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Standards and metrics for Engineering Biology in the UK

Driving growth, investment and Engineering Biology powered solutions for UK companies

December 2024

Foreword

The potential presented by Engineering Biology (EngBio), both globally and for the UK, is difficult to overstate. Realisation of this potential across sectors as diverse as health, energy, materials, chemicals production and waste management, will be achieved by providing the right tools to help companies of all sizes as they innovate and translate those innovations to commercial production scale.

Recognising the vital role of the SME ecosystem, working with established players, this workshop was convened to identify and begin to prioritise, the right technical standards, tools and metrics, needed to smooth the path to EngBio driven growth and investment in the UK. The development and delivery of the standards, metrics, measurement systems and analytical capabilities required, must keep up with the pace of innovation in EngBio. We need a rapid and iterative way of drawing on the knowledge and expertise available in the EngBio ecosystem, and in adjacent technologies, to ensure there is a recognised path to providing the tools required. This will require an accelerated way of working and doing so alongside the well-established and traditional approach to standards development, which remain vital. It is important that the UK continues its global leadership within the international standards ecosystem, supported by complementary activity to develop and implement guidance and other tools needed to grow UK EngBio companies – and to do so at pace.

Standards and metrics that enable collaboration to address pre-competitive challenges can accelerate innovation and its translation, ensuring the UK continues its science leadership as we usher in the next technology revolution built on biology. The impact of these technologies will be felt across almost every sector of the global bioeconomy, and the UK is in an enviable position to continue development of the ecosystem, through ongoing collaboration and delivery of tools required for the full potential of innovative solutions to be realised.

We recognise the scale of the challenges and opportunities presented. This report does not provide or seek to deliver a single source of all priority technical standards, metrics, tools, actions and recommendations required across the UK EngBio ecosystem. Instead, it addresses the goal of prioritising initial requirements by collating needs and recommendations recognised by industry, large and small. The

emphasis centres on enabling earlier stage organisations to scale their operations more quickly, to attract investment and to find a clear path to regulatory compliance, commercialisation and growth. The report delivers on this ambition, providing a platform from which we can continue to build on the opportunities presented. Enabling EngBio innovation and technology translation for the UK will drive clean growth, develop new and valuable products, reduce reliance on fossil fuel driven manufacturing, and address major global challenges across health, food security and mitigation of our changing climate.

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Table of Contents

Introduction

Engineering Biology is a globally transformative platform technology that can disrupt multiple application sectors and industries. Recognising its importance, the UK government has created a 10-year National Vision for Engineering Biology[1], which is focused on the key areas of:

- Economic growth
- World-leading R&D investment
- Regulation and standards
- Skills and infrastructure
- Responsible and trustworthy innovation.

This workshop was convened to bring together a representative group of UK Engineering Biology (EngBio) stakeholders from industry, industry associations, standards experts, public funding agencies, the UK measurement system, the UK catalyst and infrastructure network and academia. The goals of the workshop centred on identifying priorities and resourcing, for appropriate technical standards, tools and metrics to help smooth the path to innovation and growth for UK companies of all sizes.

Standards and metrics can support innovation, accelerate its translation and scale up, and mitigate issues associated with reproducibility and comparability of data. Standards can help investors understand risk and support development across all stages of the product lifecycle. They play an important role in helping entrepreneurs and manufacturers alike to demonstrate the control, efficacy, safety and reliability of their products, processes, or technologies. The standards developed will also support regulatory compliance, enable manufacturers to demonstrate performance, and when made available to industry, will underpin global supply chains, helping to ensure the interoperability of biological parts and processes.

[1] UK National Vision for Engineering Biology, Dec 2024. https//assets.publishing.service.gov.uk/media/656de8030f12ef07a53e01ac/national_vision_for_engineering_biology.pdf

It is important to recognise that the outputs of the workshop complement other initiatives taken to promote the development of standards and metrics for Engineering Biology[2]. Delivering the goals of the workshop will help to realise the potential of EngBio enabled solutions in the UK and bring us a step closer to the transition away from fossil-fuel dependent production systems and move towards a circular bio-based economy.

The nature of EngBio, and the broad sector scope for its application, creates complexity in addressing requirements for standards and metrics. Despite this challenge, the workshop identified a number of priority areas and actions as the next steps in developing EngBio standards and metrics. UK Government, through the National Vision for Engineering Biology, has set out the scope of ambition and priority areas for transitioning the UK to a more bio-based economy. In this report we seek to support realisation of this vision and the potential of EngBio to deliver on ambitions for climate change mitigation and significant economic growth for the UK.

> "The vision for this space is that a company with a great idea can come to market without technical and regulatory barriers. The right standards and metrics will make the process of establishing and growing a company easier – but there is a need for consensus and an open process to establish easily accessible knowledge bases that smooth the path for EngBio companies, innovators, entrepreneurs and investors."
>
> Professor Paul Freemont, Imperial College London

[2] The following two documents represent key examples of the work this workshop builds on: Engineering Biology Metrics and Technical Standards for the Global Bioeconomy; UK vision for Engineering Biology

Focus areas for this workshop

Recognising the convergence of technologies across engineering, physical, biological, chemical and data science that are enabling EngBio and the implications and opportunities this brings for standardisation and metrics, the workshop sought to deliver four main objectives:

1. Identify the areas of focus for the delivery of standards and metrics in EngBio, given the resources available for these activities.
2. Understand which types of standards are required (see section on Defining standards) that will deliver short and long-term benefits and impact to the UK's EngBio ecosystem.
3. Understand resources required and the sources of funding available to support development and implementation of standards and metrics for UK EngBio companies.
4. Agree next steps in the standards and metrics development process in the UK.

Ahead of the workshop, delegates were asked to rank suggested key areas that might be considered for standards and metrics development, as well as invited to propose additional areas for consideration. This information helped to provide an initial understanding of what the priority areas in the UK might be. Those topics were then designated as focus areas for breakout group discussions and included:

- Scale-up and scale-out
- Data and AI-driven system design and quantifying biological processes
- Life-cycle assessment (LCA) for engineering biology
- Biomass feedstock characterisation.

Delegates also recognised a number of additional areas for consideration including:

- Regulatory frameworks
- Education, skills and training
- Supply chain interoperability
- Funding and resources
- The role of metrology.

Summaries of discussions for each topic area are provided in this report. These include how the right standards and metrics would accelerate cross-sector growth and commercialisation, what those standards would look like, what are the existing issues for standards development and proposing recommendations for next steps.

It is important to note that while the focus of workshop discussions was centred on technical standards and metrics, there are wider general standards developed nationally and internationally that also have an important role to play in enabling companies to be successful at all stages of development. Learning from this wide range of existing standards where relevant, and ensuring links to others internationally, will be essential in delivering a vibrant, UK EngBio ecosystem.

Figure1: Examples of broad sector scope impacted by Engineering Biology as a platform technology

Areas outside the scope of the workshop

1. Although part of the overall workshop discussions, EngBio health applications were not prioritised, given that many regulatory approval processes for the health sector are already well developed.
2. Areas around biosecurity and nucleic acid synthesis screening were also not included as these are being addressed elsewhere - for example the recently published UK Screening Guidance on Synthetic Nucleic Acids[3].

[3] https://www.gov.uk/government/publications/uk-screening-guidance-on-synthetic-nucleic-acids/uk-screening-guidance-on-synthetic-nucleic-acids-for-users-and-providers

1. Table 1: Summary of key recommendations

Nine key recommendations arose from workshop discussions and are summarised below. Further details and context are provided in the Discussion Group Summaries section of the report. While some recommendations apply to specific topic areas, others are cross-cutting, being necessary and beneficial across multiple EngBio processes and applications. These are highlighted in the **Topic alignment** column of the table below. Recommendations are not listed by any order of priority. Instead, they highlight agreed priority actions required to establish the right technical standards and metrics to support a vibrant and fast-growing UK EngBio industry.

