SSAC Report – Engineering Biology: Opportunities for Scotland

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Executive Summary

Engineering biology (EngBio) is a platform technology with wide-ranging applications that could enable the sustainable and just transition of key Scottish industries. It includes the design, scaling and commercialisation of biology-derived products and EngBio has significant potential to aid economic growth whilst also contributing to other ambitions outlined in the Programme for Government such as environmental goals and social wellbeing. Examples of EngBio impacts include: enabling the transition of the broader chemical industry towards more sustainable bio-based alternatives; supporting the resilience of Scottish agriculture against climate change; and creating new advanced therapies for those with previously untreatable diseases.

The Scottish Science Advisory Council (SSAC) has produced this report to inform Scottish Government on the current EngBio landscape. We highlight the opportunities and foresight of the potential challenges of utilising this increasingly important technology. Our information draws on stakeholder engagement, surveys, roundtables, and desk research. Strategic action to realise the benefits for Scotland presented by EngBio is recommended.

EngBio is rapidly developing around the world, through scientific advancements and government investments. It includes the field of synthetic biology and the technological advances in the synthesis and sequencing of DNA, which have made research and development much more economically feasible. The UK had a head start with early adoption of synthetic biology as a priority technology by the UK Government from 2013[1], supported by a strong life sciences sector in general. However, many more countries are now making EngBio a strategic priority (Annex H). The UK Government laid out its commitments within their National Vision for Engineering Biology in 2023[2] but currently EngBio is not included within the Scottish Government's Critical Technologies[3].

Scotland currently has truly world-leading academic strength in many EngBio-relevant areas, and an active core group of companies that specialise in EngBio. This group is ripe for expansion and development could be nurtured by dedicated facilities such as those proposed in the Falkirk Growth Deal that would assure Scotland's place in the bioeconomy. To realise the potential economic, social, and environmental benefits of EngBio for Scotland, our key recommendations are:

1. **Strategy:** Recognise and promote EngBio as a national strength, ensuring that its impact and value is explicitly incorporated into Scottish Industrial and Innovation Strategies.

2. **Regulation:** Give clarity on the regulatory future, to enable companies and entrepreneurs to plan with confidence. In particular, Scotland should consider alignment with the 2023 Precision Breeding Act of England and Wales.

3. **Infrastructure and facilities:** Provide infrastructure and facilities for company spin-out, start-up, growth, and manufacturing through public-private partnerships targeting follow-on space, and measures to improve the sustainability and accessibility of specialist facilities.

4. **Develop a joined up public funding support pathway aligned with the needs of emerging technology** through the provision of non-dilutive Proof of Concept funding, adjustment of Scottish Enterprise's high-growth spin-out programme and the remit of the Scottish National Investment Bank (SNIB), and engagement of private investors.

1 Critical technologies: past and future (2025) Royal Academy of Engineering
2 National Vision for Engineering Biology
3 Scotland's Critical Technologies Supercluster Showcases Strength and Sets Ambitious Goal of £10bn in Revenue by 2035 at Holyrood Reception

5. **Build the workforce rapidly through consolidating skills, upskilling, and re-skilling** in addition to engaging those in education and maintaining strong doctoral training.

6. **Natural resources:** Maintain an up-to-date database of the mapped bioresources in Scotland and support technologies that enable their valorisation through EngBio and a circular bioeconomy.

Introduction: what is Engineering Biology?

The **UK Government** takes a broad approach to defining engineering biology (EngBio) as:

"the design, scaling and commercialisation of biology-derived products and services that can transform sectors, or produce existing products more sustainably. It draws on the tools of synthetic biology to create the next wave of innovation in the bioeconomy"[4].

We will also use this definition of EngBio as it embraces the whole innovation ecosystem, combining the core biotechnologies with the fields of engineering, computer science and the physical sciences. It includes activities that enhance research productivity, enable the scale-up and commercialisation of bio-processes, and creates value from the bioeconomy.

EngBio offers new opportunities for Scottish science and industry. The McKinsey Global Institute assessed several end-use applications of engineering biology that could plausibly be commercialised in the next 10 to 20 years and has estimated that they could contribute a combined global economic impact of up to $4 trillion. More than half of this is expected to be outside the human health sector[5], e.g. agriculture, biofuels, biogenic carbon capture, biomaterials, and sustainable chemical production. In Scotland, EngBio could contribute towards national goals such as economic growth and achieving Net Zero, as well as providing solutions to global challenges and international sustainable development goals[6].

EngBio can be regarded as the descendent of biotechnology, systems biology, and synthetic biology and encompasses the wider landscape facilitating the translation and application of research from synthetic biology. Synthetic biology is defined as:

"the design, engineering and re-engineering of biologically based parts, devices and systems"[7].

Synthetic biology, and therefore in turn EngBio, draws on several core technologies, many of which have only recently become possible at scale due to the rapid development in capabilities for nucleic acid synthesis and sequencing. These technologies include, but are not limited to:

- gene editing
- genetic engineering
- protein design and engineering
- epigenetic modulation
- transcriptional regulation

Additionally, EngBio is enhanced by new Artificial Intelligence/Machine Learning (AI/ML) based tools e.g. predictive modelling of protein structures achieved by the Nobel-prize winning AlphaFold. In combination with "multi-omics" approaches, enabling a new scale of data collection on the biomolecular mechanisms and interactions underlying the function of living cells, AI and advanced computing methods are creating new possibilities for developments in data-driven biology.

4 National Vision for Engineering Biology
5 The Bio Revolution: Innovations transforming economies, societies, and our lives
6 The UK Bioindustry Association report on Deep Biotech (2023) identified that the cross-cutting nature of Engineering Biology means that it can provide solutions that support as many as 10 out of 17 Sustainable Development Goals [https://deepbiotech.org/].
7 Overview of the proposed National Engineering Biology Programme

Whilst the broad and inter-disciplinary nature of the field presents wide-ranging opportunities, it also makes it challenging to accurately assess the current landscape, map the realistic opportunities and determine how to best support such a diverse range of activities. The approach adopted in preparing this report included:

a. a literature review and desk research to examine the academic and industrial ecosystem in Scotland, together with a short study of comparable international markets (methodology and findings are described in the respective Annexes);

b. a set of survey questions informed by the desk research and completed by sector stakeholders (Annex A and D);

c. an online roundtable of key stakeholders from industry, academia, and the wider public sector (Annex B and C);

d. follow-up interviews with key stakeholders for greater insights into key areas;

e. an externally commissioned analysis of patent publications relevant to engineering biology. This report draws on each of these sources of evidence and knowledge from within the SSAC to arrive at the key findings and conclusions (Annex E).

