering Biology Explained report and our 2022 Power of biology report.

This submission to the *Engineering Biology call for evidence* includes the collective views of the BIA's engineering biology membership, and individual experiences and responses from start-ups and SMEs based in the UK. Individual companies' views and responses to some of the questions are captured throughout in case study boxes.

Key messages

- **Leading with impact**: Government, industry and other stakeholder organisations should work together to consistently communicate the benefits arising from products and processes derived from engineering biology to the public, in order to promote its positive impact on global sustainability challenges, the safety of the technology, avoid misinformation, and ensure visibility and widespread uptake of engineering biology. It is important to convey to the public *why engineering biology* is a vital tool to solve the world's largest environmental and health challenges, including climate change, food security, energy, pollution, and environmental sustainability, in addition to, or instead of, other solutions where they exist.

- **Close collaboration and a coherence narrative**: Due to its nature as an underlying and enabling technology, rather than an industrial sector per se, the UK engineering biology community, while relatively well-connected, is operating in a heterogenous and fragmented landscape, with companies spanning multiple industry sectors. Closer collaboration between government, academia, industry, investors and other stakeholders is needed to create a clear, powerful and coherent narrative and voice around engineering biology in the UK, to drive its commercial uptake and shape public perception.
- **Scale-up challenge**: The UK has strong strategic networks, funding structures and a world-class research base. These strengths need to be harnessed to lead on pro-innovation regulation, standards and policy for engineering biology. Continued long-term public funding, attraction of talent and skills into the field, increased private investment and investment in scale-up infrastructure are needed to support engineering biology companies to start up and scale up in the UK and drive the wider uptake and commercialisation of engineering biology products and processes.
- **Government support**: Government should set policy, regulatory or other incentives to foster commercialisation and the growth and success of engineering biology companies in the UK, and to incentivise larger companies and existing industries more broadly to embrace engineering biology.

1. About you

1.1. If you are happy to do so include your name and organisation here.

UK BioIndustry Association (BIA).

1.2. What kind of respondent are you?

A trade organisation.

1.3. Please select the nation or region you are headquartered.

London

1.4. Which application areas do you consider yourselves involved with? Tick all that apply.

BIA members are involved in the following application areas:

- Human health
- Agriculture and food
- Chemicals and materials
- The environment
- Underpinning technologies

The majority of BIA members are involved in human health and underpinning technologies.

2. Public interest, and uptake of engineering biology products

2.1. How do you approach building the public's interest and uptake of innovations and products derived from engineering biology? What are the factors to consider when going about this?

The Government's interest in this topic is very welcome, given the vital importance of engendering public trust in new technologies being brought to market. Without public trust, it is unlikely the societal benefits of engineering biology will be realised. However, engineering biology as a technology is deeply scientific and can be difficult for the public to comprehend. They are also unlikely to be familiar with the term 'engineering biology'. The BIA has not yet engaged the public to address this, but we do work with journalists to help them understand engineering biology, the businesses developing these technologies and the benefits they could bring[1].

There is a risk that engineering biology-based products may be perceived by the public as synthetic (in part due to its still widely used name of 'synthetic biology') or unnatural and therefore hazardous, rather than biological, 'bio-based', and beneficial. It is important to communicate how engineering biology is used and what it is in an accessible way, showcase people, public organisations and existing companies who work in and with engineering biology, share the advantages of adopting engineering biology products, and demystify the technology. This includes, for example, addressing persisting misinformation around Genetically Modified Organisms (GMOs), the important and beneficial role of bacteria, or exemplifying how engineering biology was at the heart of COVID-19 vaccine development.

Leading with impact first: It is important that the benefits arising from products and processes derived from engineering biology are communicated to the public consistently, in order to promote its positive impact on global sustainability challenges, the safety of the technology, avoid

[1] See https://www.bioindustry.org/resource-listing/engineering-biology.html

misinformation (including to avoid 'greenwashing'), and ensure widespread uptake. UK engineering biology companies go to networking events and panels, and use their websites, social media channels, podcasts, blogs, and other media to promote their products, how they engineer biology to make those products, and most importantly the impact of those products. This includes direct consumer benefits, as well as indirect but substantial benefits such as the positive impact on the environment, energy, food security, net zero, global sustainability, and the potential to solve the UK and the world's most complex and pressing challenges. In the case of COVID-19 vaccines, the direct impact of the innovative mRNA vaccine technology was less well understood by the public than the wider benefits of its ability to save lives.

Leading with impact is also important to demonstrate need where no current market exists, or where the engineering-biology based product is less price competitive than existing products on the market, which is common due to the relative novelty of the technology and its applications compared to existing traditional industries. If consumers are aware of the wider benefits and positive impacts of the product, they may be prepared to pay more for the added value.

However, many companies and especially start-ups and SMEs are constrained by limited time and resource to spread information about their engineering biology products and processes. In addition, while social media works well for companies to promote themselves and connect with the wider ecosystem, the connections they make on those platforms generally do not reach far beyond people and organisations that are already aware of the technology. Where resources allow, some companies work with PR firms to increase their reach.

Advanced Bacterial Sciences

North West, < 250 employees, the environment, chemicals & materials, underpinning technologies

ABS attempts to educate NGOs via specific presentations to clients, attending industry meetings and involvement in specialist groups linked to their company direction. Wider engagement through other applications (i.e. podcasts) has not held interest as the market has been saturated. Added to that, limited resources meant it never started.

The BIA communicates members' capabilities and solutions on our website, social media platforms, and through featuring members at events and conferences in the UK and abroad. However, wider public reach can be difficult. The BIA is exploring ways to increase the visibility of its members and their engineering biology solutions.

2.2. Where and how are government, industry and academia each best placed to build public interest, and more broadly uptake of products? How can we involve the public in this conversation? What can we learn from other countries?

Close collaboration and a coherence narrative: Due to its nature as an underlying and enabling technology, rather than an industrial sector per se, the UK engineering biology community, while relatively well-connected, is operating in a heterogenous and fragmented landscape, with companies spanning multiple industry sectors. This is particularly the case for companies with non-human health applications of engineering biology, which do not benefit from being part of the UK's well-established and world-leading health life sciences sector. Closer collaboration between government, academia, industry, investors and other stakeholder organisations is needed to ensure all parties 'speak the same language', and to create a clear, powerful and coherent narrative and voice around engineering biology in the UK to drive its commercial uptake and shape public perception. All parties need to ensure that journalists are properly informed about the science and impact of engineering biology, and that the sector is well represented in the media.

Why engineering biology? Public and political acceptance can be a decisive factor in the uptake of engineering biology. Both government and industry play an important part in positioning engineering biology as a powerful and necessary solution to the UK's and the world's largest environmental and health challenges, including climate change, food security, energy, pollution and environmental sustainability. It is important to convey to the public *why engineering biology* is a vital tool to solve these problems, in addition to, or instead of, other solutions where they exist.