Recommendations	Actions	Topic alignment
Good Practice Guide for Scale-up / Scale-out	**Establish an accessible Good Practice Guide as a tool for early-stage innovators.** This should include the key metrics and potential pitfalls to be considered early in development, such as: • Options for characterisation of scaled-down EngBio building blocks and system data to be assessed in developing translation strategies to a scaled-up / scaled-out process. • Approaches to assess requirements for downstream processing - Which can account for more than 60% of process costs. While less directly relevant to the standards and metrics discussions, it was recognised that any guide produced would benefit from inclusion of a review and summary of existing UK scale-up infrastructure.	• Scale-up / Scale-out • Regulatory frameworks • Metrology
Agreed vocabulary (lexicon)	**Work with national and international stakeholders to develop an agreed vocabulary across the sector.** For all stages of the development - downstream to upstream - key metrics and measurand descriptors can enable the effective integration of AI approaches to scale-up modelling. To support data and AI-driven system design, we need to establish priorities and terms needed to allow the most effective integration of AI and ML algorithms into EngBio process design and its translation at scale.	• Scale-up / Scale-out • Data and AI-driven system design • LCA • Regulatory frameworks • Metrology

Recommendations	Actions	Topic alignment
Reference standards for DNA and cell system metrics	**Development of tools for biosystem characterisation.** Establish reference materials for characterisation of biological systems, including key DNA and cell system metrics with necessary traceability and validated through interlaboratory comparison, to enable interoperability and confidence in analytical data for EngBio building blocks and ultimately, enable greater efficiency in scale-up.	• Data and AI-driven system design • Metrology
Data standards and ontologies	**Assess existing data standards and establish a set of clear standards on data sourcing and formatting**. For LCAs, this will help to ensure that data input is reliable and comparable. Develop use case ontologies for bioprocesses that support the development of digital twins for use in system design.	• LCA • Data and AI-driven system design • Metrology
Open repository / sharing platform	**Establish an open sharing platform** where EngBio industry players can share experiences, highlight pain points, and access guidance and reference materials. This would be especially helpful in enabling start-ups and SMEs to overcome barriers. For example, the platform would allow sharing of LCAs that have been tried and tested with different EngBio applications. This would also act as a hub that collates relevant regulatory guidance for the key sectors.	• LCA • Biomass feedstock characterisation • Scale-up / Scale-out • Data and AI-driven system design
Test case-studies for LCA	**Develop a test LCA** that can be applied to varying EngBio companies as case studies. This will allow industry to test the LCA for EngBio applications, providing critical analysis and feedback on the relevance and identifying issues. Industry players should develop and define the list of characteristics needed for an EngBio LCA.	• LCA
Map of UK biomass availability	**Assess and map the up-to-date availability of biomass in the UK**, to be linked to overall international availability and accessibility.	• Biomass feedstock characterisation
Biomass specification sheet	**Develop a standardised specification sheet outlining the key attributes of biomass feedstocks** that are relevant for uses in EngBio and easily assessed. Such specifications would include composition criteria, organism compatibility, inhibitors and non-fermentable parts, and any preprocessing conditions.	• Biomass feedstock characterisation
Regulatory guidance materials	**Develop clear, accessible regulatory pathway guidance** including for example, roadmap summaries, to allow industry to navigate and gain approvals for products to be brought to market. Such materials require expertise sharing between industry and regulators, to ensure guidance as well as regulations are relevant and applicable. A clear route to dissemination and access will need to be part of this activity.	• Regulatory frameworks • Metrology

Current Landscape for Standards in Engineering Biology

Defining standards

A ‘standard’ is often something used as a measure, norm, specification or model in comparative evaluations. Standards[4] make use of metrology, metrics and measurement and may take many different forms including written guidelines, analytical methods, physical reference materials, calibrants, a measurement standard, an agreed vocabulary, specification or description of a process or methodology. In the case of internationally agreed documentary standards, these guidelines may serve to help ensure safety and a more consistent and reliable product, service or technology. However, standards are not always used in comparative evaluation. For example, they may be used simply to define good practice within an organisation, for example management system standards which seek simply to raise the bar of performance within an organisation.

A physical measurement standard (an etalon), such as a certified reference material, is used as a reference and is the realisation of the definition of a quantity with a stated value and associated measurement uncertainty. These reference materials play a vital role in providing confidence and comparability of analytical data across different measurement techniques or technologies. Whereas a documentary standard (sometimes called a norm), such as an ISO standard[5], can include a definition of terms; classifications of components; specification of dimensions, materials, processes, products, systems, or practices; test and sampling methods.

Existing published standards relevant to Engineering Biology

The EngBio community has long acknowledged the lack of relevant standards and metrics of different types that apply directly to the field. Existing standards that are applied are typically adapted from parallel sectors, such as the food or pharmaceutical industry. Physical standards used to measure and control biological systems, continue to lag behind those developed for other scientific applications. Standards developed in other sectors and applied in EngBio are not always

[4] Standardisation explained: Standardisation - GOV.UK
[5] https://www.iso.org/standards.html

appropriate and not sufficient to support this highly innovative and fast-growing sector.

The limited number of published standards highlights the issue being addressed by this workshop and discussed throughout this report: **the need for specific and open-source engineering biology standards and metrics to enable commercialisation and sector growth.** As described above, a key objective of the workshop was to begin prioritising the specific standards needed to enable UK EngBio companies to grow, thrive and attract the investment needed to realise the potential of the solutions they offer.

The International Organization for Standardization (ISO) currently comprises over 170 national standards bodies, who collaborate to draft voluntary, consensus-based international standards. The most relevant set of international standards to EngBio is the Technical Committee for Biotechnology (ISO/TC 276[6]), which has 37 published standards at the time of writing with others in development. The scope for these standards under the field of biotechnology covers terms and definitions; biobanks and bioresources; analytical methods; bioprocessing; data processing; and methodology.

On a national level, the British Standards Institution (BSI) develops and publishes standards for the UK, working closely with expert panels in the drafting stage, and incorporating public consultation. Most relevant to EngBio is the Technical Committee on Biotechnologies (BTI/1 – Biotechnologies). This committee feeds directly into international efforts, including ISO/TC 276 and CEN/TC 233 (European Committee for Standardization committee on Biotechnology).

[6] https://www.iso.org/committee/4514241.html

In-house standards

Standards can also be developed in-house, as controls for a specific system or process. These standards, most often physical reference materials[7] or calibrants, may be developed from a traceable, externally provided standard with certified measurement parameters, and are used for the routine assessment and assurance of product or raw material attributes or system suitability. A company's Standard Operating Procedures (SOP) may also be considered as another type of standard and used to describe a specific process, methodology or specification which must be adhered to.

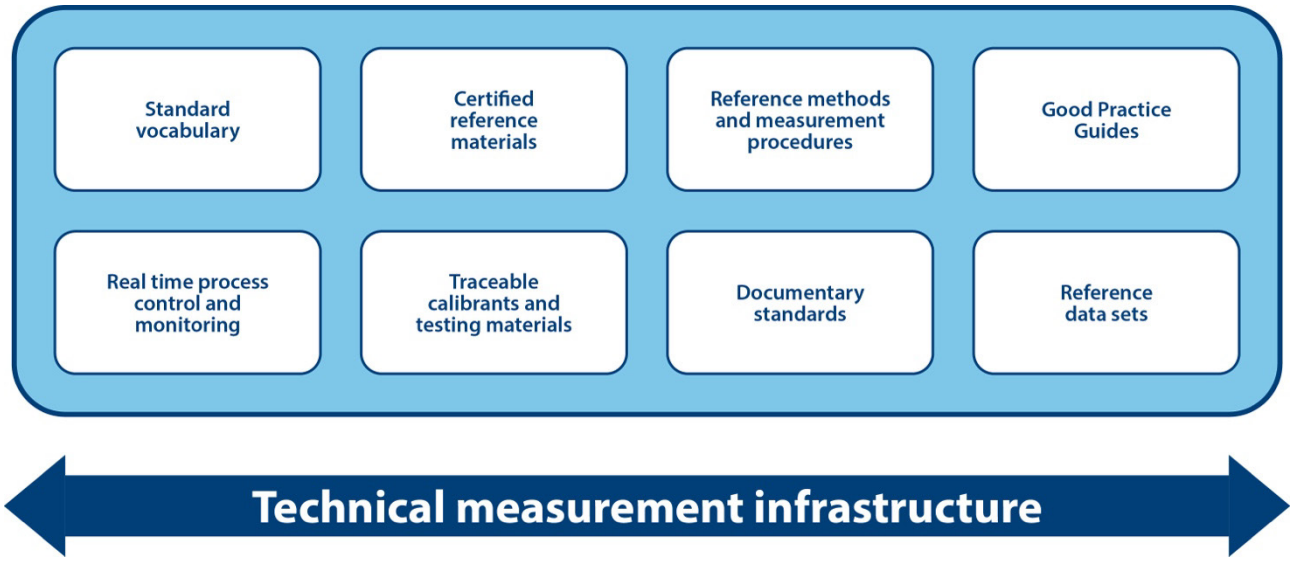

Figure 2: Examples of different types of standards impacting Engineering Biology. Standards come in many forms, from internationally agreed documentary standards to reference materials or internal best practices. Within the EngBio ecosystem, standards are underpinned to a large extent by the technical measurement infrastructure.