The Scottish Engineering Biology Ecosystem

Scotland is academically very strong in almost every aspect of Life Sciences. According to HESA data (for 2018 to 2022), Scotland received 20.3% of UK Bioscience research funding and 10.5% of UK Clinical Research funding (a considerable overperformance considering it comprises just 8% of the UK's population). This, and the associated high-quality undergraduate and postgraduate offerings, gives Scotland a powerful foundation for all aspects of Life Sciences – including EngBio. Scotland is also a leader in AI, creating many opportunities within data-driven biology and leadership thereof.

EngBio was identified as one of five critical technologies of national strength and opportunity in the UK Government's Department for Science, Innovation & Technology (DSIT) Science and Technology Framework 2023[8]. Currently, however, it does not feature in the Scottish Government's list of Critical Technologies, which are covered in the separate SSAC report on the "Critical Technologies Supercluster"[9].

Building on the Synthetic Biology for Growth programme of 2014, the UK National Vision for Engineering Biology was published in December 2023, committing £2 billion in funding to the area over the next 10 years. This UKRI-managed strategic investment has so far funded six new UK Mission Hubs focusing on different research themes, as well as a range of smaller mission awards, collaborative R&D grants, seed corn funding, Proof of Concept funding, and Accelerator feasibility awards to support the progression of academia, industry and entrepreneurship in the area.

Research

UKRI is currently the principal explicit funder of EngBio in the UK, although other UK-based agencies (Wellcome, Cancer Research UK (CRUK), British Heart Foundation, etc), are technology/approach agnostic to delivery of their missions and are open to EngBio-based funding proposals. Scottish higher education institutes (HEIs) have been reasonably effective in securing recent engineering biology-focussed UKRI funding. For instance, the University of Edinburgh hosts the **"Engineered Genetic Control Systems for Advanced Therapeutics"** Mission Hub, in partnership with the CRUK Scotland

8 The 2025 Framework has committed to encouraging the same critical technologies as the 2023 Framework, which are: Artificial Intelligence (AI), Engineering Biology, Advanced Communication Technologies (formerly Future Telecoms), Semiconductors, Quantum Technologies [https://www.gov.uk/government/publications/science-and-technology-framework/science-and-technology-framework]

9 SSAC Report - Scotland's Critical Technologies Supercluster: Challenges and Opportunities

Institute and the Edinburgh Genome Foundry. In total, Scottish academics and researchers are partners on four of the six UKRI Mission Hubs and five of the 22 Mission awards (Annex G).

UKRI funding is not devolved; however, the Scottish Government, through the Scottish Funding Council and other devolved means, can assist institutions in maximising their share of funding in priority areas by enhancing research culture and environment. In addition to providing core funding to higher education institutions, it may be necessary to explore other strategies to benefit the Scottish economy, such as fostering the translation of research and retaining talent and companies.

Innovation

Patents are recognised as indicators of levels of technological innovation and can provide useful insights into strengths and relative activity on the UK and International stage. Recent analysis by Inevus Advanced Analytics (Annex E) provided a useful snapshot of activity in the EngBio area by using a bespoke and comprehensive keyword search for synthetic biology related terms. This includes, for example, searches such as novel metabolic pathways, engineered enzymes, artificial genomes, and genetic engineering. However, due to the 18-month delay in patent publication from filing, the data represents a historical snapshot. Nevertheless, several key trends are clear from interrogation of the dataset generated using INPADOC patent families (2014-2023).

In Scotland there are 'hot spots' of patent activity around Edinburgh (and the Lothians), Glasgow, Aberdeen, Angus and Dundee City, Clackmannanshire and Fife. These probably mirror the geography of the key generators of intellectual property (IP) – the universities – including the University of Edinburgh (90 patents), University of Glasgow (39), University of Dundee (20), University of Aberdeen (12), University of Strathclyde (12), Heriot Watt University (7), and Moredun Research Institute (6).

Indeed, Edinburgh is the seventh UK region for patent families in the area of EngBio, with the top six all within the 'Golden Triangle' (Oxford, Cambridge and London). Edinburgh has thus established itself as a prominent centre for research and development in synthetic biology. Glasgow and Aberdeen City and Aberdeenshire also feature in the top 20 (14th and 20th respectively). However, there is a notable disparity between the top individual region of Cambridgeshire County Council, with 1,316 patent families (15.6% of the total), the London area (combined regions, 24.5% of the total), and Edinburgh with 161 families (2% of the total).

Commercialisation

The first engineering biology companies in Scotland were created over 20 years ago (e.g., Ingenza was founded in 2003) and there has been a steady rise in annual company listings since 2014 when the first "Synthetic Biology for Growth" Programme was launched by the UK Government. Scotland is now home to a growing base of companies deploying EngBio (Annex F). Most companies are micro businesses or small or medium-sized enterprises (SMEs), with the majority currently in the biomedicine space, reflecting the wider UK landscape as described in the UK National Vision for Engineering Biology[10].

Patent analysis suggests that more IP is assigned to academic groups than industry in Scotland: 40% of patents have academic assignees in Scotland, compared to 23% in England. This points to untapped potential for translation of Scottish IP into new companies. Nevertheless, over half (58%) of the EngBio companies registered in Scotland started as spinouts from Scottish universities. This indicates that commercialisation is underway, and we might anticipate a rebalancing of sources of IP generation over time.

