

Synthetic & Engineering Biology: A joint opportunity for the UK and Switzerland











Contents

Exec	utive Summary	3
Sumi	mary of Recommendations	4
Back	ground	erland
	Synthetic & Engineering Biology in Switzerland	6
	Synthetic & Engineering Biology in the UK	7
Reali	sing the biorevolution	7
Discı	ussion topics, reflections and recommendations	8
	Discussion topic 1: Scaling synthetic & engineering biology for climate and the environment in a sustainable bioeconomy	
	Discussion topic 2: Public awareness and acceptability of synthetic & engineering biology	9
	Cross-cutting discussion topic 1: Regulations and standards	. 11
	Cross-cutting discussion topic 2: Skills and Training	.12
Conc	cluding remarks	13
Anne	ex 1: Summit delegates	14

This report was led by Kerstin Kinkelin (University of Bristol BioDesign Institute, BBI), with support from Kathleen Sedgley (BBI), Rhiannon Wilson and Jack Dury (PolicyBristol), Linda Bedenik, Maddie Cass and Jane Wall (BioIndustry Association, BIA), Anike Te (Lucideon) and Natalie Thomas (Swiss Business Hub UK). Delegates who participated in the roundtable discussions informing this report are listed in Annex 1.

For more information on this report, or to share feedback, please contact Kerstin Kinkelin at $\underline{\text{k.kinkelin@bristol.ac.uk}}$

Executive Summary

The Synthetic & Engineering Biology British-Swiss Summit, held in May 2024 and formally opened by H.E. Markus Leitner, Ambassador of Switzerland to the United Kingdom, brought together over 25 representatives from academia, industry, and government bodies from the UK and Switzerland. Through roundtable discussions, the summit aimed to explore challenges and solutions affecting the development and uptake of synthetic & engineering biology technologies for climate and the environment, with a focus on scaling synthetic & engineering biology for environmental sustainability, and enhancing public awareness and acceptance of these technologies.

The event was part of a broader effort to strengthen bilateral cooperation between the UK and Switzerland in "deep science" and "deep tech," as per the Memorandum of Understanding signed in November 2022.

Scaling synthetic & engineering biology to address climate change and environmental sustainability faces significant barriers such as high costs, regulatory challenges, and limited biomanufacturing capacity. Discussions emphasised the need for efficient, low-cost systems to mainstream these technologies. Scaling up is essential but expensive, and significant investment and skilled personnel are required to develop new biomanufacturing processes and facilities. A predictable regulatory environment is crucial for the success of synthetic & engineering biology, but current regulations often lag behind technological advancements, creating barriers for new products.

Developing a skilled workforce is essential to support the growth of synthetic & engineering biology industries, and collaborations between educational institutions and industry need to be encouraged to align training with market needs.

The summit identified a gap in public awareness and the need for better engagement strategies. Public perception and acceptance of synthetic & engineering biology are critical for its successful deployment, and there is a necessity for ongoing education and effective communication strategies to demystify synthetic & engineering biology and its benefits.

Given the climate crisis, there is an urgent need to accelerate the commercialisation of synthetic & engineering biology technologies at sufficiently large scale, as traditional sectoral evolution will not meet this urgency.

The summit underscored the importance of international collaboration and the need for innovative approaches to scale synthetic & engineering biology technologies, enhance public engagement, and develop supportive regulatory and training frameworks.

Summary of Recommendations

To address identified challenges affecting the development and uptake of synthetic & engineering biology technologies for climate and the environment, we propose the following recommendations for Government, industry and the entire innovation ecosystem.

Our recommendations for **Government** are:

- Improve the financial landscape and provide direct support where possible to enable scaling of synthetic & engineering biology technologies.
- Emphasise and communicate to the public the challenges, limitations and detrimental impacts of existing manufacturing processes in order to drive public awareness and acceptance of synthetic & engineering biology.
- Ensure clear regulatory pathways and adapted regulatory guidance are created by working cross-regulators and with industry.
- Support vocational training routes into synthetic & engineering biology, including technical and bioprocessing skills.