[7] See ISO General requirements for the competence of reference material producers: https://www.iso.org/standard/29357.htm

Value of Standards to the Engineering Biology Ecosystem

The right standards and metrics directly support innovation, accelerate its translation and scale-up, and help mitigate issues associated with reproducibility and comparability of data. Standards and metrics, underpinned by appropriate and traceable measurements, support all stages of the product lifecycle and help assure raw material suitability. Standards, in each of their different forms, provide vital tools for users to demonstrate process control vital to efficient scale-up strategies, to ensure the suitability of process inputs, enable the assessment of end product quality, and in many cases to demonstrate adherence to regulatory requirements. In short, they help reduce risk through demonstrable control of inputs, processes and outputs.

Local and global benefits of standards and metrics

Standards can also have a geographical and/or sector specific dimension. They may be developed and adopted locally, nationally or internationally through organisations such as the BSI in the UK, the European Committee for Standardization (CEN) in Europe or ISO globally. These organisations play key roles in providing documented standards which are agreed through consensus and independently validated specifications and methods. While internationally agreed documentary standards may take years to approve, measurement standards, materials, tools, methods and good practice guides are developed for specific challenges, enabling faster access for industry looking to navigate their often-early stage, fast developing technology landscapes.

A key value driver and a recognised priority of the EngBio community, as identified by delegates from this workshop, is the need to ensure the interoperability of EngBio supply chains. As ‘biological parts’ are increasingly part of global manufacturing systems, the integrity and suitability of different elements of the process must be underpinned by traceable measurements to ensure supply chain suitability and integrity. This theme is prevalent throughout each of the discussion areas presented below, from the characterisation of biomass used to power bio-based manufacturing,

to the understanding of life cycle assessments and demonstrable assessment of the environmental impact of EngBio processes.

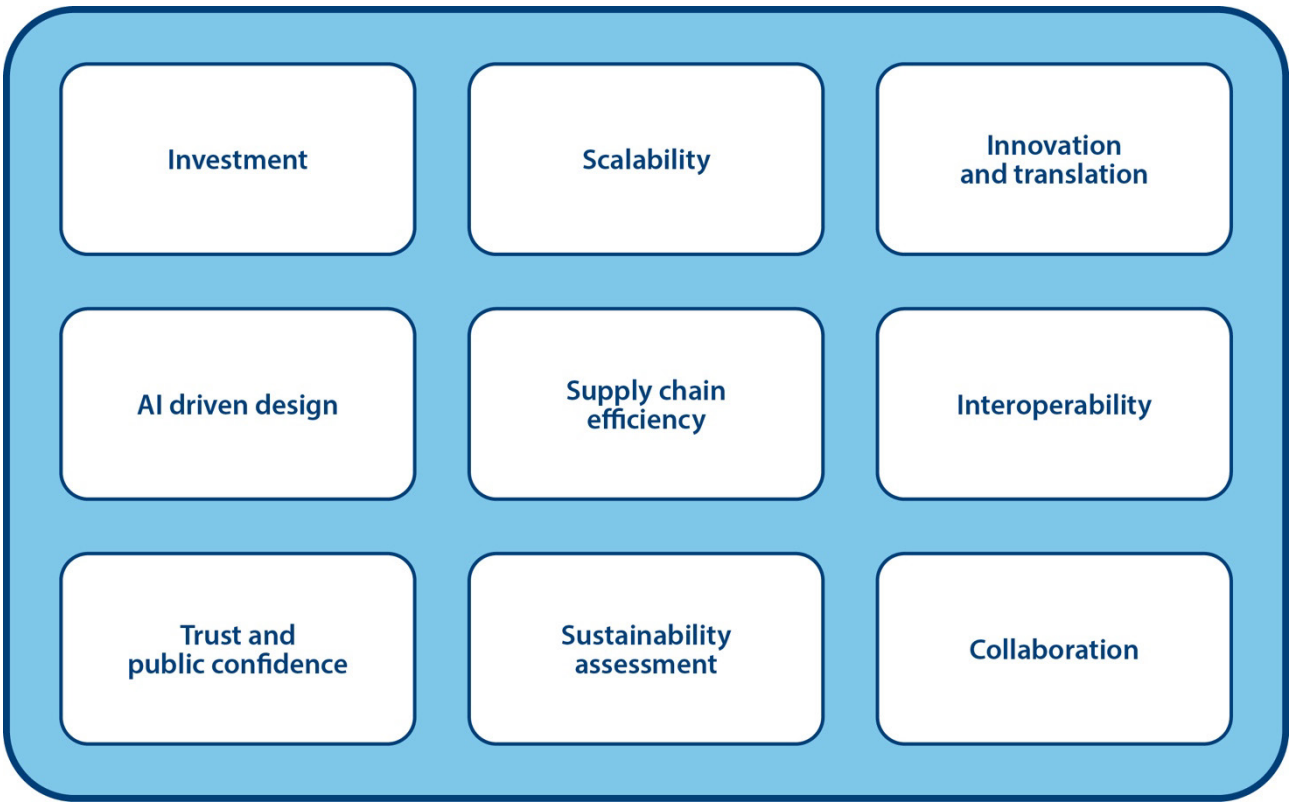

Figure 3: Example critical areas that are necessary for the growth and success of EngBio, that can be driven by the right standards and metrics.

Public confidence in Engineering Biology

Fostering public confidence and support for EngBio applications is essential to ensure sector growth. Delegates highlighted this as an important area within the UK, however this has also been a key area of discussion with regards to commercialisation of EngBio products globally. Building public confidence through transparency and traceability, as well as improved communication, will support growth and incentivise consumers to choose bio-made products. Standards and metrics have a key role to play, whether through the introduction of standard labelling to indicate products have passed a clear set of criteria to demonstrate safety and quality, or through an agreed vocabulary that can form the basis of clearer communication with the public. Product certification and the technical measurements and analytical methods that underpin them also have a significant role to play.

Regulation plays an important role in supporting public confidence. However, regulation needs to be relevant to the sector and provide guidance to industry. Setting the bar for regulatory approval in an unrealistic way not only feeds negative connotations of the sector but may discourage industry from remaining in the UK (see section on Regulatory Frameworks). The right testing and analytical methods, appropriately validated, will play a role in supporting regulation and in demonstrating compliance. Ensuring regulation is relevant and appropriate, and addresses quality and safety of products, will build consumer trust and confidence. It is also important to recognise that some existing standards and regulations will apply but are not always appropriate for novel elements of new bio-products. Novel bio-products may currently be subjected to compliance with existing standards developed for 'traditional' materials, but there needs to be consideration of what is new and how to regulate appropriately.

In an innovative sector such as EngBio where technology is developing rapidly, transparency is essential to build consumer confidence. Clear data standards and characterisation of specific applications, especially around AI and ML, will support wider understanding of the sector. Identifying key metrics that can be applied to demonstrate the safety and efficacy of a process or product will support consumer trust.

Discussion Group summaries

1. Scale-up and scale-out

How will standards and standardisation accelerate the efficient scale-up of early-stage innovation for Engineering Biology?

To realise the full potential of EngBio, and the solutions it will enable, requires the deployment of engineered biological systems at scale. The challenges of process optimisation are well recognised and while many larger companies in the sector are delivering scaled EngBio solutions with significant success, there are obstacles facing earlier stage companies in particular. These challenges, can at least in part, be mitigated through the adoption of the right standards, metrics and control parameters in the laboratory and during pilot scale development.

The UK has existing infrastructure to support scale-up solutions, but delegates recognised the need for ongoing investment – a challenge acknowledged in the Council for Science and Technology (CST) **Report on engineering biology: opportunities for the UK economy and national goals**[8]. Public sector organisations such as the Centre for Process Innovation and a range of private sector players have dedicated resources to deliver solutions to the scale-up of EngBio enabled manufacturing. There is a recognised need to continue developing this infrastructure and deliver the flexibility needed for process optimisation, using and applying a variety of biological systems and technologies. Realisation of the full potential of EngBio depends on access to the right infrastructure needed for successful scale-up, and investment in expanding the resources available to UK companies.