Although the current landscape may seem relatively small in relation to some of the other critical technologies in Scotland, it should be noted that EngBio is at an earlier stage of development. The

10 National Vision for Engineering Biology

first public funding for companies in synthetic biology was just 11 years ago, whereas funding and investment for many in the critical technologies cluster goes back over two decades.

A more detailed overview of the industrial landscape is in Annex F, and an overview of the Scottish academic network is outlined in Annex G.

Strategic focus, governance and co-ordination

Scotland has had considerable success in obtaining UK-wide competitive research project funding (which is not a devolved matter), and there is strong representation of Scottish voices on both the UK Government's Engineering Biology Advisory Panel and its Engineering Biology Responsible Innovation Advisory Panel. Yet, Scotland itself currently has no unified national strategy for EngBio.

As a platform technology, EngBio could contribute across all of the key themes in Scotland's National Innovation Strategy: Energy Transition, Health & Life Sciences (especially Precision Medicine and Advanced Medical Therapies), Data & Digital Technologies and Advanced Manufacturing. It could also contribute to the targets set out in Scotland's Net Zero 2045 Strategy. Industrial Biotechnology, and Life Sciences in general, are already core to both the Innovation Strategy and the National Strategy for Economic Transformation. The National Plan for Industrial Biotechnology has been supported by successive Scottish governments (first written in 2012, with a refresh expected shortly).

Many other well-established Critical Technologies in Scotland have a specific policy and/or strategic advisory group (e.g. Photonics Scotland) which can feed into higher-level national organisations such as Technology Scotland and Scottish Enterprise. However, the landscape is more fragmented for EngBio-relevant sectors: health-related applications are covered by Life Sciences Scotland, and non-health related applications are currently covered by the Scottish Bioeconomy Council. There are important gaps in strategic representation for areas such as farming and agriculture, and other environmental applications. This lack of connection and strategic oversight could limit the growth of the field in Scotland. Moreover, in order to achieve widespread acceptance and market traction it is also important that there is greater public knowledge of what engineering biology is and the benefits that this sector can deliver. Public perception is critical and mishandling could result in Scotland isolating itself from being able to use genetic technologies.

Other supportive networks and organisations include (but are not limited to): Industrial Biotechnology Innovation Centre, IBioIC, (SFC funded and focused on university–business industrial collaboration, scale-up and training); Cell and Gene Therapy Catapult (UK catapult but with labs in Edinburgh); Advanced Medical Therapies Network (specifically for advanced therapy medical products (ATMPs) and supported by Scottish Enterprise); Scottish Universities Life Sciences Alliance (SULSA) (strategic partnership of twelve universities and one research institution).

Engineering biology should be recognised as both a Critical Technology, and a national strength. As a cross-cutting platform technology, EngBio would benefit from improved co-ordination of efforts across relevant public bodies (including Scottish Government, Scottish Funding Council (SFC), Scottish Enterprise (SE), Scottish Environment Protection Agency (SEPA), Zero Waste Scotland (ZWS), NHS Scotland) to support EngBio translation across all relevant sectors.

An over-arching organisation with comprehensive membership from all three strands of the innovation helix (academia, industry and government) should be created. This could, for instance, be through a merge of Life Sciences Scotland and the Scottish Bioeconomy Council, to take responsibility for this strategic co-ordination and leadership, with appropriate representation from all relevant sectors.

EngBio should be incorporated appropriately into National Strategy documents. We see two options for this:

a. commission a review to map out where EngBio can be incorporated, highlighted, or supported further in existing Scottish strategies and sector-specific roadmaps e.g. National Industrial Biotechnology Strategy, Life Sciences Strategy

b. publication of a specific engineering biology roadmap for Scotland

The former option may be preferable since EngBio is a platform technology with applications across multiple sectors, and not a sector in itself. However, EngBio is a core component of our valuable biotech industry and expected only to grow in economic importance. It therefore makes more sense to consider it as integrated with existing sector areas from the national policy and strategy perspective. There is also potential synergy with an existing UK-wide roadmap for EngBio.

Regulation

The global EngBio landscape is varied, with the associated global legislation and regulatory functions at different stages of development and application. For example, the International Cartagena Protocol on Biosafety[11] is aimed at regulating risks to biodiversity and human health from trade in Genetically Modified Organisms (GMOs). However, implementation around the world varies (Annex H). **The importance of clear regulatory pathways, harmonised standards, and regulatory alignment,** especially with key trade partners within the UK and the EU, to enable Scotland-based SMEs working with EngBio to commercialise their products and remain competitive, was highlighted in questionnaire responses and the roundtable discussion.

The regulation of genetic technologies is a devolved matter in the UK. The Genetic Technology (Precision Breeding) Act[12] was passed in 2023 to allow gene editing for plants and (later) animals in England and Wales. This Act relaxed regulations for gene-edited/precision-bred organisms, in which targeted changes have been made to native genes using genetic technologies. It only permits those genetic changes that could in principle occur naturally by evolution or classical breeding. Genetically Modified Organisms (GMOs) containing genetic material from other organisms are still strictly regulated across the whole of the UK, in alignment with EU laws.

In Scotland, gene-edited organisms are still subject to the same strict regulations as GMOs. However, gene-edited/precision-bred products could still enter the Scottish markets under the UK Internal Market Act 2020[13]. There are concerns that the lack of alignment with England and Wales and the existence of a regulatory border will put Scottish businesses and communities at a competitive disadvantage.

Furthermore, uncertainty over the future, and the complexity of the regulatory landscape can discourage innovation and investment in Scotland at a crucial time for the development of the field. Business and industry generally are looking for the certainty of a stable regulatory environment to stimulate investment in innovation.

We recommend that **Scottish Government should provide clarity on the regulatory future, to enable companies and entrepreneurs to plan with confidence**. In particular, considering recent developments in the field, Scotland should update its regulations, noting the England and Wales Precision Breeding Act (2023) and the other EU member states who are adopting regulations to advance gene editing technology.

11 The Cartagena Protocol on Biosafety
12 Genetic Technology Act key tool for UK food security
13 United Kingdom Internal Market Act 2020

Other regulations around EngBio are still in development. Patent rights for precision-bred organisms remain unclear, as they were not addressed in the UK Genetic Technology Act. The EU parliament has proposed a ban on patenting gene-edited plants[14].