Government and industry should work together closely to showcase the huge opportunity engineering biology brings to society and the environment, for example by using case studies that promote existing UK strengths. These case studies need to be carefully selected and promoted: across government to increase cross-departmental knowledge and awareness of the technologies' abilities and shape policymaking; to existing industries to increase knowledge and awareness of the technology and its uptake in those industries; and to academia to increase awareness of the wide-ranging commercial applications of the engineering biology toolkit, and drive commercialisation. Identifying larger companies which are underpinned by engineering biology to showcase their success and learn from their experiences can be a powerful tool.

As well as communicating its impact, the Government also plays an important role in communicating the safety and security of engineering biology and listening to and addressing public and existing industries' concerns. The recently launched UK Biosecurity Leadership Council is a welcome step and we would strongly encourage continuing close collaboration with existing engineering biology companies.

Public involvement: As outlined in section 2.1, involving the public in this conversation should be driven by communicating the wide-ranging and positive *impact* of engineering biology and its applications. It is helpful to link the role of engineering biology and its solutions to existing well-placed and well-understood public narratives, such as those around the need to fight climate change and reach Net Zero, the long-term importance of nature-based products and processes for global sustainability, the role of One Health, and other similarly powerful concepts that are in the public's eye and existing interest. The UK engineering biology ecosystem has an opportunity to capitalise on the fact that public understanding of engineering biology has increased due to the success of mRNA COVID-19 vaccines, and the increasing focus on climate change.

US procurement and policy: The Government's procurement role can be used to create levers for growing a market for engineering biology-based products and processes. The US BioPreferred Program[2] is a positive example of how government-led initiatives can assist in the development and expansion of markets for biobased products. Companies active in the non-human health areas of application of engineering biology need policies, incentives, and subsidies to enhance their innovative efforts and increase the manufacturing of their products at scale and lower cost. These measures would further incentivise the uptake of engineering biology and reward technologies with positive environmental impacts.

The leadership taken by the US Government is a useful example of how governments can build public interest, industry engagement and cross-departmental focus. President Biden's Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy[3] and the following White House report on Bold Goals for US Biotechnology and the Biomanufacturing[4] set out a clear US bioeconomy strategy, highlight what could be possible with the power of biology, and how US Federal Departments and industry can work together to reach these goals.

3. UK value chain for engineering biology

3.1. With regards to the whole sector, what do you think the UK's key strengths are in engineering biology?

The UK has a successful, world-leading life sciences sector. UK engineering biology companies operating in the human health space are part of that ecosystem. The strengths of the sector should be harnessed as a foundation for non-health engineering biology innovations, and the weaknesses learnt from for applications of engineering biology tools and techniques across sectors. For example, the scale up of engineering biology can benefit from the UK's existing biopharmaceutical and traditional industrial biotechnology industry sectors, particularly when it comes to manufacturing and bioprocessing. The growing cultivated meat sector is an example of how the UK's existing bioprocessing capabilities can be harnessed to drive manufacture and scale-up for other applications[5].

Public funding structures: The UK has a well-functioning network of public funding agencies, including UKRI and its councils. BBSRC, EPSRC and Innovate UK are of particular importance to UK engineering biology start-ups and SMEs, with flagship programmes such as the National

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[2] See https://www.biopreferred.gov/BioPreferred/
[3] See https://www.whitehouse.gov/briefing-room/presidential-actions/2022/09/12/executive-order-on-advancing-biotechnology-and-biomanufacturing-innovation-for-a-sustainable-safe-and-secure-american-bioeconomy/
[4] See https://www.whitehouse.gov/wp-content/uploads/2023/03/Bold-Goals-for-U.S.-Biotechnology-and-Biomanufacturing-Harnessing-Research-and-Development-To-Further-Societal-Goals-FINAL.pdf
[5] See https://www.extracellular.com/insights/extracellular-opens-europes-largest-contract-pilot-facility-for-cultivated-meat-seafood/

Engineering Biology Programme (NEBP) which should be expanded and built upon. Continued, long-term support and public funding is vital to support both academic and business R&D in engineering biology in the UK, and to drive collaboration and commercialisation. The Biomedical Catalyst (BMC) is an example of a successful funding model that should be built upon to offer early-stage funding to R&D intensive companies who apply engineering biology to areas outside biomedicine – a funding area that is currently fragmented.

Strategic networks: The UK engineering biology company landscape features strong and long-running networks such as the Industrial Biotechnology Leadership Forum (IBLF), Engineering Biology Leadership Council (EBLC), the IBioIC, the BIA's Engineering Biology Advisory Committee (EBAC), and others, most of which are closely inter-connected. The expertise and strategic role of these networks and groups should be harnessed to further grow and connect engineering biology companies with the wider ecosystem and create a coherent, strong voice for engineering biology in the UK and ensure coherent industry-led policymaking.

Leading on standards, policy & regulation: The UK has the opportunity to be at the forefront of creating standards in engineering biology, including technical and documentary standards, that can ease research translation, commercialisation and uptake from fundamental research through to commercial businesses. The BBSRC and LGC are currently leading the way to create ISO standards in multiple areas of biotechnology, including engineering biology. The UK is also part of international initiatives that seek to drive standardisation in engineering biology to drive a global sustainable bioeconomy[6]. The UK also has the opportunity to lead on pro-innovation regulation, including in engineering biology. *Please see section 7.2 for more on the role of standards and regulation*.

The UK is in a strong position to take advantage of its world-leading research and biotechnology sector, following recent government policy activities such as the Council for Science and Technology's report on 'Engineering Biology: opportunities for the UK economy and national goals'[7], the recent launch of the UK Biosecurity Leadership Council, and the Government's Pro-Innovation Regulation of Technologies Review[8].

The ambition to move to a model where regulation is seen as a channel for innovation rather than a hurdle that companies need to clear could be a significant strength for UK engineering biology. The direction and principles for regulatory reform set out in the Pro-Innovation Regulation of Technologies Review for life sciences and other highly innovative technologies could supercharge the UK position as a leading country for the commercial application of engineering biology.

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[6] See https://www.engbiosgb.org/

[7] See https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1156813/20230502_CST_Engineering_Biology_Report.pdf

[8] See https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1159408/Life_sciences_report_-_Pro-innovation_Regulation_of_Technologies.pdf

Strong research base: The UK has a strong research sector, particularly in the life sciences, both in academia and business. The UK's academic ecosystem is a global reference point and is at the forefront of engineering biology research globally. In the human health sector, specific research strengths include vaccine development (mRNA and viral vectors), engineered stem cells (therapeutics and cultured meat), and engineered microbes for microbiome therapeutic applications (including cancer). In the industrial biotechnology sector, strengths include engineered microbes for application in sustainable materials, fuels, chemicals, and feed (e.g., single cell proteins), and significant advances in gas fermentation with potential applications from chemical synthesis to alternative proteins, among other. The strength of the UK's research and science base can serve as an anchor for the establishment of UK start-ups and spin-outs.

bit.bio

East of England, < 250 employees, human health & underpinning technologies

bit.bio has chosen to headquarter in the United Kingdom due to its world-leading centres of research excellence and pool of skilled researchers, a key criterion for the decision of *bit.bio* to choose Babraham Research Campus as its global headquarters. With these institutions and talent, the UK is well-positioned to take advantage of both in terms of human health applications and economic growth borne out of synthetic biology applications. Achieving these ambitions depends upon getting the right processes, funding, regulatory environment, and research facilities in place.