Our recommendations for **industry** to drive the scaling of synthetic & engineering biology technologies are:

- Investigate novel mechanisms for manufacturing unlike those used in the petrochemicalbased industries.
- Consider modular and data-rich scale-up models as well as manufacturing at the point of need
- Explore the use of mobile or semi-mobile equipment for scaling existing facilities.

Our recommendations for the entire **innovation ecosystem** are:

- Establish and/or contribute to a registry of relevant scale-up and downstream processing equipment nationwide to streamline access for scaling synthetic & engineering biology technologies.
- Recognise the shared responsibility to engage in dialogue with the public to drive public awareness and acceptance, through
 - Supporting studies of public attitudes in order to shape future public dialogue on new emerging synthetic & engineering biology technologies; and
 - Coordinating efforts across education, university outreach, and government support.
- Encourage the creation of a supportive regulatory environment by ensuring that regulators are given sufficient resources and appropriate support to review the innovations entering the market.
- Break barriers between academic and technical experts to foster exchange of knowledge, skills and talent.
- Increase the visibility of and encourage participation at synthetic & engineering biology competitions, including for technical apprentices.

Background

The Synthetic & Engineering Biology British-Swiss Summit is a collaborative venture between academic and industry leaders across the UK and Switzerland, organised by the <u>University of Bristol's BioDesign Institute</u>, the <u>Swiss Business Hub UK</u>, the <u>Bioindustry Association (BIA)</u> and Lucideon.

Designed to bring together diverse voices, the Synthetic & Engineering Biology British-Swiss Summit aimed to transverse geopolitical borders and foster dialogue on advancing synthetic & engineering biology — a field of strategic importance for both the UK and Switzerland — and ultimately identify routes to impact.

More than 25 representatives from British and Swiss universities, SMEs, startups, corporate organisations, Government, funding bodies and policy makers joined roundtable discussions at the Embassy of Switzerland in London in May 2024, to explore challenges and solutions affecting the development and uptake of synthetic & engineering biology technologies for climate and the environment. Parallel roundtable discussions were held focusing on two topics:

- Scaling synthetic & engineering biology for climate and the environment in a sustainable bioeconomy
- Public awareness and acceptability of synthetic & engineering biology

From these discussions, two cross-cutting topics emerged::

- Regulations and standards
- Skills and talent

The resulting recommendations align with the <u>Memorandum of Understanding</u> signed in November 2022 between the two countries, which aims to "encourage cooperation in 'deep science' and 'deep tech' (including life science), as well as commercialisation through innovation, and policy and diplomacy in science and innovation."

What is synthetic & engineering biology?

Synthetic & engineering biology is a powerful enabling technology that underpins much of modern industrial biotechnology today. At its core, it involves the manipulation of biological building blocks including nucleic acids (DNA/RNA) and proteins with the aim of designing and engineering biomolecules or biosystems with new or improved biological functions.

The universal nature of the genetic code and other biological building blocks across species means that the synthetic & engineering biology toolkit can be applied across many sectors. Synthetic & engineering biology is increasingly being leveraged to address some of the biggest challenges society faces. It is being applied to healthcare (e.g., novel diagnostics and therapeutics), what we eat (e.g., alternative and cultured proteins), the clothes we wear (e.g., textile fibres originating from engineered microbes), how we build our homes and workplaces (e.g., mycelium-based construction materials with enhanced carbon capture technologies), and even the way we travel (e.g., mobility powered by sustainable bio-based alternatives). Innovative companies powered by synthetic & engineering biology are also addressing urgent challenges, such as environmental pollution and waste, and the climate crisis.

Case study: <u>Phycobloom</u> is developing microalgae for oil production, which can serve as a biofuel or as a feedstock for other products. Their long-term vision involves engineering microalgae to secrete oil, simplifying the harvesting process compared to traditional methods. Phycobloom's technology holds significant potential for reducing greenhouse gas emissions by replacing fossil fuels with algae-derived oil.