The EU Artificial Intelligence (AI) Act will be fully implemented by 2026, with regulatory implications for any UK firms selling AI-driven products or software into the European market for commercial or clinical use[15]. The UK and Scotland do not currently have any regulation on the use of AI in EngBio, or the commercial implications or regulations for marketing products created through these means, although this is likely to be a matter of increasing importance.

Where wider regulation and governance are being developed in relation to engineering biology, **it is vital for Scotland to fully embrace opportunities to shape international law, regulation, and policy**. Examples include policy regarding trade, patent rights and labelling of gene-edited or genetically modified products, or regulation around the application of AI in EngBio.

Competition and collaboration

Globally, EngBio is dominated by the United States and China (in terms of publication volume, patents, market share and investment). However, the UK as a whole ranked **third globally** for private investment in EngBio from 2017 to 2022, and ranks highly in citation impact, demonstrating the quality of its academic output.

Aside from the United States, China and the UK, other countries with strong strategic focus on EngBio include Japan, Singapore, New Zealand and South Korea. Some countries such as Australia and Canada have non-governmental strategies or roadmaps for EngBio (or related areas) developed by experts in the field. In other countries, EngBio-related initiatives are embedded within existing wider strategies for innovation, bioeconomy, or biotechnology. For example, the EU Commission stated that **"biotechnologies and biomanufacturing are key to the competitiveness and modernisation of EU industry"**.

Responses to our consultation highlighted significant and ongoing uncertainty regarding the strategy and funding for EngBio and bioscience in the United States under the current administration. Whilst this may make collaboration less attractive, it potentially creates new opportunities for Scotland to attract talent and investment that is now looking elsewhere for a stable and supportive environment.

We already have **strong academic research collaborations**. For example, network analysis by Inevus Advanced Analytics showed that, the University of Edinburgh had notable research links with other leading universities, both within the UK and worldwide, and connections with multiple companies. Examples of bilateral research partnerships which have supported Scottish research include the UK-Japan collaborative research programme in EngBio, a joint venture between the UK Government's International Science Partnerships Fund, and the Japan Science and Technology Agency. These collaborations are often co-ordinated on a UK level and participation should be encouraged to enable Scottish research to remain at the forefront of innovation in a rapidly evolving field. Other relevant funding sources for EngBio include global philanthropic funding (especially for health/disease research areas) and EU Horizon funding programmes (accessible if collaborating with partners in EU member states). Scotland has had reasonable success with both streams for Life Sciences, and could continue to do so with **support for Horizon Europe connections**.

14 What are the patentability implications of deregulating gene editing in plants in the EU?; The UK is developing its approach to deregulating gene editing in plants

15 Decoding the EU AI Act's Impact on Biotech

There may be further opportunities for Scotland to develop knowledge-exchange partnerships with a specific technological focus. It could be mutually beneficial to co-develop applications of EngBio-related technologies together with regions with similar characteristics, natural assets, and key industries. For example, Scandinavia, which has similar industries including forestry and seaweed, and natural assets such as renewable energy and water, or Germany, which has strengths in engineering that could provide technologies to scale and translate the discovery-based research within Scotland.

Scotland, and the UK in general, lags in scale-up capacity, particularly for food-grade and non-pharmaceutical fermentation facilities. This is a major barrier to translation and contributes to the offshoring of SMEs. Investors are typically reluctant to fund production scale facilities, so it is often essential to have access to shared scale-up facilities or pilot plants for companies to grow into an investible asset. This key deficiency could be targeted through international collaboration in **infrastructure and scale-up**. Europe has numerous state-of-the-art facilities for biomanufacturing scale-up (e.g. Bio Base Europe Pilot Plant, Belgium), captured in the easily accessible database **Pilots4U**, that are so popular many US companies choose to access them. UK-based companies have, however, found it difficult to access EU-funded facilities after Brexit. Partnering with more distant countries is, of course, an alternative. Networks such as the **Global Biofoundry Alliance** provide platforms for infrastructure sharing but strong relationships with the EU have been highly emphasised throughout our consultation as essential both as a partner for the advancement of research, and as a driver of translation and commercialisation.

An in-depth review of the international landscape is outlined in Annex H.

Future Opportunities and Challenges

Opportunities

Scotland has an ideal combination of assets to realise the benefits of EngBio across multiple sectors in the near to medium term. The country has a winning combination of world class academic research, vibrant companies and a wealth of natural resources. Harnessing the potential of EngBio could be transformative for many sectors and, with the right ecosystem in place, this can be converted into economic benefits.

Next-generation healthcare: In the aforementioned patent analysis, where synthetic biology patent filings were mapped against 60 key topics, the top scoring topics in the UK were healthcare related including "pharmaceuticals", "antibodies", "cancer related" and "diagnostics". The dominance of the bio and pharmaceutical sector in UK EngBio innovation probably reflects the investment in R&D by the pharmaceutical sector and is eased by greater clarity of routes to market for new medicines, and the return on investments for investors is also clearer.

Near-term wins are being delivered in the biomedicine arena in Scotland where EngBio offers potentially transformative benefits for hard-to-cure diseases such as some cancers and inherited disorders. For example, Trogenix is developing a gene therapy that will target hard-to-treat brain cancers, while Resolution Therapeutics is developing engineered cell therapies for end-stage liver disease, where the only alternative is transplant. Cell and gene therapies offer cures rather than symptomatic relief of terminal diseases. Scotland also has strengths in other next-generation healthcare areas such as precision medicine, diagnostics, vaccine development, drug discovery, and screening. All of these can be accelerated using EngBio.

Scotland's strong life sciences sector includes: small entrepreneurial companies; clinical trials services; contract research, development, and manufacturing organisations (CRDMOs); and analytics providers. All of these can support fast tracking of engineering biology-derived healthcare products to the marketplace.