3.2. With regards to the whole sector, what do you think are the UK's key challenges over the next five years?

Policy and investment continuity, increasing commercialisation and uptake of engineering biology across sectors, visibility, innovation-friendly regulation and scaling up our infrastructure and manufacturing capabilities are key challenges to the success of the UK's engineering biology sector in the coming years. It is important for engineering biology to remain an area of focus and priority across government, and to continue regardless of changes in political leadership. Only through long-term commitment will the UK be able to grow and scale up engineering biology across the UK.

Visibility: Engineering biology is not well understood by the public, and potentially by many existing traditional industries that would benefit from using engineering biology processes and products. The uptake of engineering biology will depend on the visibility of the technology and more importantly the innovative companies which offer novel products, services and ultimately solutions. Small innovative companies, especially in the non-human health application space, are faced with the time-consuming and often difficult task of educating larger industries about their process or product and the underlying technology.

The Government can drive the uptake of engineering biology by creating policy and regulatory levers and incentives. This could include connecting engineering biology more closely to the

Government's sustainability agenda, communicating the technology's strengths and capabilities, and creating incentives for industries to 'use' engineering biology.

Private Investment: While the UK is a leader in health life sciences and biotech, UK company fundraises continue to be outpaced by the US and the Far East, where equity finance continues to be easier, faster and cheaper to access. Moreover, the lack of UK-based investors in larger funding rounds weakens the incentive for UK companies to remain and grow in the UK, meaning jobs and economic activity are lost and UK science is commercialised elsewhere. This is a well-documented problem in life sciences and is likely to true for engineering biology companies operating outside the health space too. UK engineering biology start-ups are experiencing a shortage of UK investment capital not only at the scale-up and growth stage, but at the pre-seed and seed stages. An inability to attract funding at these early stages means that incipient start-ups either cannot get established or go out of business.

While a lack of UK private investor access is a known picture among human health life sciences, it can also increasingly be observed in other application areas of engineering biology, such as cultured meat. For example, Singapore has taken a leading role in creating and financing a supportive environment for the cultured meat sector. The UK's scientific landscape is well set up to achieve economic success in engineering biology if it can encourage UK investors. Due to its relative novelty, engineering biology can be perceived as a risky investment, especially when applied to new areas where the regulatory landscape is uncertain. UK private investors are seen as more risk-averse in their investments, though with a growing number of impact-focused private investors, this is slowly changing. Sustained public investment is needed to crowd-in, incentivise and de-risk private investment.

Access to UK private investment for engineering biology businesses is vital so that companies can start, grow and stay in the UK, driving research, jobs and economic growth here. Government and industry have a role to play in building investor confidence in engineering biology, shifting the narrative away from risk and 'failure' in engineering biology business ventures and towards impact, and enabling UK venture and patient capital for investment into engineering biology businesses. The recently announced Mansion House Compact is a significant step forward with the potential to drive growth in the engineering biology sector. It is vital to ensure a share of the patient capital will be invested in high-growth engineering biology companies in the UK.

Continued public funding: Public funding agencies such as UKRI and its councils, and Innovate UK in particular, play an important role in bridging the valley of death[9] and helping the translation

[9] The Valley of Death is used to describe a point during product development and/or company growth when significant investment is required to progress it but its value proposition is not yet proven, making raising that investment challenging. R&D-intensive startups in particular require significant amounts of investment during that time, with no sales or profit being made, increasing the risk of failure. See for example https://raeng.org.uk/media/gaele1fj/bridging_the_valley_of_death_improving_the_commercialisation_of_research-

and commercialisation of engineering biology, particularly where private investment is difficult to raise. The UK's commitment to funding fundamental science and research at universities and research organisations is equally important, underpinning the success and future growth of the UK's engineering biology ecosystem.

To support the start-up, growth and success of engineering biology companies in the UK, the Government should commit to consistent, predictable, and increased long-term public funding, both at early and scale-up stages. While there is a diverse range of public funding opportunities especially for R&D activities across the UK's research funding councils, the funds available are relatively small. Flagship funding programmes such as the Biomedical Catalyst, available to SMEs in the biomedical space, are successful but oversubscribed, meaning that many eligible companies that score high enough to receive funding in theory, will not receive that funding as the size of the fund is too small. The budget of Innovate UK, BBSRC and EPSRC should be increased to sufficiently fund engineering biology. In addition, funding timelines are often compressed and calls not anticipated sufficiently in advance, resulting in a protracted application process which can impact the quality of submissions or make it difficult to respond, specifically for smaller companies with limited time and resource.

Access to international funding schemes for UK SMEs , such as Horizon Europe, is also important to expand opportunities for research collaboration and connect with the international engineering biology ecosystem. We therefore welcome the recent association agreement, but it is currently unclear how and to what extent engineering biology SMEs will be able to access funding via the framework.

Government subsidies can play an important role in incentivising the right kind of innovation. Engineering biology has the potential to solve some of the world's most pressing issues and can help the UK reach its sustainability goals. Subsidies can help companies to develop or adopt new engineering biology technologies which are frequently costly at early stages but have a long-term benefit. Similarly, the role of R&D tax credits cannot be over-stated. To build a world-leading engineering biology-powered industry, R&D tax credits for innovative companies should be globally competitive.

Translation & Commercialisation: The UK has a strong academic science base in engineering biology, and life sciences and biotechnology in general. More emphasis needs to be placed by academia on translating that research into real-world and commercial applications to benefit society and the economy. The ongoing independent review of the university spin-out ecosystem, and the recently published University Start-up Investment Term (USIT) Guide[10] are welcome steps.

The UK needs a long-term vision and commitment to support the commercialisation of engineering biology, especially in areas with existing UK strengths. The UK needs to build on its

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2012.pdf#:~:text=The%20'valley%20of%20death'%20is,outweigh%20any%20potential%20future%20return.

10 See https://www.bioindustry.org/static/70bc6769-bd9f-41cc-9a6711d8357dc66d/USIT-Guide-2023.pdf

academic strength and provide more support for translation, scale up and manufacturing to help brilliant innovations become embedded into industry. As an enabling technology with diverse areas of application and a wide range of products, routes to scale and commercialise can differ significantly, with different skills and funding required. An integrated, multidisciplinary team effort is needed to drive the commercialisation of engineering biology products, and engineering biology as an underlying technology. Government, industry, academia and regulators need to work together closely in the coming years to better understand and realise engineering biology commercialisation pathways.

Infrastructure & lab space: A current hindrance to companies in the UK is a lack of laboratory space, especially observed in the human health sector. In parts of the UK there is a significant lack of purpose-built labs available, especially in London, Oxford and Cambridge. While this is gradually being addressed by the private market and through the Life Sci for Growth Package, it is causing mounting pressures on companies, especially those in the R&D stages of growth which are in need of business continuity. While many benefit from incubation at the early stages to provide lab space and small-scale equipment, start-ups are facing the prospect of being left behind simply because of a shortage of space where they can set up and grow their business. The growth of start-ups in in the UK could be seriously hindered unless the issue of lab space is solved in the coming years.