Synthetic & Engineering Biology in Switzerland

Switzerland is dedicated to research and innovation. According to the Federal Act on the Promotion of Research and Innovation, the Confederation aims to encourage scientific research, science-based innovation, support the analysis and exploitation of research results, ensure cooperation between research bodies and the economical and effective use of federal funding for scientific research and science-based innovation. Synthetic & engineering biology falls under this type of research and innovation.

Synthetic & engineering biology is being developed by leading academic institutions such as the Swiss Federal Institute of Technology Zurich (ETH) and École Polytechnique Fédérale de Lausanne (EPFL), and supported by key pharmaceutical corporations such as Novartis. The Swiss Innovation Parks across the country support research and development, including synthetic & engineering biology focused startups and SMEs.

Synthetic & Engineering Biology in the UK

In the UK, focus has largely transitioned from "synthetic biology" to "engineering biology": synthetic biology describes the field of science focused on building new biological systems, while engineering biology captures the entire innovation ecosystem, including advances in synthetic biology research, as well as its translation, commercialisation and application.

Engineering biology is one of five critical technologies prioritised by the UK Government, in which the UK could be world leading, including in associated areas of regulation, standards, and responsible innovation.

The <u>National Vision for Engineering Biology</u> outlines the UK Government's £2bn plan to have a broad engineering biology ecosystem that can develop and commercialise the opportunities that come from the technology and the underlying science across a range of sectors. This builds on a decade of strategic investment in synthetic & engineering biology across the UK, including most recently an investment of £73 million in <u>engineering biology missions hubs and awards</u> to pull through new applications to tackle global challenges.

Realising the biorevolution

The emergence and use of these novel biotechnologies is often referred to as the biorevolution, which drives the creation of a sustainable bioeconomy. In 2020, McKinsey estimated that the 'direct annual global impact of the biorevolution could be \$2 trillion to \$4 trillion in 2030-40', while the Boston Consulting Group reported in 2022 that by the end of the decade, synthetic & engineering biology could be used extensively in manufacturing industries that account for more than a third of global output, or just under \$30 trillion in terms of value.

Significant obstacles must still be addressed so that lab scale synthetic & engineering biology solutions can more efficiently translate out of the lab at scale and deliver meaningful impact. Multiple factors risk holding back the biorevolution. Challenges include an immature or uncertain regulatory environment, lengthy product development timelines and high costs to commercialise, lack of established business models and go-to-market strategies for novel products, as well as varying levels of public awareness and perception regarding the opportunities and risks of synthetic & engineering biology with regards to solving societal challenges (Deep Biotech Report).

Established industries may struggle to change their operations to incorporate bio-based processes and solutions, which, due to their early stage of development, may be less economically competitive with both existing industries and consumers for the time being. Building consumer confidence in the use of complex technologies takes time, and regulators and policymakers are challenged to create an environment conducive to supporting existing and emerging innovative companies in this space and enabling the far-reaching uptake of their products. In addition, there could be too few private investors with the expertise and risk appetite to support the development of cutting-edge technologies and innovative companies essential to the commercialisation and success of synthetic & engineering biology.

It is possible to conceive of a future where synthetic & engineering biology can deliver high-impact commercial solutions that are less carbon intensive, resource restorative and sustainable by design. In a world where we remain disproportionately dependent on carbon-intensive chemicals for everything from our clothes and medicines to energy and fertilisers, such alternatives are crucial

Discussion topics, reflections and recommendations

Discussion topic 1: Scaling synthetic & engineering biology for climate and the environment in a sustainable bioeconomy

Synthetic & engineering biology plays a central role in the development of a sustainable bioeconomy, as it allows us to promote economic development by deploying tools and techniques that aid us in managing resources efficiently and sustainably.

However, three major constraints are preventing synthetic & engineering biology applications from becoming mainstream: cost, an absence of clear regulatory pathways, and the limited availability of biomanufacturing capacity. How can these challenges be overcome, and what are the existing solutions in the UK and Switzerland?