Industrial biotechnology: There are encouraging signs of innovation (as seen through patent analysis, Annex E) around non-human-health synthetic biology applications including "micro-organisms", "biocides", "biodegradable materials", "foods and alternative proteins", "cellulose-related", "waste conversion/recycling", "fermentation and bioreactors", "biofuels", "textiles and fibres", "leather and dyes", and "recycling and microorganisms."

Industrial biotechnology offers routes to manufacture chemicals in a more sustainable manner, and to convert bioresources (virgin biomass/biomaterials or waste from other industries such as brewing, whisky or fishing) into new materials. Industrial biotechnology can also use yeast or other microbes as fermentation factories for a wide range of products from food ingredients, dyes and textiles to cosmetic ingredients, bioplastics, and biopolymers. EngBio can create the efficiency gains required to make a bioprocess commercially viable and more cost-competitive with fossil-fuelled production processes. Scotland is home to many companies leveraging Scotland's natural resources: e.g., MiAlgae (algal-based fish oil using whisky coproducts), Oceanium and BioMara (nutraceuticals from seaweed), and Ripcell (organic solvents from distillery waste).

Biomanufacturing using decentralised, smaller-scale, 'biorefineries' could enable a more democratic distribution of economic benefit of the bio-based economy. Beyond the Central Belt, companies could tap into local biomass and other natural resources to create local opportunities for economic opportunity in bio-based manufacturing.

There is also an opportunity to consider the utilisation of non-food crops and bioarisings (bio-derived wastes and by-products) as a source of biomass to feed fermentation or other bioprocesses in Scotland. This would alleviate competition with food crops and reduce the demand to import biomass in sufficient volumes to feed bioprocesses.

Food security: Our climate is changing, and farmers and growers alike are increasingly concerned around its impact on crop yields and the spread of diseases. Scotland has one of Europe's largest clusters of agricultural and veterinary research. With appropriate and proportionate regulations, Scotland could harness EngBio approaches to improve food security and compete internationally with locations employing more permissive regulation.

EngBio is rapidly making an impact globally on production of disease-resistant crops (especially those that reduce the need for pesticide applications), improved crop yields, better climate resilience, enhanced nutritional value, and improved soil health. Genome editing can also benefit livestock – both yields and animal welfare – and reduce methane production and hence the impact on global warming. At present, Scottish regulations prevent the deployment of such techniques locally, much to the frustration of Scottish farmers.

The environment: Another area that is often overlooked, but critical, is the application of EngBio in bioremediation of contaminated soil and water. EngBio approaches are being explored in bioremediation of soil (e.g., from mining activities), detecting pollution and in cleaning up wastewater.

Scotland has the advantage of having a single public-private company – Scottish Water – that provides the nation's water. Scottish Water has a proactive and innovative approach to identifying and deploying new technologies, and working with Scotland's Environmental Protection Agency, and can therefore lead on creating a more circular and sustainable water sector.

Summary: The opportunities for EngBio cross multiple sectors, underpinning national and global demands for more sustainable healthcare, animal welfare, consumer goods, food security, and environmental protection. One of Scotland's unique advantages is its breadth of activity (seen in patent subtopics) that was not seen across the other devolved nations. Scotland therefore has an opportunity to grow capability in a wide range of sectors and potentially take a lead in specific sectors, if proactive and with the right regulatory measures in place.

Challenges

Scottish HEIs overperform, per capita, in terms of Life Sciences research grant income from UKRI, charitable, and other sources (see above), but Scotland generally underperforms in terms of commercialisation of the IP. For example, Scotland houses only 6% of the UK Life Sciences industry, according to the Office for National Statistics.

Scotland has a relatively supportive entrepreneurial environment for emerging EngBio businesses. This includes dedicated networks and support organisations, some incubation space for spin-outs and start-ups, support to pilot scaling up innovative processes, public and private financial mechanisms, and the talent to help companies grow. A supportive regulatory and fiscal environment is also essential. However, consultation responses noted several gaps that pose challenges specifically for spinning out and scaling companies:

- lack of general laboratory space for spinouts (leading to migration of invested companies to elsewhere);
- lack of appropriate specialist and scale-up facilities (and affordability thereof);
- lack of funding, specifically Proof of Concept funding to convert innovations to investible assets, support to access scale-up facilities and capex for manufacturing;

- lack of energy cost certainty (especially important for biotech companies); and
- lack of seasoned managerial talent that have 'been there, done that' in growing bio-based businesses.

1. Incubation space

Innovation Centres and Incubators can support start-ups and spin-outs by providing laboratory and office space, and a physical base for collaboration, innovation, and commercialisation.

Scotland has several innovation centres and hubs. Many are jointly funded by a university and local authority, such as through the recent Scottish regional and city deals[16]. Those supplying wet lab space include ONE BioHub (Aberdeen), Life Sciences Innovation Hub (Dundee), Life Sciences Innovation Centre (Inverness), Edinburgh Innovation Hub (East Edinburgh City), and National Aquaculture Technology and Innovation Hub (Stirling). This complements pre-existing hubs at BioCity Glasgow (between Glasgow and Edinburgh), Edinburgh BioQuarter (Edinburgh), Roslin Innovation Centre (Roslin), Edinburgh Technopole (Penicuik), and Health Innovation Hub at Queen Elizabeth Health Innovation Campus (Glasgow).

However, despite these innovation spaces, many companies still struggle to access wet lab bench space at affordable prices. A recent survey by IBioIC and Scottish Enterprise showed that >90% of respondents needed more lab space within a year, and most of the incubator space in the Central Belt is full. Lack of availability of the right space in the right place poses a risk to sector growth. Provision of Innovation Centres and the like can nucleate clusters of companies and provide the driver for private-sector investment in follow-on infrastructures. Clustering around existing facilities and centres of expertise can have many beneficial effects, especially in the early stages of a field that requires highly skilled workers and close links between academia and industry, building the critical mass required for growth of a self-sustaining community and ecosystem. In the longer term, strategic clustering around the country (e.g. based around bioresource) could bring benefits to communities outside of the Central Belt due to distributed biomanufacturing enabled by EngBio.