A further significant hindrance is the lack of scale-up manufacturing facilities, for novel technologies and especially for industrial applications of engineering biology. Scaling up an engineering biology-based product or process can be a difficult process, as it is sensitive to small changes, with impacts on the cost and quality of the end products. In addition, manufacturing and testing capabilities are often too costly for small companies, so that they rely on existing processing and manufacturing capabilities. This can lead to delays in R&D and thus progression within the wider sector or result in companies moving abroad.

Nottingham-based CHAIN Biotechnology partnered with a Japanese company to manufacture their spore-based microbiome therapeutics in Japan, as there are no GMP[11] contract manufacturers with the capability to produce this product in the UK.

The UK's biofoundries and institutions such as CPI need to be built upon and expanded in the UK to bring engineering biology innovations to scale. They can offer access to proof of concept work and scale-up testing facilities, helping start-ups and SMEs to grow and advance. For example, 'test and translate' centres with the ability to work across diverse application and product areas could be established to help companies reach scale, including pilot bioprocessing facilities.

Pro-innovation regulation: Over the coming years, regulation can play a powerful enabling role in the safe and increased uptake of engineering biology products and processes in existing industries. *Please see section 7.2 for more on the role of standards and regulation*.

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[11] Good Manufacturing Practice (GMP) describes the minimum standard that a medicines manufacturer must meet in their production processes.

3.3. Detail your own personal experiences with the engineering biology value chain outlined below. Where do you source these inputs to your work? What difficulties have you experienced? And what do you think needs to change? Please mention where appropriate any scientific and technical advances required.

BIA members' experiences with the engineering biology value chain across human health, chemicals & materials, the environment, and underpinning technologies, are outlined in the case studies below.

An area of concern to the UK value chain is the difficulty in accessing strains materials for academic and commercial engineering biology projects. This causes delays and additional expenses due to the resulting need to resynthesize DNA materials instead of being able to obtain them from biorepositories of research organisations. For example, it has recently been challenging to access E. Coli strains, fundamental to bioengineering, due to the closure of the Coli Genetic Stock Centre at Yale University, highlighting the need for the UK to hold its own guaranteed supply.

Anonymous

London, < 250 employees, chemicals and materials & the environment

Small scale equipment: *The company* mostly buy the small scale equipment they need, but if acquisition is cost prohibitive they opt for using equipment for a fee externally (through limited availability of non-profit laboratories open to external users), or they engage with private service providers, which is costly.

Biological materials and reagents: *The company* purchase their materials and reagents from companies such as Sigma-Aldrich (US) and Fisher Scientific (US).

DNA sequencing and synthesis capabilities: *The company* have engaged with suppliers located in Germany (Eurofins, ThermoFisher), the US (Twist Biosciences), and more recently with a very interesting full-plasmid sequencing company from the UK (Full Circle Labs).

A major challenge for the company is to find equipment and analytical service providers (e.g., GC, HPLC) and, once they are identified, interaction is often very expensive, even with those provided by non-profit organisations. Overall, the limited availability and high costs related to the engineering biology value chain in the UK is a big challenge for R&D in this field.

Bitrobius Genetics

North West, < 250 employees, human health

Bitrobius Genetics source all of the subcontracted services they require from UK-based companies or universities. They order all **reagents** from the UK branches of mainly US-owned companies. *Bitrobius Genetics* have not encountered any problems with the supply of the services and **reagents** that they need, and the lead times on key molecular biology consumables such as plasticware have returned to normal following the end of the pandemic. **Reagent** prices have increased slightly as would be expected in the current economic environment. Delivery charges have increased significantly, so the free delivery that is offered by partner suppliers via membership of organisations such as the BIA is particularly valuable to smaller companies.

Advanced Bacterial Sciences

North West, < 250 employees, the environment, chemicals & materials, underpinning technologies

ABS struggles with the fact that the cheapest products are often available on the other side of the world, for example in China. As a company that aims to reduce its ecological impact at every stage of its product development, following the 'stage gate process' often used in the pharmaceuticals industry, the ecological impact of importing from far-away places is large. However, at the same time the ethical sourcing of local products leads to a more expensive value chain, which often dissuades uptake from clients as harmful chemicals are often cheaper. *ABS* want to only use local suppliers, materials, and products where possible, to avoid supply chains with large global carbon footprints in order to protect the environment.

Another issue in the value chain is the legislation. ABS uses bacteria as an eco-friendly solution to contamination or pollution. The bacteria they use are endogenous to the site in which they are released. There is currently a lack of clarity in legislation as to how engineering biology solutions utilised in industries such as agriculture, which impact environmental concerns, are controlled by legislation. *ABS* develops, manufactures and deploys products to tackle issues upstream of where the issue is legislatively controlled, i.e., treating waste at its source before it gets into the rivers where it is legislatively controlled.

Bit.bio

East of England, < 250 employees, human health & underpinning technologies

Small scale equipment: *bit.bio*'s experience with the value chain has generally been positive. They work through big vendors for such equipment.

Automated platforms: *bit.bio*'s recent partnership with Automata allowed them to make use of their leading expertise in laboratory automation at scale. Automata have worked with bit.bio to support the automation of the manufacturing process of iPSC (induced pluripotent stem cells) – a derived human cell product. *bit.bio*'s precision cellular reprogramming technology opti-ox™ is ideally suited for automation because it enables unprecedented consistency and scalability for the manufacture of human cells from iPSCs. The UK needs to take a leading role in fostering companies like Automata that work with innovative businesses to improve efficiency and reduce bottlenecks.

Mass manufacturing: There are some Contract Development and Manufacturing Organisations (CDMO) that work in cell therapy. However, the focus of these organisations is often on too small a scale, for example, taking cells from patients and putting them back into patients. In strong contrast, bit.bio offers potential applications on a much larger scale. There is a growing fostering of home grown CDMO's that are looking at cell therapy. Others produce viral products, but this is complicated as it adds risk, for example, producing cell therapy in the same environment as a viral product.

Biological materials and reagents: For some materials bit.bio needs to secure overseas suppliers, for example in Japan, and has experienced some minor customs issues when importing materials.

DNA sequencing and synthesis capabilities: bit.bio often have to outsource to a Chinese company but would prefer to be able to find a source in the UK.

Diagnostics: As regards diagnostics, some of the best CDMOs are UK based.

Omics and compute: Borders do not really get in the way, but there does need to be a focus on building a home grown CDMO for this part of the value chain. The Catapult Network, and in particular the Cell and Gene Therapy Catapult is great and useful, and increasing their support and capacity in this area would deliver good results.

Anonymous 2

London, < 250 employees, chemicals and materials & the environment & underpinning technologies

Small scale equipment: *The company* source their hardware from commercial suppliers (Fisher Scientific, etc.). Their building also provides large autoclaves to tenants as part of the services – it would not be feasible for each tenant to install such autoclaves in their demised premises.

Pilot scale assets: *The company* collaborate with external companies to scale up protein production. For example, they work with Prozomix for scaled-up protein production at the 100g to 1kg scale. They also also plan to collaborate with the Henry Royce Institute at the University of Manchester for pilot scale fibre manufacturing.