The wide-ranging applications of EngBio driven manufacturing does however present challenges. The scale-up of processes requires significant investment as a company begins to grow and to cross the “valley of death” translating their processes from earlier stage TRL’s. It is vital that early-stage companies can demonstrate predicted scalability of their technologies and processes to attract the right

[8] Prime Minister’s Council for Science & Technology (CST) Engineering Biology Report. https://www.gov.uk/government/publications/advice-on-engineering-biology/report-on-engineering-biology-opportunities-for-the-uk-economy-and-national-goals-html

investment and resources needed to move their innovations out of the laboratory and into pilot and production scale systems. The right standards and metrics are recognised as having a key role to play in helping mitigate the risks associated with driving scale in these approaches.

Addressing the challenges of scale-up also requires recognition of the links to the other areas of discussion described below, particularly the optimisation of biomass and the understanding derived characterisation in scaled down processes. Discussions included input that larger companies with greater resources often have existing expertise and know-how developed from investigations of failed approaches, often involving investigation of parameters at smaller laboratory scale. There was a broad discussion amongst the group on how to leverage that expertise in pre-competitive consortia to support early-stage standards development in scale-up. This group also recognised the opportunities to learn from standards and regulation within the healthcare sector; where understanding what makes biomedical applications so well-defined from target to discovery and development phase, through to the final drug or therapeutic application, helps drive success and makes investment in those industries more attractive.

Recommendations:

- Establish an accessible Good Practice Guide as a tool for early-stage innovators which includes the key metrics and potential pitfalls to be considered. This should include options for data to be assessed in developing an innovation translation strategy to scale-up, along with considerations for downstream processing and a review of the infrastructure available to UK companies in support of delivering their scale-up/ scale-out and downstream processes.
- Incorporate key metrics and measurand descriptors in an agreed vocabulary for scale down and the translation to scale-up to enable the effective integration of AI approaches to scale-up modelling.
- Convene an EngBio investor workshop (along with other sub sector focused events) to establish key risk drivers and requirements for investors in assessing risks associated with companies moving from early stage to pilot and production scale of emerging EngBio technologies – see also the reference to this workshop in the Biomass section below.

Specific challenges identified and discussion points recognised in the focus groups included:

- Many early-stage companies and investors need improved guidance on developing a process to allow efficient consideration of scalability and specific testing capabilities to identify which parameters to control and measure. The standards requirements which enable this will depend on the company's stage of development, and for those developing a truly novel approach, standardisation will present significant challenges.
  - The challenge was articulated that perhaps we are too early in the understanding of scaled manufacturing in bio-based systems to allocate resources to standardisation at this stage of the "sector's" life cycle.
- There is a recognised challenge in distinguishing between scaled up and scaled out processes. In some applications, it may be more appropriate to deliver scale across multiple sites rather than a single large-scale system, and this approach should also be considered when developing standards and control metrics.
- How do we enable greater pace for new innovations to become industry-ready faster? There is a need to focus on what to measure and consider specific process control parameters.
- Supply chain and systems interoperability is key and needs to be improved for EngBio systems.
- How organisms change over time is a key consideration in control of biological systems and fermentation. The efficiency of the cells or biological systems used in production needs to be monitored and controlled in a way that allows manufacturers to identify which cells are delivering the most efficient outputs, i.e., is this stable or changing, and what specific measurands can be investigated to identify changes early in the production process.
  - This further highlights the need for agreed testing regimes.
  - Many EngBio products and processes rely on recombinant products which would benefit from the right standards being in place to ensure they can meet future requirements.
- The scaling-up of processes cannot be divorced from downstream processing applications. We tend to focus on the fermentation and the upstream, but we also

need to consider the downstream as this can be over 60% of the costs (e.g., how are we going to purify our bio-product). We need to work with innovators at the beginning of the process to determine what their target is and what they're going to use it for; what is the environment it's going to be used in when developed.

- Measuring of trends rather than exact quantifications may be required (DNA would be difficult in this area).
- Having the right infrastructure and ensuring companies have access to it is important. Consider in healthcare, for example, you "don't need to build a hospital to demonstrate that your therapeutic is going along a pipeline".
  - There is recognition that an enabling infrastructure must already exist (in this case a healthcare system/hospital) that drives the pull through.
- Standards need prioritisation and investment of scale-up - good practice guides representative of a suite of materials and technologies, and usable reference materials. Flexibility must be built in and there is a recognised scale-up infrastructure that can be marshalled across the UK to deliver the necessary expertise.
- The role of AI systems in modelling from bench to pilot and manufacturing scale is key. There is also a link between AI, biological system characterisation and big data and ensuring the necessary data standards will play an important role. Identifying specific elements of fermenter design to consider early in development can help early-stage companies generate a clearer path to scale-up and generate the next stage investment and resources vital for growth.

"Optimising access to existing infrastructure, supported by ongoing investment in new facilities to enable the evaluation and development of scaled processes for EngBio are vital. The discussion on understanding the scaled down building blocks of EngBio-driven processes is also relevant and must be recognised as we look to understand and model processes in the lab and use those insights to deliver a more reliable approach in large volume manufacturing processes, whether that is in single large scale centralised manufacturing systems or scaled out processes where reproducibility is key and must be underpinned by the right standards and metrics." Dr Michael Adeogun, National Physical Laboratory

2. Data and AI-driven system design and quantifying biological processes

What standards are needed to achieve for characterisation and effective application of AI / ML in Engineering Biology?

The rise of EngBio is being driven by a convergence of technologies. This convergence includes our ability to interrogate and understand biological systems in new and (where possible) quantifiable ways. Systems exists to manage the vast volumes of data which are generated from these investigations and these data sets are enabling the application of AI / ML approaches to the design of new bio-based systems. At the same time, we are now able to write in the language of DNA at scale, providing the foundation for delivering increasingly complex instructions to cellular systems which can be exploited to deliver novel processes, systems and solutions.

The ability to understand biology using a ‘scaled down’ approach, which enables the characterisation of the building blocks of a biological system, and to subsequently apply AI driven design principles to build new systems, is essential and already

driving increased success in our ability to deliver manufacturing scale. There is, however, a recognised need for standards which allow the effective, comparable and reliable measurement and characterisation of these biological building blocks if we are to best employ the power of digital based design. Algorithm driven approaches can facilitate the design of novel biological systems capable of using new forms of energy, transforming waste and making a direct link to scalability, but there is a need for standards including for example, specific nucleic acid, protein, cell system and cell process reference materials.

Recommendations

- Work with national and international stakeholders to establish key priorities and terms needed for inclusion in an agreed vocabulary, building on any existing work where possible. An established lexicon in this area would support the most effective integration of AI and ML algorithms into EngBio design.
  - There are recognised opportunities to leverage BSI's membership of the international ISO/TC 276 with the UK taking a strategic lead with support from experts across the ecosystem including the national measurement systems laboratories where NPL has considerable cross sector expertise that can be applied
- Establish reference materials for key nucleic acid and cell system metrics with necessary traceability and (where needed) certified through interlaboratory comparisons and metrology institutes employing traceable, fit-for-purpose methods to enable confidence in analytical data for EngBio building blocks and assure interoperability.
- Assess existing data standards and develop use case ontologies for bioprocesses that support the development of digital twins, validated by experiment, for use in system design.
  - This will be supported by the efforts to establish a lexicon described above and can support early-stage system characterisation.
- This is a broad area and so will require several different approaches and formats for standards development and adoption – from agreed lists and definitions to support a specific data vocabulary or lexicon, to specific reference materials to enable assessment of system building blocks such as DNA (to assess structure,

size, purity, etc.) or cell chassis to enable assessment of process efficiency. These reference standards may need to be applicable for use across a variety of analytical technologies and agreed analytical methods, which will also be valuable once documented and appropriately validated.