Follow-on space is potentially even more critical. Generally, a lack of follow-on space leads to loss of companies from Scotland when they start to grow, or prevention of growth and a blockage of incubator space for other companies to move into. There is an urgent need to invest into strategic public-private partnerships to create follow-on space for company growth within Scotland. This would serve to encourage more companies to scale-up and to improve the retention of these companies within Scotland, while freeing up incubator space for new start-ups and spin-outs, thus addressing both problems to a certain extent.

2. Access to specialist research facilities

Equipment to support EngBio R&D is costly, and requires specialist expertise to run. Scotland is fortunate in having a wealth of publicly-funded expertise and state-of-art equipment including: Edinburgh Genome Foundry (automated DNA assembly, single cell culture and analysis); Edinomics and Glasgow Polyomics (metabolite and proteome analysis); the Dundee DNA sequencing and Proteomics facilities; and extensive microbial collections such as the National Collection of Industrial, Food, and Marine Bacteria (NCIMB) and the Culture Collection of Algae and Protozoa (CCAP). Other facilities available at the manufacturing hub CMAC and the National Manufacturing Institute Scotland (NMIS), in particular the new oligonucleotide capability, offer further capability in process development. A few companies such as Ingenza and The Antibody Company offer commercial services that overlap with and complement some academic facilities.

16 Scotland's hub for regional economic development

One of the challenges faced by companies is identifying where support can be found. Although organisations such as Interface, IBioIC and the Scottish Universities Life Sciences Alliance (SULSA) signpost companies to HEI-based facilities, there remains underuse of some facilities. For example, the Edinburgh Genome Foundry has Edinburgh, English and international clients, but no other Scottish users. However, this may also be a reflection of the maturity of EngBio across Scotland. In theory, a centralised searchable database might help connect end users with those that can provide services, which would be especially useful as the field continues its growth.

Another challenge for companies is the cost of services. These are increased by the funding models for HEI-based facilities, in which equipment costs are provided by funders but not staff costs to operate the equipment, nor costly equipment service contracts. The latter operational costs have to be cost-recovered at a local level. This is a complex and time-consuming procedure that can result in access being too costly and complicated for potential clients. Perhaps as a result, many facilities do not operate at capacity.

Recommendation: support the sustainability and accessibility of existing biosciences facilities for our academics and SMEs. Scottish Government and SFC should develop advice on how universities could contractually and financially offer commercial access to their facilities including exploring alternative cost-recovery models and business interaction incentives. Awareness and promotion of existing capabilities can be improved by creating and maintaining a centralised searchable database of facilities.

3. Scale-up and manufacturing

Regardless of sector, scaling up technologies from lab bench to the marketplace takes time and investment. For industrial biotechnology products, companies need to evidence the industry readiness of a biological process by proving it can scale from lab bench (one litre) to a larger volume (ideally >500 litres). This is a ‘valley of death’ for industrial biotech processes and requires both expensive equipment and expertise.

Some universities have their own internal capability for establishing feasibility, and companies including the Midlothian-based CRDMO Ingenza offer bioprocess development support and scaling up to 20 litres. Academics and companies can access the technical support, offered on an open access, fee-for-service, at the IBioIC’s FlexBIO Scale-up Centre hosted at Heriot-Watt University. A recent investment from Scottish Enterprise has purchased a 300 litre fermenter for FlexBIO, which increases scale-up capability tenfold. FlexBIO also offers upstream and downstream processing on a fee-for-service basis.

Across the UK there are other bioprocess development centres that offer similar or complementary support on a fee-for-service basis (e.g., Beacon in Aberystwyth and Bioresource Development Centre in York). The largest is the UK’s flagship facility CPI (Centre for Process Innovation), a member of the High Value Manufacturing Catapult headquartered in Wilton offering a fermentation capacity of 100, 400, 2,000 and 10,000 litres. There is currently no capability in Scotland offering open access to such large volumes (>300 litres), which are vital for reassuring end users and investors of the commercial viability of a process. However, funding to support such a facility was ringfenced for Grangemouth in the Falkirk Growth Deal and local needs are currently under review.

Access to scale-up capability is critical for companies. In the past, Scottish companies have accessed this capability in Europe but then gone on to relocate their entire manufacturing processes there – losing Scotland jobs, skills, and the associated economic benefits of scaled businesses. Another crucial aspect is the need for a company to be close to sources of biomass, and to have biomanufacturing plants near key services such as power, water and transport. Scotland does not, as yet, have such a ‘sticky’ site to attract and anchor businesses. Nevertheless, the Green Freeports and Grangemouth have potentially suitable attributes.

Scotland does, though, have good support for medical and healthcare biotech applications with Roslin CT (cell culture capability), Cell and Gene Therapy Catapult (GMP labs), several Contract Manufacturing Organisations, and early-stage clinical trial capabilities. This would provide a supportive ecosystem to bring novel medical applications of EngBio towards the market.

Recommendation: continue to monitor the scale-up needs of companies to assess future requirements including, for example, seeking funding to build a site which would enable clustering of companies and better anchor businesses.

4. Investment and support for commercialisation

The provision of early-stage public funding is essential to enable the growth of small or micro companies to a stage that can attract private sector investment. EngBio technologies (as with most biology-based concepts) have long development times and therefore require substantial and long-term investment[17]. A joined-up public funding support pathway would align with the needs of emerging technology. This would contribute to the translation of relevant academic strength within our HEIs into investible assets. Public body investment would de-risk advancement in transformative areas and address current investment challenges in areas such as digital automation for therapeutics manufacture. In conjunction, it is important to build strong relationships with the right type of investors to accelerate growth.

Beyond the substantial investment made in EngBio research by UKRI, public and private investment is available from a variety of sources. SynbiCITE is the UK's national centre for the commercialisation of synthetic biology established in 2013 with funding from the EPSRC, BBSRC, and Innovate UK. It has supported over 50 start-up ventures, 15 Proof of Concept projects, and one development of prototype project[18]. It has interactions with Scottish businesses and includes the University of Edinburgh amongst its academic partners. Scottish entrepreneurs also have access to the UK Innovation and Science Seed Fund (publicly funded) and the Science Creates Accelerator, which both have EngBio as a priority area, and also access to Innovate UK's highly successful ICURe programme.