Mass Manufacturing: *The company* have not yet reached the stage of mass manufacturing, although they are planning for it. They are working on grant applications with CPI for strain and process development for scaling up manufacturing. They have spoken to numerous CMOs for scaling up protein production. The key lesson has been that all require existing detailed SOPs and processes from the client and may charge a tech transfer fee to receive these documents. Clients then pay for associated labour and material cost for bioreactor time at their own risk.

Biological materials and reagents: *The company* sources these from commercial suppliers.

Feedstocks: *The company* sources these from commercial suppliers.

DNA sequencing and synthesis capabilities: Synthesised DNA is sourced from commercial suppliers (IDT, GeneArt, etc). Sequencing is also sourced from commercial service providers. *The company* pay for full plasmid nanopore sequencing from a small start-up called Full Circle Labs.

Diagnostics: Diagnostics are not too relevant for *the company* as a materials company. However, they use facilities such as Royce at Imperial for more specialised equipment for characterising materials – e.g., Raman, FTIR, X-ray diffraction.

Omics and compute: *The company* do not 'do' Omics, but they do use cloud providers, including AWS, Google Cloud for deep learning training and inference of their models for protein materials design.

The company's requirements as a materials company are somewhat different from a typical company in biotech. For them, the main difficulty is going beyond lab-scale to pilot scale and beyond. Producing protein at higher than lab scale (i.e., more than 10g of material) is very expensive and risky, and also requires the development of detailed processes before it is transferred to CMOs. In their experience, except for a small number of centres, there is a lack of fermentation capacity and expertise in the UK. The UK has not had a sustained and long-term commitment or strategy to developing a strong manufacturing base.

4. Knowledge pipeline

4.1. Within your domain, what are the key scientific and technical opportunities over the next five years for advancing the development of engineering biology, including its foundational technologies?

Opportunities within underpinning technologies include:

- The integration of AI, data analysis, meta genomics, meta-analysis and quantum computing will transform engineering biology and bring a new level of understanding to the industry, for example, by helping to model, predict and design experiments and enabling better control of biological systems. However, many SMEs will not be able to afford the technology despite having the skills within the workforce to use it.
- While the Government rightly identified agriculture and food, human health, renewable fuels, chemicals and materials, and the environment as the five sectors of the bioeconomy that engineering biology positively impacts, there is a suite of UK engineering biology companies that develop and drive advances in new engineering biology mechanisms, processes and techniques for their adoption across multiple sectors. Examples include advances in DNA sequencing (Oxford Nanopore, Ingenza), DNA synthesis (Touchlight, Evonetix), or experimental design (Synthace).

Opportunities within the human health domain include:

- Cell programming/engineering, enabling scientific breakthroughs in the discovery of novel drug targets, the development of biohybrid devices, and - outside human cells - cultured meat.
- Improvements in vectors and oligonucleotides for gene therapy, enabling previously uncurable genetic diseases to be treated
- CRISPR-based gene editing for multiple therapeutic applications
- Engineered live biotherapeutics

Opportunities within non-human health domains include:

- Single cell protein from gaseous/waste feedstocks
- Advances in biological controls (herbicides & pesticides)
- Renewable surfactants, solvents and other chemical building blocks with improved function
- Biohydrogen, e.g., from wastes/oil reservoirs
- Advances in gas fermentation and fermentation science in general
- Advances in carbon sequestration

4.2. Within your domain, what are the key scientific and technical challenges over the next five years for advancing the development of engineering biology, including its foundational technologies?

Within the human health domain, technical advances are needed to decrease error rates in large-scale DNA synthesis, and to address synthesis of challenging sequences (e.g., high CG content and repetitive sequences).

4.3. What works well within the current landscape of UK research institutions? What is missing? Are there examples from other countries we can learn from?

Engineering biology research in the UK is amongst the best in the world. UK research institutions have an important role to play in increasing commercialisation in engineering biology (*please see section 3.3*). This includes embedding entrepreneurialism in universities, supporting the formation of spin-outs, licensing technologies into business for commercial development, and collaborating with existing industry.

The upcoming UKRI Engineering Biology Mission Hubs, which offer a continuation to the UK's Synthetic Biology Research Centres (SBRC), and Centres for Doctoral Training, are an important step to continue to deliver UK research in engineering biology, drive the technology's development and uptake, and stimulate innovation to tackle major challenges.

5. Talent and skills

Talent refers to influential named individuals and our ability to attract and retain them. Skills refers to the development of scientific or technical capabilities through training for the wider workforce.

5.1. In order for your domain or the domains of those you represent to develop, scale and commercialise products derived from engineering biology, what are the key technical and non-technical skills?

In the BIA's experience, the general biology skills, genetic engineering, microbiology and molecular biology are well covered by undergraduate and postgraduate programmes. Chemical engineering, chemistry and biochemistry fundamentals are also well established as individual disciplines. The challenges lie in attracting talent with various combinations of interests necessary for engineering biology, largely because universities tend not to work well across faculties.

There is a skills gap in bioprocessing, which has been highlighted by the Cell and Gene Therapy Catapult's biannual Skills Demand Survey[12], as well as in bioinformatics. Some companies are using apprenticeships to upskill staff in these areas. Companies also face challenges in attracting data science, computational sciences, automation, robotics and machine learning skills and talent into the engineering biology and wider biotechnology sector. The BIA is addressing this challenge through our #BIGIMPACT[13] campaign, which is targeting graduates with digital skills into the sector.

Some of the non-technical skills gaps in industry include regulatory skills in both companies and regulators, ethics, project management and leadership skills.

5.2. Please indicate what is working, not working or not to a sufficient scale.

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[12] See https://ct.catapult.org.uk/resources/skills-survey
[13] See https://www.bigimpact.org.uk/

Scale 1= working well, 3= working but not to a sufficient scale/remit, 5 = not working or not happening, 6 = not relevant to me

- *Support for early-career researchers* – **3**
  Individual programmes work well as a subject specific area, but there are very few which integrate all the different aspects of skills needed for engineering biology.
- *Support for mid-career researchers* – **3**
  Individual programmes work well as a subject specific area, but there are very few which integrate all the different aspects of skills needed for engineering biology.
- *Support for late-career researchers* **3**
  Individual programmes work well as a subject specific area, but there are very few which integrate all the different aspects of skills needed for engineering biology.
- *Programmes to support technicians careers* –**5**
  Technician careers are unfortunately not seen as a route into the industry, when they should be. While scientists with advanced degrees are usually the founders and drivers behind engineering biology spin outs and SMEs, apprenticeships are often overlooked as an essential route into the industry, e.g., for technicians, manufacturing and bioprocessing skills.
- *Programmes to support regulatory skills* – **3**
  There is not enough knowledge yet in the teaching of regulatory skills, as well as among regulators.
- *Programmes to support entrepreneurship* – **3**
  Entrepreneurship programmes are working to some extent, but they are fragmented and difficult to find.

In the human health space (and increasingly including non-health applications of biotech), The BIA runs multiple programmes to support new entrepreneurs and small companies to help them start and grow.