Reflections:

• Scaling synthetic & engineering biology technologies for non-health applications depends on creating efficient, low-cost systems at scale. This is currently a costly endeavour that has only been feasible for niche, high-value products.

Case study: Hyaluronic acid (HA) for example, a \$10 billion skincare ingredient which was originally derived from animal sources, is now produced commercially through fermentation. A recent World Economic Forum report highlights that innovation around new forms of HA are improving product functionality, and recent breakthroughs in HA bioprocessing led to a 91% reduction in environmental impact (based on cradle-to-gate Life Cycle Assessment).

- Unlike traditional industries with established, cost-efficient manufacturing processes, new biomanufacturing requires significant investment, skilled personnel with relevant bioprocessing expertise, and suitable downstream processing and scaling facilities, which are currently lacking or have limited capacity.
- Given the climate crisis, there is a sense of urgency to translate and commercialise synthetic & engineering biology technologies. Waiting for natural sectoral evolution to drive down costs will not address this urgency.

- Current value chains favour drop-in substitutions that are competitive on price and performance, creating a Catch-22 for synthetic & engineering biology: achieving economies of scale is necessary to compete on price, but scaling up is difficult with more expensive bio-sourced products.
- Alternative solutions, including leveraging existing facilities abroad (such as the <u>Bio Base Europe Pilot Plant</u>) or exploring unconventional fermentation venues like breweries, have been considered but present practical difficulties.
- Addressing these issues is critical for advancing these technologies and overcoming the 'Valley of Death' between innovation and commercialisation.

Recommendations:

Government: Seek to improve the financial landscape, providing direct support where possible, as the cost of scaling up commercial synthetic & engineering biology outputs is currently very high.

Industry: Consider novel mechanisms for manufacturing synthetic & engineering biology products, moving away from scale-up models equivalent to those used in the petrochemical-based industries. These could include modular and data-rich models as well as manufacturing at the point of need.

Industry: Consider the use of mobile or semi-mobile equipment for scaling existing facilities, offering flexibility and enabling deployment across various geographic regions and time frames.

The entire innovation ecosystem: Establish and/or contribute to a registry of relevant scale-up and downstream processing equipment nationwide, and streamline access to necessary facilities within a geographical area.

Discussion topic 2: Public awareness and acceptability of synthetic & engineering biology

Like many emerging technologies, applications of synthetic & engineering biology will create public benefit but also have the potential to generate societal, health and environmental risks, so there is a need for continuous engagement with the public throughout their development.

How can we demonstrate to the public that synthetic & engineering biology is an important tool especially with regards to the climate and environment challenges the world is facing?

Reflections:

- Awareness of synthetic & engineering biology is low among the general population.
 Challenges for public understanding include the high complexity and interdisciplinary nature both of the field itself, and the ethical and societal questions resulting from it.
 - » Making false or misleading claims about a product's positive environmental impact ('Greenwashing') creates distrust and scepticism.

- Public resistance can be rooted in habits, costs, values, and cultural influences. Communicating benefits of new technologies, including entirely novel benefits, can drive appetite for change.
- Public attitudes towards and therefore acceptance of synthetic & engineering biology vary widely across different technologies, generally based on perceived risks versus benefits.
 - There is broad acceptance of synthetic & engineering biology technologies where there is clear and direct personal benefit to the consumer. This includes healthcare, and technologies enabling consumers to maintain current lifestyles (such as alternative fuels).
 - Sontrary to that, acceptance in the food sector is lower due to the lack of perceived urgency in regions with good food security, and the initially polarised media conversations around the safety of genetically modified food products.
 - Equally, support drops significantly for environmental applications with no immediate personal benefit, coupled with a perceived risk of environmental release.
- Public acceptance is crucial for long term success of any new technology.
 - Public consultations are an excellent mechanism to engage in longitudinal dialogue with the public, gauge opinion, reflect and respond to concerns, and ultimately drive towards impactful, acceptable innovations.