Scotland has a vibrant Angel Investor landscape with several groups (e.g., Archangels and EOS Advisory) interested in science and technology investments, including EngBio, that complements the Scottish National Investment Bank and Scottish Enterprise investments. However, there is a lack of biotech-specific venture-capital investors in Scotland who understand the associated business models, in contrast to many more deep-tech focussed investments in the 'Golden Triangle'.

Scottish Enterprise's High Growth Spinout Programme (HGSP) is a great asset for Scotland in supporting spin outs across all technology areas. Scottish Enterprise (SE) also offers additional funding mechanisms such as SMART awards, which complement UK-level investment funding mechanisms for SMEs. However, there are some gaps in the pathway which could be strategically targeted to help innovations in emerging areas such as EngBio:

- **Proof of Concept funding:** Non-dilutive public sector funding is available in many successful biotech countries including Singapore, Israel and Ireland where it has had a great impact on the number of spin-outs and start-ups. There are currently limited opportunities to obtain this early-stage high-risk funding in Scotland that would support innovative ideas to progress through the opportunity qualification stage and into the later stages of the HGSP.
- **High Growth Spinout Programme:** Whilst overall the programme provides valuable support for new companies, there are particular challenges in enabling EngBio companies to reach the point of becoming a viable investment proposition for private investors, by conventional criteria. It can be hard for disruptive technologies without an established proven path or business trajectory to conform to the criteria set by the programme, for example in projecting future employment numbers.

17 Royal Academy of Engineering in 2019: Engineering Biology: A priority for growth
18 Start-Ups & SMEs

Some specific issues mentioned in consultation responses include:

- The terms of the HGSP convertible loan can be off-putting to some investors because of the level of equity retained by SE.
- The amount of investment provided may be insufficient to fully bridge the 'valley of death' in progressing to higher technology readiness levels in sectors with significant capital expenditure requirements, so it is more suitable for companies in less capital-intensive sectors such as financial technology (fintech) and AI rather than EngBio.

- **Later investment:** As noted above, EngBio ventures, especially those targeting scale-up, have a high requirement for capital expenditure. This can be a barrier to securing investment from venture capitalists (VC) and private investors. There are many SMEs and start-ups initially funded by public and private seed sources, but with a high attrition rate after 2-3 years. Consultation responses asserted that there was not a large, risk-taking investor community in Scotland relevant to the sector, in comparison to the South East of England or in some other regions outside of the UK. Furthermore, it is important to build strong relationships with investors to enable understanding of the differences between the business models relevant to the different industrial sectors, such as therapeutic companies and industrial biotechnology companies.

Recommendation: consider how Scottish Enterprise's High Growth Spinout Programme might evolve to embrace the full spectrum of commercialisation opportunities resulting from EngBio.

Recommendation: Scottish Enterprise should consider instigating an annual showcase targeted at reaching the international VC community to attract long-term private investment and highlight the full range of EngBio taking place across Scotland and the opportunities that it provides.

We would also encourage institutes to learn from successful long-term industry–academia partnerships which have stimulated research funding and created a strong reputation for translational research in Scotland such as Dundee Life Sciences' Division of Signal Transduction Therapy (DSTT), or the University of Edinburgh's Centre of Excellence in Bioprocessing, and replicate these elsewhere.

5. Natural resources

Bioresources: Bioarisings, the bio-derived wastes and by-products, from one company can be the fuel for another. Multiple companies in Scotland have already innovated in this area, in part because of Scotland's drive for a more circular economy and good business networks. The 2023 SSAC Report – Towards a Circular Economy: Scotland's Bioresource Flows[19] – tackled this topic and provided recommendations on how to derive greatest value from bioarisings. In short, improved up-to-date mapping would allow businesses to make data-informed decisions for sustainable biomanufacturing based on transportation distances and carbon savings.

Water: There is a greater importance of water supply as a resource for EngBio and biotechnology when compared to other critical technologies. Scotland has 90% of the UK's fresh water[20] and, certainly in this respect, offers a far more suitable location than elsewhere for the scale-up of EngBio and resultant biomanufacturing industries.

Energy: A number of our respondents noted high UK electricity costs (noting coupling to the gas price), thus presenting a barrier specifically for the scale-up of bioprocesses, as most of these processes have an energy-intensive stage for removing water to recover their product. Investors are reluctant to invest in projects with high energy requirements, and uncertainty over future prices presents a high risk to return

19 SSAC Report - Towards a Circular Economy: Scotland's Bioresource Flows
20 SEPA 2009 (The river basin management plan for the Scotland river basin district 2009–2015)

on investment. Other countries have lower business electricity prices, and have used models whereby the government underwrites fixed energy prices for the duration of an investment project, incentivising private investment e.g., Scandinavia and the Netherlands.

6. Skills

The key skills gaps identified from our consultation relate to two aspects of growth:

- creation of small companies (relevant for current early-stage of the EngBio landscape in Scotland)
- scaling up of companies (for example, as highlighted in House of Lord's report 'Don't fail to scale')

Company creation in the EngBio sector generally requires highly skilled graduates (at MSc or PhD level) with complementary commercialisation and business skills. The emerging sector of data-driven biology also requires specific skills in AI and data science. Although some Scottish universities have a strong reputation and funding success for doctoral training in AI and data, there has never been a dedicated EngBio or synthetic biology doctoral training centre in Scotland. We therefore recommend that **support mechanisms for relevant training at the postgraduate level are developed, perhaps supplemented by potential BBSRC funding.**

Regarding the challenges for company scale-up, the main skills gaps highlighted to us were for fermentation technicians, and process and chemical engineers with the relevant biological expertise. Companies in the sector generally struggle to hire employees with the relevant skills from the UK due to the lack of relevant training pathways. These gaps will become even more pressing with future growth of the sector as more companies begin to scale-up.