- Our Start Up Festival[14] offers the leadership of early-stage companies to learn from each other and from invited thought leaders in the sector, and meet with mentors, collaborators and investors.

- PULSE[15] is a free leadership and entrepreneurship training programme for up and coming life sciences entrepreneurs developed by BIA and the Francis Crick Institute. The programme is aimed at aspiring entrepreneurs and first-time CEOs looking for advanced practical advice, support and feedback from established CEOs, leading entrepreneurs and renowned professionals. In the coming year, he BIA aims to expand this programme to include engineering biology-based companies with applications beyond human health.

[14] See https://www.bioindustry.org/event-listing/bia-start-up-festival-2023.html
[15] See https://www.biapulse.org/

- The BIA Manufacturing Advisory Committee Leadership Programme (BIA MAC LeaP)[16] supports the development and training of managers in the biopharmaceutical and cell & gene therapy industries through cross-sector learning and peer networks, helping deliver future leaders.

Bit.bio

East of England, < 250 employees, human health & underpinning technologies

Support for early-career researchers: *bit.bio* has had good experience with internships and work experience schemes. They have found that it is key that the programmes they offer are fit for purpose, that the students have a positive experience, and that there is value gained for *bit.bio*. In terms of early career researchers, *bit.bio* fill 85% of its research roles through universities. They attend careers fairs and have good relationships with academic institutions. They are aware of where the key MSC programmes in regenerative medicine and in the cell therapy space are taking place and keep in regular contact with those institutions. They have a very good flow of candidates with the right skill set.

Support for mid/late-career researchers: Open positions at *bit.bio* attract interest from individuals later in their careers e.g., 10-year post-doc after a PhD. This is helpful in filling more senior positions.

Technicians: *bit.bio* would like to see more apprenticeships and internships that are supported by Government. The Apprenticeships Levy helps with regard to technicians. They are looking at rolling out an apprenticeship programme through a local Cambridge college for laboratory support in the future.

Entrepreneurship: *bit.bio* have and continue to support entrepreneurship programs at the University of Cambridge as well as in the wider ecosystem (e.g. iGem). Many individuals in *bit.bio* are also personally engaged and provide mentorship and guidance to early-stage founders. Finally, *bit.bio* has a track record of collaborations with early, mid and late-stage companies. *Bit.bio* implement the best solutions and are happy to embrace novel technology.

Advanced Bacterial Sciences

North West, < 250 employees, the environment, chemicals & materials, underpinning technologies

ABS are pleased to say that they have a multicultural, international team, which is important to them as they value diverse perspectives in order to apply their solutions across borders and to places with distinct local challenges. The majority of employees at *ABS* are former PhD students from the University of Lancaster which is local to where ABS is based. However, the rising cost of studying at university has impacted the diversity of talent available, as studying science, especially to PhD level, has become a privilege.

ABS believe in taking on employees from all backgrounds and training them in-house, but as an SME, *ABS* cannot afford to offer extensive in-house training, or support employees through qualifications. They can only afford to hire those who require less development. Some larger companies, like Thermo Fisher Scientific, are able to put employees through internal training and use the Government's apprenticeship scheme. Unfortunately, taking on and training apprentices is not possible for many resource-constrained SMEs, including *ABS*, who are under pressure to deliver and produce at pace.

[16] See https://www.bioindustry.org/membership/advisory-committees/mac/leap.html

6. Business ecosystem

6.1. How do we create mechanisms which bring engineering biology small and medium enterprises (SMEs) together with their customers (including larger firms) in a way that promotes a clear understanding of each others' requirements? What are the barriers to this in practice? What can we learn from other countries?

The BIA has been successful in bringing together the UK biotech and life sciences ecosystem, including SMEs, start-ups and larger firms, through numerous events and networking opportunities, roundtables and workshops, as well as online communities. While these activities have focused on the health sector, the BIA's engineering biology membership is growing, with an increasing number of companies active in non-human health application areas. BIA networking and events activities are expanding to serve this growing community.

In practice, the onus is on small innovative and resource-constrained companies to identify and then educate larger companies about their product and underlying technology. This can be a lengthy and difficult process. It remains a challenge to convince many big firms to take on new products or change their processes or operations to embrace engineering biology. Large companies have invested heavily in their supply chains and can therefore be resistant to disruptive engineering biology products that would require them to invest in new ways of working.

In the human health sector, working with large pharmaceutical companies is challenging for SMEs due to the protracted timelines involved. For example, it took Cambridge-based SME bit.bio 18 months to complete a deal with Bayer.

In the chemicals and materials sector, London-based SME Epoch Biodesign struggled to achieve the scale of large volumes of materials that chemicals and recycling companies require for their testing procedures. In these cases, SMEs require large companies (customers) to help them reach scale.

Government should explore setting policy, regulatory or other incentives for larger companies to embrace engineering biology, and to meet with innovative engineering biology-led companies. This could be done through match-making events in collaboration with relevant trade bodies, organisations, and investors.

Advanced Bacterial Sciences

North West, < 250 employees, the environment, chemicals & materials, underpinning technologies

When working with customers, *ABS* frequently find themselves in a position of educating businesses not just on *ABS'* technology and the science behind it, but on making sustainable choices when purchasing products. One challenge ABS faces is that it is too easy for manufacturers to make green claims about their products. Often products, which make green claims, actually have a negative impact on the environment. *ABS* uses deep science to interrogate these claims, and offers a truly 'green' alternative. Customers frequently find it difficult to believe *ABS* when they disprove green claims made by products they buy, meaning that *ABS* have an uphill struggle to educate their customers around what constitutes a green product. *ABS* feel that relations between themselves and their customers could be improved if guidance and regulation around making green claims were made more ironclad.

ABS struggle with receiving the information necessary from customers to apply their bacterial solutions. Companies that caused pollution are often hesitant to disclose what chemicals they released into the environment. This lack of transparency forces *ABS* to use the lengthy Freedom of Information request process in order to establish the facts they need to solve the issue. One example was a site polluted with hexavalent chromium. *ABS*, while scientifically and technically able to remove the pollutants through their technology, were unable to retrieve the necessary information on the polluted site from the responsible company who were slow to respond and hesitant to disclose that information.

ABS also face challenges around the uptake of their product from companies not willing to fund proof of concept trials, yet enforcing high stipulations that are not always relevant upon *ABS* due to a lack of understanding, thus requiring trials.

ABS has found working with the agricultural sector challenging. One issue is that farmers typically cannot afford to take on projects which involve high upfront costs, especially where any direct or immediate benefits do not directly impact their productivity, even if there is the potential for huge long-term benefits. Another hurdle is that *ABS's* solutions focus on planetary benefit. It can be difficult to convey how long-term planetary benefits align with farmers priorities. For example, *ABS* wanted to work with the National Farmers Union (NFU) to develop a new biofertilizer out of brewery grain. Unfortunately, the NFU could not see enough direct benefit to their members, and felt the upfront costs were too high so chose not to work with *ABS* on this project.

6.2. How is your firm considering overseas production of your products, or exporting to international markets? What are, or would be, the implications of these decisions for your UK-based activities?