Case study: In the UK, a <u>public consultation</u> formed part of a 17 year review process regarding the ethics of mitochondrial donation, which can give some women with mitochondrial DNA disease the opportunity to have a healthy child that is genetically related to both parents. This involves a 'third parent' donating healthy mitochondria to the baby. Following public dialogue, consultations and reviews, the procedure was approved by the UK's Human Fertilisation and Embryology Authority (HFEA) in 2016.

- Engaging in dialogue with the public as early as possible allows for concerns to be identified and addressed alongside technology development, and will ultimately accelerate momentum towards acceptance.
- Access to technical information can be difficult for those seeking to educate themselves.
- Storytelling is a key method for conveying these messages, with successful case studies demonstrating its effectiveness.
- Using gateway applications like fashion can help the public feel more familiar and comfortable with synthetic & engineering biology, both by increasing exposure and also by demonstrating real-world, every-day products rather than just concepts or invisible, high-end products and processes.

Case studies: Switzerland-based <u>Climeworks</u>, a carbon capture & sequestration company, uses the CO2 it captures for carbonated beverages and as a fertiliser for tomatoes and cucumbers. UK-based <u>Tropic Bioscience</u> made bananas more resistant to a deadly fungus that is threatening the whole banana industry in the Americas.

Recommendations:

Government: Consider playing a part in focusing efforts towards emphasising the challenges, limitations and detrimental impacts of existing technologies that synthetic & engineering biology is poised to positively disrupt, and communicating this to the public.

The entire innovation ecosystem: Recognise the shared responsibility to engage in dialogue with the public.

Collaboration between universities and media can be explored to enhance public dialogue on synthetic & engineering biology. Determining who should lead these efforts is essential, and will require coordination across education, university outreach, and government support.

The entire innovation ecosystem: Consider getting involved in conducting studies of public attitudes towards synthetic & engineering biology. In the UK, this can build on the ongoing review of how public engagement has been conducted for synthetic & engineering biology historically. The results can then help shape future dialogue and communications with the public on new emerging synthetic & engineering biology technologies.

Cross-cutting discussion topic 1: Regulations and standards

A predictable, forward-looking regulatory environment is essential for the success of emerging companies. Synthetic & engineering biology involves complex and emerging technologies that often span multiple scientific disciplines. Regulators may lack the specific knowledge and frameworks required to effectively assess these new products. Existing regulatory frameworks are often based on older technologies and may not be suitable for the novel characteristics of synthetic & engineering biology products. This can result in a lack of clear guidelines and standards for innovators to follow.

Reflections

- Synthetic & engineering biology solutions can be subject to outdated regulations that have failed to keep up with the pace of developments in innovative biosolutions. This is delaying the adoption of the green transition.
- Many synthetic & engineering biology products fall between the scope of regulators or within regulations that are not fit-for-purpose.
- The UK is currently undertaking a series of 'Regulatory Sandboxes' to develop plans for pro-innovation regulatory reform and encourage business innovation and investment.
- Regulatory convergence vs. divergence from the EU and other key international markets
 has benefits and disadvantages. While convergence helps the ease of business in
 bringing products to market, divergence from outdated regulatory frameworks can
 create a competitive advantage.

- Relevant standards and metrics are required to accelerate commercialisation of synthetic & engineering biology. They should be supportive rather than restrictive, and focus on risk management rather than risk elimination.
- There is a need for international collaboration and harmonisation with regards to implementing new standards for synthetic & engineering biology.
- There are unique challenges in developing standards for bio-based technologies that may include higher degrees of variability.
 - » ISO standards are perceived to not be adapted as quickly as new technological developments emerge.

Recommendations:

Government: Support regulators to create safe and clear regulatory pathways, and work cross-regulatory bodies and with industry to build understanding, and support commercialisation of synthetic & engineering biology products.

Government: Support regulators to provide adapted and updated regulatory guidance to suit novel synthetic & engineering biology products and processes, taking aspects of flexibility and adaptability into account.