Re-skilling is an often-neglected aspect of skills training, especially relevant in an inter-disciplinary environment where there is an advantage to having a certain level of life and industry experience. There is therefore a fortuitous opportunity for the **strategic reskilling of those in large Scottish industries such as the petrochemical industry, brewing and baking (e.g., chemical and process engineers) within months-to-a-year to fill current skills gaps. The provision of fast-response microqualifications would enable rapid growth of the EngBio area.**

For general sector growth, Life Sciences as a whole is competing with other sectors for access to individuals with multi- and interdisciplinary skills, often against higher paying industries. Creating a supportive and attractive environment through enacting some of the recommendations outlined in other sections will support the retention of graduates trained within Scotland, the recruitment of skilled people from outwith Scotland, or even sideways movement of those with transferable skills currently working in other related fields (e.g., encouraging graduates trained in AI and data science to stay in Scotland to work in EngBio and the Biosciences).

Awareness is another major factor determining entry and recruitment to the field, with a lack of understanding of the range of roles available being noted as a key barrier to Life Sciences recruitment in Scotland. Skills Development Scotland (SDS) potentially play a key role in tackling this, through engagement of those still in education. Some of their key roles include training careers advisors for Scottish secondary schools, distributing information to 'Developing the young workforce' co-ordinators and for apprenticeships and skills training in colleges. **Developing education campaigns with SDS to spread more awareness of the roles available within EngBio could help to engage and recruit the next generation, developing the workforce from the bottom up and shoring up science and maths skills within our schools.**

SDS also provide employer services, helping industry understand their skills needs, aligning them with local provision or with the enterprise agencies, and reviewing the training provision with trade bodies and sector skills bodies (ensuring the qualifications are still meeting the needs of industry). **Companies in**

an emerging sector such as EngBio may benefit from engaging with SDS at an early stage to communicate their likely skills needs in upcoming years.

Recommendations

Our recommendations are:

1. **Stimulate recognition and promotion of engineering biology as both a critical technology and a national strength**
   a. Designate or create an over-arching body with comprehensive membership from all three strands of the innovation helix (academia, industry and government) for better representation of all the stakeholders of EngBio at the policy level, e.g., through a merger of Life Sciences Scotland and Scottish Bioeconomy Council. This body could have responsibility for co-ordination and leadership on several of the actions below.
   b. Commission a review to map-out where EngBio can be highlighted, incorporated, or supported further in existing Scottish strategies and sector-specific roadmaps (e.g., National Industrial Biotechnology Strategy and Life Sciences Strategy).
   c. Explicitly incorporate EngBio into Scottish Industrial and Innovation Strategies, to ensure the technology can be harnessed towards the Scottish national priority areas (i.e., Economic Growth, Environment, and Just Transition).
   d. Enhance public knowledge of EngBio in Scotland, including explaining what it is and the benefits that it can deliver across sectors.

2. **Commit to legislative clarity**
   a. Scottish Government should consider how to provide clarity on the regulatory future, to enable companies and entrepreneurs to plan with greater confidence. In particular, Scotland should consider whether it might be appropriate to update its regulations, noting (for example) the England and Wales Precision Breeding Act (2023) and actions by other EU member states who are adopting regulations to advance gene editing technology.
   b. Where wider regulation and governance are being developed in relation to EngBio, it is appropriate for Scotland to fully embrace opportunities to shape international law, regulation, and policy (e.g., regarding trade, patent rights and labelling of gene-edited or genetically modified products, and the application of AI in EngBio).

3. **Provide infrastructure and facilities for company spin-out, start-up, growth and manufacturing**
   a. Investment in public-private partnerships to create more follow-on space for growing companies in areas with high demand would accelerate company growth and free up incubator space for new companies.
   b. To support the sustainability and accessibility of existing biosciences facilities to our academics and SMEs, Scottish Government and SFC should develop advice on how universities could contractually and financially offer commercial access to their facilities, including exploring alternative cost-recovery models and business interaction incentives. Awareness and promotion of existing capabilities could be improved by creating and maintaining a centralised searchable database of facilities.
   c. Continuing to monitor the scale-up needs of companies to assess future requirements including, for example, seeking funding to build a site which would enable clustering of companies and better anchor businesses.

4. **Develop a joined-up public funding support pathway aligned with the needs of emerging technology**
   a. Introduction of non-dilutive public sector 'Proof of Concept' funding.
   b. Adjustment of Scottish Enterprise's high-growth spinout programme so that it aligns with the full spectrum of commercialisation opportunities resulting from EngBio.
   c. Adjusting the remit of what the Scottish National Investment Bank will invest in to address the most challenging gaps and barriers for emerging high growth areas.
   d. Scottish Enterprise should consider organising an annual showcase targeted at reaching the international venture capital community to attract long-term private investment and highlight the full range of engineering biology taking place across Scotland.

5. **Build the workforce rapidly through re-skilling and upskilling**
   a. Consider providing support for specific doctoral training of suitably skilled students should other resources, for example from the current round of BBSRC investment prove insufficient.
   b. Skills Development Scotland should consider creating an engagement campaign for those in education to raise awareness of the career opportunities available within EngBio in Scotland, and the potential future applications.
   c. Invest in strategic reskilling for people with transferable skills and expertise to fill skills gaps in EngBio; for instance, chemical and process engineers from the petrochemical industry, brewing and baking.

6. **Utilise Scotland's natural resources in a circular bioeconomy for competitive advantage**
   a. An organisation, such as the IBioIC, should be resourced to maintain and raise awareness of an up-to-date database of the mapped bioarisings, as recommended in the previous SSAC report on a Circular Bioeconomy.
   b. Strategically invest more effort into developing a circular bioeconomy within Scotland, which could become a priority for Zero Waste Scotland.

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Annexes

Annex A – Invitation and questionnaire

Annex B – Roundtable programme, attendees and notes

Annex C – Roundtable presentations

Annex D – Summary of survey responses

Annex E – Analysis of synthetic biology patent publications (Inevus Advanced Analytics)

Annex F – Overview of Scottish industrial landscape

Annex G – Overview of Scottish academic landscape

Annex H – Review of international competition and collaboration opportunities

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scottishscience@gov.scot