BIA members' considerations for overseas production or export are outlined in the case studies below.

Advanced Bacterial Sciences

North West, < 250 employees, the environment, chemicals & materials, underpinning technologies

ABS is a company that aims to support the environment and reduce its carbon footprint. They are currently considering expanding into other countries, but prefer to work locally without large supply chains. If *ABS* do expand their operations overseas, they want to do their manufacturing at small local sites, all with an identical set up, working with local suppliers, materials and workers.

Bit.bio

East of England, < 250 employees, human health & underpinning technologies

bit.bio's biggest overseas market is the US. The most significant pinch point on supply chain and logistics is getting through FDA and customs which can cause unavoidable delays. In response, *bit.bio* have considered the possibility of opening a logistics centre in the US and then distributing from there. If delays continue, then one option would be to examine the benefits of a second manufacturing site in the US. *bit.bio* would welcome Government examination of what measures or future framework could avoid or significantly cut down on such delays.

Anonymous 2

London, < 250 employees, chemicals and materials & the environment & underpinning technologies

Currently, *the company* is in its R&D phase and not yet at the stage of full-scale production. However, their long-term vision includes servicing global markets with their products.

Brexit presents challenges in supply chain management and regulatory compliance. A primary concern is navigating supply chains across different customs territories. Potential delays at customs and administrative tasks can increase lead times and costs. Inconsistencies in customs procedures and documentation across territories may strain *the company's* resources and reduce their market competitiveness. The increased post-Brexit regulatory burden mean they must adhere to unpredictable changing rules and standards for product safety, quality, and compliance.

Given these challenges, overseas production or sourcing might become a consideration to maintain a competitive edge. Such a move would impact their UK-based operations, affecting their workforce, investment decisions, and strategic direction.

The company's commitment remains to the UK's bioeconomy. They aim to stay globally competitive while benefiting the UK's economic landscape.

6.3. At what stage and investment size have your company (or those you represent) found it challenging to raise finance? What were the barriers you faced at each of these stages? How did you solve these barriers?

Difficulty level 1= secured investment with relative ease, 3 = challenging but achievable, 5 = very challenging, 6 = don't know or not relevant

- *< £500K*
- *£500k - £1 million*
- *£1 million - £2 million*
- *£2 million - £20 million*
- *£20 million+*

Please explain your responses.

The above brackets do not adequately portray the large amounts of capital and funding required to start and grow an engineering biology business, particularly in the human health space. In addition, many companies, while successful in raising finance, face difficulties in getting sufficient investment from *UK-based* private investors and venture capital, with easier access to investment from Europe, the US and Asia. UK engineering biology companies experience the UK investor community as more conservative than US investors. UK investors are less likely to invest in high-risk ventures, which is a barrier for funding access for R&D intensive engineering biology companies which are often perceived as high-risk investments.

Companies offering platform technologies can find it challenging to get investment. VC firms tend to prefer to invest in products as it is difficult for platform technology companies to build revenue models. This is especially true for engineering biology companies outside of the human health sector.

Bit.bio

East of England, < 250 employees, human health & underpinning technologies

bit.bio was spun out of the University of Cambridge in 2016, and is now at Series B stage and is pre-clinical. During this time, they raised a total of $200 million capital from Arch Ventures, Foresite Capital, Milky Way, Charles River Laboratories, National Resilience, Tencent, and Puhua Capital, and others.

The importance of successfully channelling early-stage investment and the resultant economic dividend cannot be underestimated. However, the cautious nature of investor funds in the UK towards early-stage commitments, compared to funds in North America, needs to change if we are to leverage the opportunities presented by engineering biology.

Bitrobius Genetics

North West, < 250 employees, human health

Bitrobius Genetics is an early-stage research company with no products on the market yet, but they only plan to manufacture material for clinical trials within the UK. Their pre-seed fundraise in 2021 was relatively straightforward, but it has taken significantly longer to secure their investment this year.

Anonymous 2

London, < 250 employees, chemicals and materials & the environment & underpinning technologies

The company raised a £3.1 million seed funding round in April 2022 which was their first and only funding raising attempt. The main barrier to this funding round was caused by the difficulties of spinning out from a university. IP licencing negotiations took around a year to complete and seemed not to be based on commercial considerations.

Advanced Bacterial Sciences

North West, < 250 employees, the environment, chemicals & materials, underpinning technologies

Investors looking for sustainable investments are more inclined to invest in ambitious ventures where they can demonstrate direct, long-term impact. *ABS* have noticed that investors are more willing to invest in large projects (e.g., cleaning up industrial pollution incidents, improving crop yields or ensuring food security), than smaller, less ‘appealing’ yet essential business ventures (e.g., replacing environmentally damaging cleaning products with eco-friendly bacterial solutions).

7. Regulatory environment

7.1. Do you expect, or have you encountered, any specific regulatory issues when developing, scaling and commercialising products using engineering biology?

Please provide as much technical background as needed to fully explain the issue, and an outline of how you navigated the regulatory system.

BIA members' regulatory challenges are outlined in the case studies below. Please also see our response to section 7.3.

Anonymous 2

London, < 250 employees, chemicals and materials & the environment & underpinning technologies

As a novel materials company, *the company* is primarily affected by regulations such EU and UK REACH. The divergence between the EU and UK regulatory frameworks, following the UK's exit from the EU, has raised potential complexities for their compliance efforts. The UK's separate REACH framework means the start-up has to navigate two parallel regulatory systems. This not only adds to their administrative duties but also leads to separate registrations, distinct data submissions, and varied safety assessments for the same products.

Additionally, the potentially distributed nature of their supply chain across various customs territories can lead to potential delays, especially at customs. The differences in regulatory frameworks might accentuate these holdups as materials could be subject to added checks or certifications.

For businesses like *the company*, who operate across borders, it is imperative that lawmakers and regulatory authorities grasp the implications of their decisions on UK manufacturing. Emphasising the benefits of mutual recognition or a harmonised standard can ease the operational strains without compromising on product safety or efficacy.

Bit.bio

East of England, < 250 employees, human health & underpinning technologies

bit.bio have found that the MHRA moves relatively quickly in terms of reviewing drugs ahead of approval, but the problem is getting an initial consultation with them, which can take up to 10 months. *bit.bio* welcomes the recommendation from the 'Pro-innovation regulation of Technologies Review: Life Sciences' around the focus on streamlined approvals and international partnerships for the MHRA and NICE and the creation of an Engineering Biology Regulatory Network.

The MHRA regulatory approvals process is a clear area where improvements can be delivered to bring the UK closer to the speedier approval timelines for equivalent products in the US. Some approvals can take three times as long compared to those in the US, showing the scale of opportunity for UK life sciences should it be able to compete on a more level regulatory playing-field.

Anonymous

London, < 250 employees, chemicals and materials & the environment

The company works on developing materials and packaging that are derived from microorganisms and are biodegradable. However, the cost of their products is higher than petroleum-based plastics. One of the specific regulatory challenges they face is that their material is subject to the UK Plastic Packaging Tax. This tax further adds to *the company's* production costs.

7.2. How should government look to influence the development of international regulations, standards, and norms to help grow the UK sector and protect the UK's capabilities?