The entire innovation ecosystem: Ensure that regulators are given sufficient resources and appropriate support to review the innovations entering the market and assess whether they are equipped to regulate them. technologies.

Cross-cutting discussion topic 2: Skills and Training

Synthetic & engineering biology demands a workforce equipped to work across disciplinary boundaries, able to embrace emerging digital and data-centric approaches, and with entrepreneurial expertise to support research, product development, and commercialisation.

Skilled professionals, such as process engineers and fermentation scientists, are essential for translating research into commercially viable products, as they design, maintain, and operate scale-up production facilities.

Reflections

- Access to scale up facilities is not the only blocker to accelerating the commercialisation
 of synthetic & engineering biology technologies. There is also a pressing need for
 people to be trained to be able to support scale up and bioprocess engineering.
- Interdisciplinary training (including beyond synthetic & engineering biology) needs
 to take place much earlier than at PhD level, by providing education across the
 sciences rather than siloed into individual scientific subjects, and ideally combined with
 entrepreneurial training.

• The International Genetically Engineered Machine competition (iGEM) is influential in synthetic & engineering biology communities. It serves as an excellent model of the team science approach that is synonymous with the field, bringing together multidisciplinary teams, including those with entrepreneurial skill sets.

Recommendations:

Government: Encourage and support higher education providers to offer more vocational training routes into synthetic & engineering biology, including a focus on technical skills provided as part of undergraduate degrees, as well as routes into bioprocessing from outside of universities.

The entire innovation ecosystem: Break barriers between academic and technical experts to foster exchange of knowledge, skills and talent. This is exemplified in different models, for example the innovation ecosystem across Bristol, Imperial College's White City campus, and the EPFL Innovation Park.

The entire innovation ecosystem: Promote and support participation in synthetic & engineering biology competitions, such as the international Directed Evolution Competition (<u>iDEC</u>), Global Open Genetic Engineering Conference (<u>gogec</u>), and <u>iGEM</u>, and specifically explore routes for technical apprentices to participate in these.

Concluding remarks

This report delves into two of the most pressing challenges for advancing synthetic & engineering biology technologies addressing climate and environmental issues, and poses specific recommendations to governments, industry and the entire innovation ecosystem to act upon. It was informed by roundtable discussions held at the Synthetic & Engineering Biology British-Swiss Summit.

The report is intended for a variety of stakeholders with the aim to move forward joint Swiss and UK challenges in the field of synthetic & engineering biology, and – in light of the climate crisis – emphasise the urgent need to accelerate the commercialisation of these technologies.

Annex 1: Summit delegates

Name	Affiliation	Country
Mariluz Bagnoud	Agroscope	СН
Steve Bates	BioIndustry Association (BIA)	UK
Linda Bedenik	BioIndustry Association (BIA)	UK
Maddie Cass	BioIndustry Association (BIA)	UK
Lionel Clarke	BioenerG	UK
Frederic Coulon	Cranfield University	UK
Jack Dury	PolicyBristol	UK
Neil Goldsmith	Baselaunch	CH
Thomas Gorochowski	University of Bristol	UK
Edward Green	Chain Biotech	UK
Ramdane Haddouche	Croda	UK
lan Hu	Phycobloom	UK
Kerstin Kinkelin	University of Bristol	UK
Tony Kinsella	Lucideon	UK
Harris Luk	Sulzer	CH
James MacDonald	Solena Materials	UK
Rowan McKibbin	BBSRC/UKRI	UK
Angela McLean	Chief Scientific Adviser to the UK Government	UK
Holly Reeve	HydRegen	UK
Serina Robinson	EAWAG	CH
Kathleen Sedgley	University of Bristol	UK
Anike Te	Lucideon	UK
Yiea Wey Te	Member of the Parliament of Canton Zurich	CH
Natalie Thomas	Swiss Business Hub UK	CH
Isabel Webb	Department for Science, Innovation and Technology	UK
Meng Zhang	Hub for Biotechnology in the Built Environment	UK