Specific challenges identified and discussion points recognised in the focus groups included:

- Data integrity and quality is key to AI / ML applications and a system to control and manage effective data quality, curation and characterisation is a vital area for a standardised approach. There is a need for centralised coordination to deliver a consensus across industry through community driven guidance, describing the type and format of information innovators must generate when data is published.
  - We must create a framework that is accessible and available to everyone, leading to a national standard rather than something adopted from external sources. Any UK EngBio standards and regulatory framework to enable characterisation must be centred on the needs described by industry.
- Reference standards (including etalons and guidelines) are essential for data integrity, comparability and interoperability. EngBio is developing fast and the ability to create an agile reference data system to coordinate metrics and standards once they're developed will be key to ensuring ongoing relevance and suitability for evolving industrial applications.
- Digital twins are a necessary opportunity - how these are best developed for EngBio and linked to reference standards is an urgent area for consideration.
- Resources needed for QA, testing, and regulatory compliance will add costs, but ensuring the right standards are well-constructed is key to adoption.
- Training, skill sets and education. How do we train early adopters to show value in a standardised approach?
- The characterisation of bio systems at an early stage and through scales, and the ability to model outputs using agreed algorithms supported by well curated and characterised data, will allow innovators to fail early and save money and effort, quickly moving on to new approaches.

- Standardised descriptors of bioprocesses and facilities. It would be highly impactful if one could describe a bioprocess and upload it to an app and get matched with a bioproduction facility who could carry out the process or reference standard to benchmark the process. Similar initiatives are already being developed overseas, e.g., in China, where apps are made available to link to a specific calibration service or reference material. There is a clear incentive for doing this.
- Biosecurity and biosafety concerns are recognised as an important element of this topic and others summarised in the report, but as these challenges are being addressed separately, they are not the focus of this report.

> "Our ability to describe the performance attributes of EngBio systems in quantitative terms will drive greater success in the translation of early stage innovation from the lab, through pilot processing and scale down to manufacturing and scale up. Measurement standards supported by quantitative metrics of biological systems, downstream processes and agreed data formats will have a vital role to play for the interoperability of manufacturing models that enable the realisation of Engbio processes at scale"
>
> Professor Max Ryadnov, National Physical Laboratory

3. Life-cycle assessment for Engineering Biology

How will standards in Life-cycle assessment (LCA) for Engineering Biology enable accelerated commercialisation?

Agreed approaches to Life-Cycle Assessment (LCA) for EngBio enabled products and processes has the potential to be a valuable tool enabling better comparison between bio-made products and their fossil fuel-based equivalents. As we seek to accelerate the path to commercialisation, to grow the bioeconomy, and move towards a more sustainable future, standards for LCA that are applicable to EngBio should be developed to support industry and allow agreed articulation of the benefits of Bio-enabled production.

An effective LCA should demonstrate the environmental impact of the product, including the process taken to develop that product, the inputs (e.g., feedstocks), and any waste products. By showcasing the sustainability of the product, the LCA should therefore be of benefit to the producer, as well as investors and consumers. However, issues have been raised around the lack of specificity in existing LCA standards. For example, ISO 14040:2006 includes principles and a framework for LCA, however does not describe technique or methodologies for applying the LCA. Therefore, users are able to interpret and adapt the guidelines and framework in different ways. This results in an unlevel playing field, where the outcome of the LCA is not comparable across products, let alone across industries. When developing a standard LCA applicable to EngBio, it is important that existing standards (such as ISO 14040 and CEN/TC 411) are not overlooked; EngBio specific requirements should be developed and linked to existing published standards for LCA, rather than being developed in silo. Within the UK, the BSI (specifically BTI/1: Biotechnologies committee) is well placed to lead on liaising with relevant international committees.

As well as identifying the benefits of LCAs specific to EngBio, workshop delegates highlighted the lack of resources to support startups and SMEs in conducting the LCA. SME representatives noted the need for clearer guidance, and access to additional funding, to allow them to undertake LCAs.

Recommendations

- Prepare a series of case-studies and apply test LCA's to 4 or 5 companies in EngBio, that have varying inputs and outputs. This will allow industry to test and provide critical analysis of how the LCA can be applied and identify areas that need additional consideration. Industry players in collaboration with regulators, and with input from funders, should develop and define the list of characteristics needed for an EngBio LCA.
- Develop an open source sharing platform that includes the tools needed by SMEs to enable a reliable assessment and showcase of their LCA data.

Specific challenges identified and discussion points recognised in the focus groups included:

- Can we develop a standardised approach to environmental impact measurement, not just one element of the process but a framework that allows assessment of the whole process, cradle to grave? Such a standard needs to consider the full life cycle of the product.
- A list of specified criteria for EngBio products is needed to ensure the industry can apply an LCA standard effectively. This list should be defined and tested by industry players in collaboration with regulators, and with input from funders, and be relevant across the spectrum of bio-made products.
- LCA criteria referenced in the report on EngBio Metrics and Technical Standards for the Global Bioeconomy[9] provide a useful reference and are directly applicable to the UK focused approach – these include:
  - Characteristics of feedstocks, including renewability, environmental impact of transportation, and treatment.
  - Land use
  - Biodiversity impacts
  - Carbon intensity (to include carbon emitted from infrastructure use)
  - Impacts of any waste or by-products
  - Recyclability

[9] Engineering Biology Metrics and Technical Standards for the Global Bioeconomy. London, UK. Freemont, P.S., Ni, C., Aurand, E., Chang, M.W., Hook-Barnard, I., Malley, J., Romantseva, E., Strychalski, E., Vavitsas, K. 2024.

- There is recognised uncertainty around how LCA is appropriately applied to highly innovative companies, where the end-product may be unknown. Any cradle to grave approach will require flexibility to assess one part of the chain for earlier stage innovations.
- Data input formats need to have clear standards for data format, metadata, data sharing and data input. An agreed approach will allow LCA data to be reliable and comparable and provide confidence in the assessments
- Guidance materials appropriate for SMEs (including funding for the necessary resources) operating alongside an open-source platform for sharing data will provide a valuable support tool.

4. Biomass feedstock characterisation

How will standards and metrics for biomass feedstock enable accelerated commercialisation?

Biomass used for feedstocks can be any organic matter; plant, animal, waste, or in some cases, feedstocks may be purchased in the form of a pre-processed powder or liquid, meeting a set of key specifications and quality criteria.

Development of biomass into EngBio feedstocks may arise because of waste products needing a purpose (e.g., crop wastes, algae, or organic wastes), or conversely, they may be product-led, whereby a desired product requires a feedstock that meets a set of criteria. Delegates noted that the latter of these – product-led feedstocks – are often the most successful but require specific selection criteria to be applied, including assessment of any impurities that may negatively impact a desired metabolic pathway in the producer organism. This highlights a key area in which standards and metrics applied to biomass for EngBio processes could support industry across many different sectors. At the highest level, standards would allow users to more easily access key information, including the geographical source of the biomass, availability, and to assess factors which impact suitability for incorporation into their processes e.g., composition, seasonality and sustainability. This will have a positive impact on supply chains through a reduced need for individual testing of raw materials or more targeted testing to ensure suitable quality. Recommendations in this area would build on existing efforts and data sources, such as the UK Biomass Strategy 2023[10], and the approaches adopted by the global Food Authenticity Network[11].

[10] UK Biomass Strategy 2023. https://www.gov.uk/government/publications/biomass-strategy/biomass-strategy-2023-accessible-webpage
[11] https://www.foodauthenticity.global/

“Standardised metrics for biomass feedstock characterisation are essential for ensuring quality, optimising conversion efficiency, and fostering a sustainable bio-based chemicals and materials industry. They create a common language across suppliers, producers, and researchers, enabling consistent quality, improving environmental outcomes, and advancing innovation in alternatives to fossil-based incumbents.”

Jen Vanderhoven, Bio-based and Biodegradable Industries Association

Recommendations

- An up-to-date assessment or mapping of biomass availability in the UK, that can be potentially linked to international availability and accessibility databases. The wide range of biomass used in EngBio applications, and the range of potential biomass sources, means that having a reliable and continuously updated database of biomass availability and its uses in the UK will be highly valuable, not only to UK-based EngBio companies but also to better understand the supply chain and quantify the UK's potential within the growing international biomass trade.
- Develop a standardised specification sheet outlining the key attributes that are relevant for uses in EngBio production processes. There are potential learnings from processes used to establish standardised data to be included in globally harmonised Material Safety Data Sheets (MSDS), for example. Specifications should be developed in collaboration with expert UK organisations such as the Biorenewables Development Centre.
- A specification sheet for biomass feedstocks that would be most relevant for the EngBio sector could include:
  - Specific composition criteria, e.g., carbon content, sugar content, lignin content, sulphur compounds, overall component ratios, etc.
  - Inhibitors, impurities and non-fermentable parts
  - Preprocessing conditions (where applicable)
  - Origin

Specific challenges and discussion points recognised in the focus groups included:

- As with all biological systems, biomass is variable by nature. We need to apply standards and metrics that are appropriate for different applications, rather than following other sectors' requirements (for example those adopted in pharmaceutical manufacturing).
- Delegates reported that standards and metrics for biomass would be especially useful to SMEs. At present, analysis of a feedstock to test purity can only be carried out if the volume of feedstock is sufficient. Typically, SMEs would not be able to purchase feedstocks at volumes large enough to drive the need for such

testing, therefore the lack of standards around feedstock specifications is more detrimental for them as they need to take risks in assuming the required purity is met.