Over the coming years, regulation will play a powerful enabling role in the safe and increased uptake of engineering biology products and processes in existing industries. UK regulators therefore need to be thought-leaders and rule-setters not just in the UK but on the international stage.

As a technology with potential impacts across many UK sectors, many regulators are faced with understanding and correctly supporting engineering biology approaches and products. Innovative start-ups and SMEs are faced with regulatory uncertainty and a lack of guidance due to the novelty of their products. We welcome the establishment of the Engineering Biology Regulatory Network (EBRN) and sandboxes. Regulation should be pro-innovation and industry-led, with regulators working closely with existing engineering biology companies. The recommendations of the Pro-Innovation Regulation of Technologies Review and the CST's report on 'Engineering biology: opportunities for the UK economy and national goals' should be implemented.

Better regulatory and financial environments elsewhere can be a pull for companies to leave the UK and set up their business abroad. In the human health sector, MHRA regulatory approvals processes and efficiencies need to be brought back up to speed and in line with approval timelines for equivalent products in the US. Similarly, the capacity and speed at which to conduct clinical trials in the UK needs to be significantly improved. Forging international approval partnerships for MHRA and NICE can have significant merit, though the principle of reciprocity will be important.

The UK's departure from the EU has left us with the opportunity to create better regulation for businesses in the UK. For example, the Genetic Technology (Precision Breeding) Act was a positive step forward for the UK to enable the release and marketing of gene edited or 'precision bred' plants, with the EU slowly following suit. Over the coming years, the Government should carefully assess a safe regulatory process for the release of Genetically Modified Organisms (GMO), in the first instance plants, that could have been produced by traditional breeding methods, to ease scientific research. However, any changes to retained EU regulations should be made in close consultation with stakeholders, and the impacts of regulatory divergence from the EU carefully considered.

International policy developments are likely to impact the engineering biology sector in the UK. Human and non-human genetic resources, or information thereof, are at the heart of engineering biology. UK businesses face several burdensome international obligations when conducting R&D with the use of genetic resources, such as those required by the Nagoya Protocol under the Convention on Biological Diversity (CBD). The ongoing negotiations under the CBD to implement a multilateral benefit sharing mechanism for Digital Sequence Information (DSI) of genetic resources further runs the risk of inhibiting innovation in the UK. Innovative businesses must be closely consulted to ensure international regulations are fit for purpose and do not stifle engineering biology in the UK. Industry should be closely consulted on any changes to the regulation and patentability and other protection of genetic resource materials and synthetically engineered matter.

Standards act as a universal benchmark and allow scientists around the world to collaborate and reproduce each other's work. They are a powerful tool to ensure the accuracy, reliability and reproducibility of data generated by UK engineering biology businesses, researchers, and organisations, and support the advancement of engineering biology. Most importantly, standards can support collaboration between businesses, and business and academia, and drive commercialisation from fundamental research through to business R&D and final product development.

The Government plays a supportive role in identifying and developing key standards in close collaboration with researchers and the engineering biology industry. Signposting innovation-supportive standards and methods can help businesses demonstrate the safety and performance of engineering biology products and processes. The UK should lead international efforts in standards for engineering biology by supporting the UK standards and metrology community on the international stage. This will ensure that the needs of UK industry stakeholders are addressed and any national and international standards, and any potential future regulatory standards, that are developed support the growth of the UK engineering biology industry. Many engineering biology companies with value chains that reach across borders could benefit from internationally harmonised standards, and it is important not to create divergence in engineering biology standards and regulations which could inhibit cross-border collaboration and access to markets.

Lastly, setting international standards can be a helpful tool to communicate the power of engineering biology to the public.

UK BioIndustry Association

Bit.bio

East of England, < 250 employees, human health & underpinning technologies

bit.bio supports recommendations from the National Measurement Laboratory and the Council for Science and Technology for the Government to set a target for the UK to become a world leader in measuring complex biological systems and establish a bio-sector measurement standards and metrology board comprising of relevant national standards bodies. This would act as a national consortium for standardisation in engineering biology. As part of this, a roadmap on standards and metrology for biomanufacturing would be developed. The focus of this should be on supporting start-ups, SMEs and industry.

It is worth reflecting on the profound opportunity presented through the application of engineering principles to biology. The most important aspect of a standard is that it serves as a universal benchmark that enables comparability. In the life sciences achieving such standards is infinitely more complex as it requires standard models of relevant cells that are sufficiently scalable and reproducible. Even widely used cell lines are known to change their characteristics over time, making them not useful as a standard. The only avenue that has the potential to tackle this issue is engineering biology – applying engineering principles to biology.

The reproducibility issue in life sciences research is in large part the consequence of the absence of standards in life sciences. A critical application for *bit.bio*'s ability to create human cells should be in addressing the reproducibility crisis. For the first time in biology, *bit.bio* has been able to reach a definition and specificity of cell products that enables large scale experimentation with human cells. The observed batch-to-batch variation is minimal. This has attracted considerable interest from pharma, biotech and recently US based funding bodies to use *bit.bio*'s cells as research standards.

8. Future expectations

8.1. For your own domain or the domains you represent, please select the top three areas from the UK's Science and Technology Framework you would want government to prioritise in any future plans for engineering biology. These are outlined further in The UK Science and Technology Framework linked here.

All areas are from the UK's Science and Technology Framework should be supported by government alongside the priorities listed below. The Government should explore the role of procurement in driving the uptake of engineering biology products and processes. Establishing a pro-innovation culture within the public sector that adequately supports and rewards innovation while unblocking systemic barriers is essential.

For the human health domain, the top three areas for *government* to prioritise are:

- ***Signalling UK strengths and ambitions****: Promoting domestic and international recognition of the UK's strengths and ambitions in science and technology to ensure that all stakeholders have the confidence to invest their time, money and effort supporting our science and technology vision.*
- ***Regulations and standards****: Utilise post-Brexit freedoms and put the UK at the frontier of setting technical standards and shaping international regulations.*

- ***Financing innovative science and technology companies****: Improve access to capital at all stages with increased participation from domestic investors, and an environment to grow and scale large globally competitive science and technology companies that drive growth in the economy and high-skilled employment opportunities for citizens.*

For the non-human health domains, the top three areas for *Government* to prioritise are:

- ***Signalling UK strengths and ambitions****: Promoting domestic and international recognition of the UK's strengths and ambitions in science and technology to ensure that all stakeholders have the confidence to invest their time, money and effort supporting our science and technology vision.*

  This includes promoting engineering biology to existing traditional industries and communicating its safety and impact to stakeholders and the public.

- ***Investment in research and development****: Focus UK R&D investment to match the scale of the Science and Technology Superpower ambition, and have the private sector take a leading role in delivering this.*

  This includes unlocking increased private investment and patient capital for R&D conducted in engineering biology businesses and increasing long-term public funding for R&D in engineering biology across areas of application.

- ***Financing innovative science and technology companies****: Improve access to capital at all stages with increased participation from domestic investors, and an environment to grow and scale large globally competitive science and technology companies that drive growth in the economy and high-skilled employment opportunities for citizens.*

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