- Standards and metrics on feedstock characteristics could also play a key role in ensuring safety and transparency. For example, ensuring feedstocks coming into the UK are compatible with the Nagoya Protocol[12], or more simply confirming that a particular feedstock is free from heavy metals and other impurities that impact efficiency of a specific bioprocess or pathway.
- Delegates acknowledged that there are limitations on UK biomass sources due to land mass but having standards to assess feedstock supply chains in the global market will become essential.
- Competing demands for available biomass must also be considered, e.g., biomass used for UK electricity, heat and transport (of which 66% was from domestic sources in 2022[13]). However, agricultural waste and other wastes are available in the UK, and there is a high appetite for production in EngBio that could utilise these.
- For both biomass and LCA standards, it will be important to link to existing international standards activities, including ISO 14040:2006, ISO/TC 276 and CEN/TC 411, among others. Organisations such as BSI are ideally positioned to lead these activities.
- Delegates discussed sugar as a potential platform, where primary waste producers would focus on pre-processing to recognised “sugar” feedstock, and fermenters could design processes around specific sugar grades based on energy delivery.

[12] Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity: text and annex / Secretariat of the Convention on Biological Diversity. 2011. ISBN: 92-9225-306-9

[13] Report: The government’s support for biomass, 24 January 2024. Department for Energy Security & Net Zero, Session 2023-24, HC 358. https://www.nao.org.uk/wp-content/uploads/2024/01/Summary-the-governments-support-for-biomass-.pdf

- When utilising imported biomass, the need for standards that can be understood and adopted internationally is essential to enable users to be confident in the quality and safety of the feedstock. Internationally recognised certification schemes, for example, identify key criteria against which the biomass can be tested; only if the biomass meets the set criteria would it be awarded certification. Existing examples of these include the Forest Stewardship Council (FSC), and the International Sustainability and Carbon Certification (ISCC). A similar scheme might be developed that would identify key criteria are met, as indicated by the EngBio sector as relevant attributes.
- There is a recognised link to LCA requirements, specifically noting the need to capture the full biomass value chain in the LCA for EngBio products and processes.

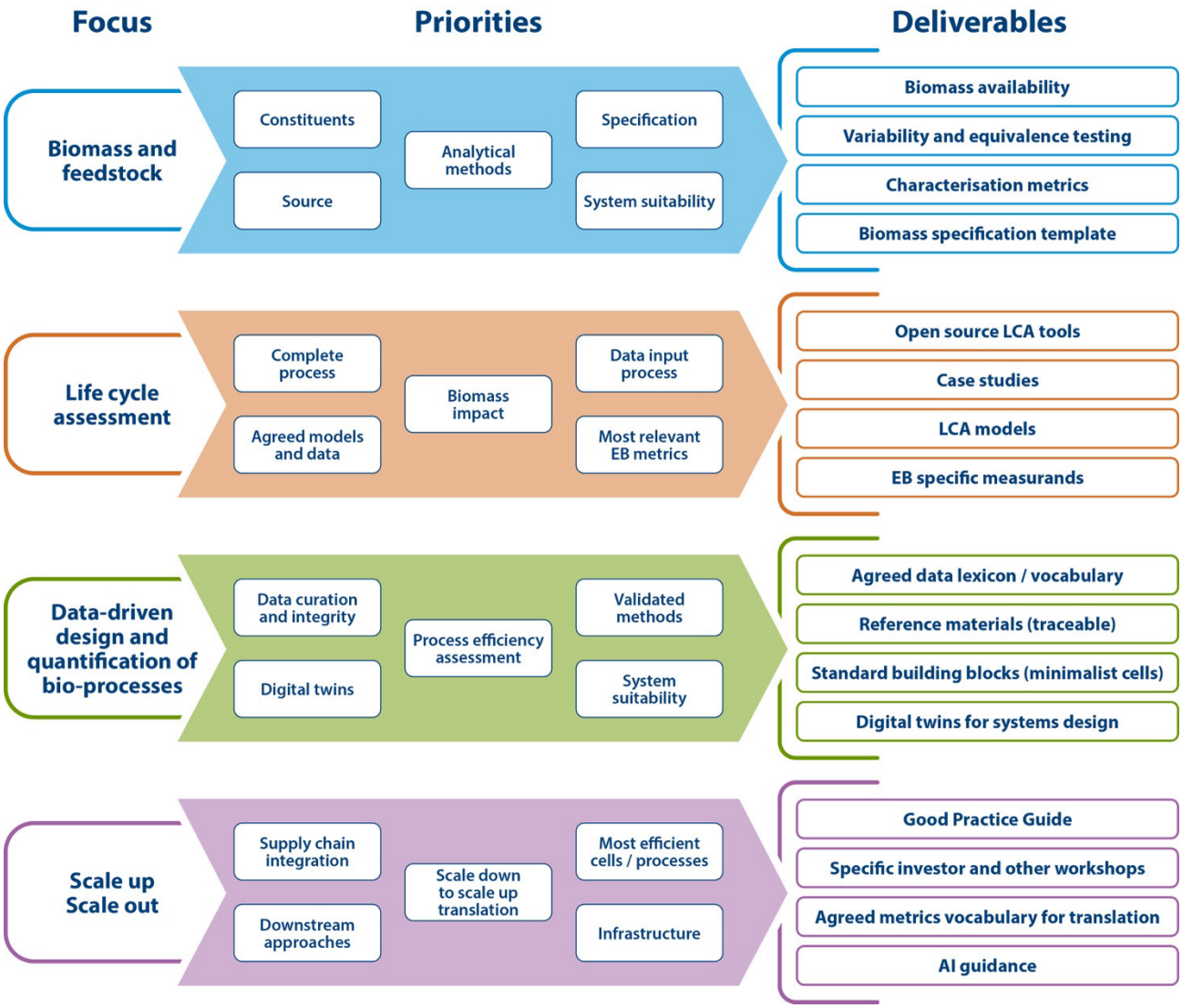

Figure 4: Key areas discussed, and the deliverables required to enable development of the right standards and metrics. Within each focus area (e.g., Biomass and feedstock), key priorities were discussed that would underpin and support the identified deliverables.

Additional key areas raised

5. Regulatory frameworks

How can regulatory frameworks enable accelerated commercialisation?

The role of regulators and current regulatory frameworks was raised by delegates in multiple focus group discussions, and it was recognised that regulators will continue to have vital roles to play in supporting the growth of EngBio in the UK. Existing regulations and frameworks in the UK for this sector are recognised as complex and sometimes difficult to navigate, and in some instances are yet to be established. Some delegates noted examples of SMEs formed in the UK choosing to relocate for the production phase of their development to internationally, for example to the US, where product regulatory approvals can be easier to navigate. To support the UK EngBio community through the development and production phases, increased engagement is needed between regulators and industry. This is a two-way requirement, with a need for regulators to ensure regulations are clear and guidance accessible, as well as a need for industry representatives to share expertise and specific requirements or pain points with regulators. The newly established Regulatory Innovation Office is an example of an expert body assembled to address some of these challenges and there is a focus on EngBio through that forum. Similarly, the Regulatory Horizons Council has initiatives focused on developing the foundations for an agile, fit-for-purpose EngBio regulatory framework.

Delivering the required solutions in emerging technology areas, such as EngBio, requires a recognition that companies often face different types of challenges in issues relating to regulatory compliance. Often the best solution is to create an ecosystem whereby early stage companies have a streamlined pathway, providing easy access to experts who can advise on their specific situation. Guidance documents are valuable tools but need to be accompanied by access to up-to-date guidance from experts in the sector.

Industry representatives at the workshop suggested that consumers would not typically pay more for a sustainable bio-made product; and if higher cost was the result of changing a process to a biobased approach, then it is likely that this would

often prevent consumers switching to a “bio-alternative”. The sector therefore cannot rely on consumer-driven market pull alone and appropriate regulatory change will help reduce investment risk, and support a top-down effect, to enable clear articulation of the benefits of a built-in bio approach.

Recommendations

- Development of an easily accessible platform to enable the sharing of expertise between industry and regulators and help ensure regulations are relevant and applicable.
- Clear, accessible guidance materials to allow industry to more easily navigate and gain approvals for products to be brought to market. This is especially critical for SMEs.
- An open repository or hub that collates relevant regulatory guidance for the key sectors, including a simplified top-level overview.

> “Regulating engineering biology is essential to ensure that advancements in this field are safe, ethical, and beneficial for society. By establishing clear guidelines and standards, we can harness the potential of synthetic/engineering biology while minimising risks and fostering innovation. The FSA recognises the potential of such products and is delighted to have won funding from the Government’s Engineering Biology Sandbox Fund (EBSF), to launch an innovative sandbox programme for cell-cultivated products, set to begin in 2025.”
> Amie Adkin, Food Standards Agency (FSA)

6. Education, skills and training

While not a focus of workshop discussions, the importance of addressing challenges associated with access to talent and skills must not be underestimated. This includes understanding the skills required to develop and deliver the right training programmes. Helping early-stage innovators understand the value of planning for the whole product development process at the outset and not just the end product market will significantly increase the translation success of early-stage innovations. Activities such as this workshop are helping inform company priorities, and future initiatives are already in the pipeline on standards, regulation, and working

internationally. Initiatives such as the BBSRC funded project led by NML@LGC, for example, has enabled the development and dissemination of EngBio metrology training for industry and academic stakeholders across the EngBio ecosystem.

Collaborations between all stakeholders across industry, academia and the public sector will be a key driver for realising the full potential of previous public investment in EngBio to boost the bioeconomy. Research England have developed a framework to allow researchers to publish their entire project data including failed experimental data.

Investors do not always monitor company metrics when looking at their foundational processes and there is a need for education in the value of doing so as a tool for understanding the risks associated with early-stage companies.

7. Supply chain interoperability

Assuring the quality of biological materials, parts and processes which deliver Engbio enabled manufacturing is another area in which standards and metrics can directly support UK companies. As we move away from traditional approaches to manufacturing, the international trade in biological parts will underpin the global supply chains which make use of EngBio technologies. It was recognised that these supply chains will be global in nature and while the focus in this workshop centred on requirements to support UK companies, recognition of the international element of the market for EngBio technologies is inescapable, particularly in consideration for interoperability. Each of the areas discussed above has a major part in providing the infrastructure to underpin the global trade in EngBio technologies, raw materials and outputs.

> "As global trade in the biological parts, feedstocks and manufacturing technologies which drive Engbio increases, the standards and metrics which assure quality could not be more important. These standards must be underpinned by agreed, widely validated measurements and analytical methods as the foundation of robust, efficient, quality assured supply chains to support investor and consumer confidence."
>
> Anonymous workshop participant

8. Funding and resources

The launch of the UK National Vision for Engineering Biology in December 2023 was accompanied by a commitment to invest at least £2Bn in UK EngBio over 10 years. The UK government, primarily through UKRI Research Councils, has already made a number of substantial investments to enable the research needed for the development of EngBio enabled solutions. The announcement of the 6 Engineering Biology Mission hubs (and a supporting programme of 22 mission award projects) across the UK saw the award of £100Mn to support 5-year projects and is one example among several other significant investments across the ecosystem. Similarly, delegates discussed contributions industry and the bio investment community has made, making substantial resources available to UK EngBio companies at different stages of their development. The most recent finance report from the UK BioIndustry Association (BIA) focusing on health biotech as one example, indicates continually high levels of investment at all stages, from seed investments through Series A-C, with £808Mn in venture capital and public financing raised by the UK biotech sector in 2024 Q3[14].

It is recognised that specific resources dedicated to the development of EngBio standards and metrics (in all their forms) are needed to support both continuation of the thriving UK EngBio innovation ecosystem and importantly the translation of those innovations in a way that makes them scalable and attractive to private sector funding. A clear pathway, supported by an agile standards and regulatory network, will pave the way for successful growth and attract the investment needed to thrive. DSIT have allocated resources to a programme of Regulatory Sandboxes to support the development of industry aligned solutions for regulatory development, initially focused on the food sector. This initiative is recognised as an excellent start, but the cross-cutting nature of standards and metrics creates a need for specific funding in addition to engaging with such initiatives, to ensure it is not overlooked in more specific, end-use focused research programmes. Investment in the underpinning measurement science infrastructure will directly enable the development of an agile, fit-for-purpose and widely agreed standards infrastructure as an enabler of company

[14] BIA UK biotech financing July – September 2024. biotechfinance.org/2024-q3

growth and assurance of global supply chain interoperability. Specific areas for investment are described in the recommendations and next steps sections below.

Workshop recommendations

This workshop brought together key stakeholders within the UK EngBio sector, representing industry, industry associations, standards experts, public funding agencies, the UK measurement system, the UK catalyst and infrastructure network and academia. Delegates discussed current needs and opportunities for standards and metrics to address existing barriers to commercialisation of EngBio products, with an emphasis on needs of UK companies across different stages of the investment and development lifecycle. The nine recommendations below summarise the outcome of these discussions. Recommendations comprise a mix of standards, metrics, guidance materials and other tools, as well as recognition of the need to convene further workshops in some specific areas. They represent opportunities to help smooth the path to growth for UK EngBio companies and to realise the benefits this will bring to the UK economy, including the move towards a circular bio-based economy with a reduced reliance on fossil fuel dependent production and supply chain systems.

It is recognised that much of the work required to deliver the recommendations of this report will enable private sector organisations but will require the allocation of resources to public sector and academic partners across the UK EngBio ecosystem. The benefits will be significant but an investment in delivery of the recommendations proposed will be needed and is an area for further investigation. The realisation of the opportunities listed below will require specific dedicated funding in order to deliver the outputs described. Ongoing discussions across the ecosystem on resource allocation represents a key general next step.

1. Good Practice Guide for Scale-up

Development of a tool for early-stage innovators to provide much-needed guidance and information on the opportunities and potential pitfalls associated with scaling-up an EngBio company in the UK. Companies who have successfully scaled their processes can provide valuable contributions to this guide, including best-practice recommendations and key metrics to consider. UK regulators also have a role to play in providing detailed guidance to support the scale-up process. Other public sector organisations, such as NPL and partners within the National Measurement System (NMS) laboratories working alongside specialists

within organisations such as the Centre for Process Innovation (CPI), can contribute specific metrology expertise and access to infrastructure. An assessment of available infrastructure for the EngBio sector should also be included and there is significant capability and expertise across the academic sector.

Recommendations: Assemble a relevant group of EngBio experts to lead consultations with key EngBio companies, relevant public sector organisations and academic experts, to develop an outline of considerations in the scale-up process. This must include companies with a successful track record in delivering scaled processes who will be invited to review and corroborate the outline. It is envisaged that this will be an assessment of pre-competitive technologies and include a review of available infrastructure that is accessible to early-stage innovators. It will be important to facilitate access to the relevant experts and expertise, particularly for early-stage companies.

2. Agreed vocabulary (lexicon)

An agreed vocabulary of key terminology which can be applied across the sector, incorporating key metrics and measurand descriptors will enable the effective integration of AI approaches to scale-up modelling amongst its key benefits. This must be developed in collaboration with national and international stakeholders and build on existing national and international efforts in this area[15]. An important application of an agreed vocabulary will be to enable effective integration of AI and ML algorithms into EngBio design. An effective list of key terminology will also be accessible to those outside the sector, including consumers and policymakers, enabling better understanding and transparency of the EngBio sector. Further, an agreed vocabulary is an essential tool to support international efforts which will underpin trade and growth of the sector.

Recommendations: Developing an agreed vocabulary for the EngBio community will be a long-term process, executed in a prioritised way to enable short-term milestone delivery. Existing efforts should first be reviewed both nationally and internationally to align with current initiatives. Where differences in

[15] For example, the NIST Bioeconomy Lexicon: www.nist.gov/bioscience/nist-bioeconomy-lexicon

national definitions exist, these should be clearly identified to support transparency across the sector. A lexicon developed by the UK EngBio community should include input from industry, academia, and metrology labs and make use of similar efforts in adjacent technologies.

3. Development of tools for biosystem characterisation

Development of tools such as reference materials, calibrants and reporters for key system measurands, including DNA structure or cell and process metrics, will enable effective characterisation of the biological systems which underpin EngBio. Sequencing standards have been developed through a range of sources but there is a need for biochemical and biophysical measurement reference standards to benchmark EngBio components, systems, and processes. Just a few examples of the specific assessments to be enabled include:

- Morphological and structural purity and consistency (DNA, protein),
- Gene synthesis and assembly
- Protein (polypeptide) synthesis and conjugation,
- Gene packaging and delivery systems
- Engineered cells and cell systems and chassis (including membrane, and component assembly).

Recommendation: National Measurement Systems experts including NPL, NML@LGC and MHRA, have a strong history in the development and certification of reference materials (with required traceability) and can lead the next steps in defining and developing the materials described.

4. Data standards and ontologies

Development of a set of standards defining data sourcing and data formatting requirements for EngBio will require a paradigm shift in which hybrid and proxy measurement data will be used to characterise biological systems. Therefore, it is important to consider not only comparability, but how to combine datasets that are from different sources that may not be aligned. These standards can be supported through development of relevant ontologies for bioprocesses that help enable digital twins for use in system design and process modelling. Data standards will ensure data input across the sector is more easily comparable and

more reliable. Existing data standards should first be assessed and built upon, adding specificity for EngBio applications.

Recommendation: There is existing expertise in these areas within the UK and it will be important to leverage that work. The UK's EngBio stakeholders must work collaboratively, bringing together industry partners and experts across the ecosystem, and drawing on expertise from adjacent sectors. For example, NPL is a key partner within the UK's AI Standards Hub, working in collaboration with partners across different AI applications to bring insights to the exploitation of biological systems. Working in partnership with data standards experts, National Measurement System organisations, recognised academics and industry leaders should come together to develop an assessment of the external standard ontologies/taxonomies and other similar structures available across the digital manufacturing space. These include:

- High-level definitions of semantic technologies with focus on ontologies and knowledge graphs for use in pharmaceutical manufacturing.
- Evaluation metrics for assessing ontologies.
- Assessment of open-source and publicly available ontologies, taxonomies, and standards that can be used to inform and accelerate data-driven manufacturing approaches.
- Inputs from collaborators for assessment of available open-source ontologies.

5. Open repository / sharing platform

An open information and resource sharing platform should be developed to provide a space for EngBio companies to share successes, highlight pain points, source reference materials and methodologies, and access guidance, including regulatory requirements. Such a tool will provide a particularly valuable resource for early-stage companies, providing access to key materials that will support them in alleviating risks by removing some of the unknowns associated with EngBio technologies. Some existing efforts have encouraged sharing through academia but focus here is on industry sharing.

Recommendation: Public sector organisations operating across multiple sectors, can bring together stakeholders across the ecosystem to identify requirements for delivery and hosting of a sharing platform. This should include

an open-source depository of reference materials, methods and protocols for industrial participants. Existing efforts, such as that by Research England and proposed bio networks, are also integral to delivery and must be leveraged to ensure there is no duplication of effort. Successful deployment of such a resource will require a concerted, ongoing effort to ensure all materials are regularly updated; populating and maintaining such a large repository would therefore require long-term funding – the source of this needs to be identified, as well as the responsible stakeholders.

6. LCA case-studies

An EngBio specific LCA model should be developed that can be applied to multiple case-studies across different EngBio applications. An EngBio specific LCA approach will provide a more level playing field across the sector, and a benchmark to compare and demonstrate sustainability factors of EngBio products with those manufactured using different technologies. Building on existing LCA standards with specific characteristics for EngBio applications identified. Data standards will be linked to LCA inputs and assessment.

Recommendation: Identify key characteristics that would allow an LCA to be directly applicable to EngBio products. These should be developed through collaboration between industry players, academia, and with input from regulators. A range of EngBio companies should be selected to test the LCA on different products and processes, (for example food, chemicals, biotherapeutics), providing critical analysis and feedback that can then be used to refine the list of assessed characteristics.

7. Map of UK biomass availability

An up-to-date assessment of the availability (including accessibility and key characteristics) of biomass in the UK is needed. Making this information available through an open access portal would allow EngBio companies to more easily identify potential biomass sources and their suitability, as well as providing key information to HMG on the overall feedstock supply chain in the UK. This would be closely linked to the application of biomass specification sheets, described below.

Recommendation: Building on existing efforts to assess availability of biomass in the UK and extending to global assessment, this mapping exercise will require ongoing updates and input from stakeholders who develop the relevant biomass, as well as feedback from industry users.

8. Biomass specification sheet

A standard specification sheet identifying the key attributes of biomass feedstocks that are most relevant to EngBio companies should be drafted. Such specifications would include source, composition criteria, seasonality, organism compatibility, inhibitors and non-fermentable parts, and any preprocessing conditions. A standard specification sheet would need to be understood and adopted internationally to better enable the use of imported biomass, therefore agreed terminology is important. Developing a certification scheme that indicates the biomass has been tested against a set of key criteria would demonstrate quality and safety of the feedstock.

Recommendation: Identify key feedstock characteristics that are relevant to the EngBio sector and translate this into a standard specification sheet that can be agreed and adopted by industry and subsequently applied and understood internationally. Documentation can be underpinned by agreed reference materials to support analytical data included on biomass specification over time.

9. Regulatory guidance materials

A set of guidance materials to support EngBio companies in navigating the pathway to commercialisation. Clear and accessible guidance should be developed in collaboration with regulators, relevant public sector bodies and other experts, with input from industry experts to ensure specificity and relevance to the EngBio sector. This guidance is particularly beneficial for early-stage companies and can help drive greater translation of early-stage technologies and investment.

Recommendation: Establish a working group, including public sector organisations recognised industry experts, who can enable collaboration with regulators to lead development of relevant and specific guidance materials, drawing on expertise and real-world case studies. Existing networks could be

utilised to support this initiative, for example the Engineering Biology Regulators Network.

Appendices

Agenda

Time	Topic	Title	Duration
09:00	Arrival – coffee		30 mins
09:30	Welcome and plans for the day	What are the outcomes we would like to see from the day. **Michael Adeogun (National Physical Laboratory) and Paul Freemont (Imperial College London)**	10 mins
09:40	Global context	What we've learnt from the recent effort: regional contexts and key recommended areas. **Paul Freemont (Imperial College London)**	15 mins
09:55	UK scene-setting and standards overview	The current state of engineering biology in the UK. **Scott Allen (Department for Science, Innovation and Technology)**	15 mins
		Metrology and standards - aligning to drive value and growth. **Jeffrey Anthony (National Physical Laboratory)**	20 mins
10:30	Q&A	Questions and discussion. **Facilitated by Paul Freemont (Imperial College London)**	30 mins
11:00	Break		30 mins
11:30	Existing barriers for UK industry, and priority areas for standards and metrics	Insights into existing barriers to engineering biology in the UK: Food **Jeremy Bartosiak-Jentys (The Supplant Company)**	15 mins
		Insights into existing barriers to engineering biology in the UK: Biochemicals **Jim Ajioka (Colorifix)**	15 mins
12:00		Panel discussion: Priority standards and metrics for engineering biology in the UK. **Facilitated by Jen Vanderhoven (BBIA)**	30 mins
		Open discussion, Q&A	20 mins
		Plans for breakout groups	10 mins
13:00	Lunch		45 mins
13:45	Breakout groups	**Table 1:** Biomass feedstock characterisation **Tables 2 & 3:** Data and AI-driven design, and quantifying biological processes (e.g., DNA synthesis) **Tables 4 & 5:** Scale-up (and scale-out) **Table 6:** Life-Cycle Assessment for engineering biology	60 mins
14:45	Break		15 mins
15:00	Breakout groups	Breakout group feedback (5 mins each)	20 mins
15:20	Open discussion	Where do we go from here, what outputs are needed from this workshop, and resourcing priority actions?	60 mins
16:20	Meeting adjourns / Networking reception		

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Providing the measurement capability
that underpins the UK's prosperity
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