

Written evidence from National Physical Laboratory (ENB0039)

1. The National Physical Laboratory (NPL)¹ is a public sector research establishment (PSRE), owned by the Department for Science, Innovation and Technology (DSIT). NPL is the UK's National Metrology Institute (NMI), providing the traceable measurement capability that underpins the UK's prosperity and quality of life.
2. From new antibiotics to tackle resistance and more effective cancer treatments, to secure quantum communications and superfast 5G, technological advances must be built on a foundation of reliable measurement to succeed. Reproducible, accurate and comparable measurement underpins all science, research and innovation and enables business and trade. The UK's National Measurement System² science programmes support the development of the metrology needed to enable the uptake of critical technologies.
3. Over the past decade, NPL has been building its capability to support engineering biology (Eng Bio), applying our expertise in standards and engineering to biological systems. NPL has been working on the development of measurement tools, including reference materials and calibrants, and agreed methods that allow the accurate and precise characterisation of biological molecules, cells, cellular and subcellular processes and systems. These tools enable developers to test and validate their products and processes reliably and reproducibly.
4. The effective exploitation of Eng Bio will rely on the development and implementation of appropriate reference standards to benchmark the performance of Eng Bio processes and systems as well as Eng Bio products.
5. NPL scientists and engineers represents the UK on many international metrology and standardisation committees and working groups (e.g., ISO, BSI, BIA, CCQM). NPL chairs a technical working area in VAMAS³, which serves as a pre-standardisation vehicle for Eng Bio supporting the development of standards, harmonised measurement and testing that enable the global trade and adoption of products and services.

On UK strengths

¹ <https://www.npl.co.uk/>

² <https://www.gov.uk/government/publications/national-measurement-system/uk-national-measurement-system>

³ <http://www.vamas.org/>

6. The diversity of the UK's research, development and innovation (RDI) ecosystem is a key strength. This ecosystem includes academically excellent universities, mission driven public sector research establishments and a world-leading national quality infrastructure – all of which support the translation of research into impactful applications and high-tech and innovative companies.

7. As a specific example of an element of the UK's RDI ecosystem focussed on Eng Bio, NPL established a virtual UK Centre for Engineering Biology, Metrology and Standards⁴ in 2019 with funding from Industrial Strategy Challenge Fund (ISCF), in partnership with the National Measurement Laboratory at LGC and the National Institute for Biological Standards and Control (now part of the Medicines and Healthcare products Regulatory Agency, MHRA), and SynbiCITE at Imperial College London. The UK Centre for Engineering Biology, Metrology and Standards has enabled NPL to identify and develop metrology support for Eng Bio early adoption by industry in the UK by addressing technology and measurement challenges Eng Bio industry faces. The ISCF funding also enabled NPL to establish their first facility in cryogenic electron microscopy to provide the highest point of reference for accurate measurement and validation of commercial biological systems as well as the first Eng Bio reference calibrants and standards.

8. There are many other examples of Government investment in public and academic engineering biology infrastructure over the last three years, including the development and set up of 22 mission award centres, six new mission hubs, five bio-foundries, Innovation and Knowledge Institutes (IKCs) and seven basic Research Institutes alongside Industry driven infrastructure.

9. This infrastructure has supported many successful and fast-growing organisations operating across a diverse range of sectors. Just a few examples are provided below:
 - Touchlight Genetics⁵: DNA manufacturing company who developed a revolutionary manufacturing process enabling to produce DNA at unprecedented speed, scale, and purity.

 - Biologic Technologies⁶: An innovative company with a unique perspective of designing biocomputers – machines aiming to revolutionalise biology processing using the same principles that revolutionalised information processing.

⁴ <https://www.npl.co.uk/biometrology/metrology-for-engineering-biology/standards-centre>

⁵ <https://www.touchlight.com/>

⁶ <https://biologic-tech.com/>

- Ingenza⁷: A Scottish company which innovates Eng Bio manufacturing processes and engineer biological systems to make everything from therapeutics to enzymes and consumer products.
 - EnzBond: An innovative company which developed *in-silico* technology to utilise enzymes for the manufacture of high value drugs which are challenging to produce.
 - Activirosomes: Vaccine developers providing effective and affordable technologies for the treatment of rare and serious diseases as well as the prevention of viral infection outbreaks.
11. NPL has recently secured funding from the Department for Science, Innovation and Technology (DSIT) Research and Innovation Organisations Infrastructure Fund (RIO IF) to procure a state-of-the-art bio-foundry. This will give NPL core Eng Bio capabilities focusing on DNA synthesis and cell engineering. This is the first metrological bio-foundry in the UK and the first bio-foundry amongst National Metrology Institutes worldwide.
12. The National Vision for Engineering Biology identified the need for dedicated metrology infrastructure and reference standards to enable and support the transition of Eng Bio technology from research to products. Building on our work and successes to date, NPL aims to establish an Institute for Engineering Biology, Metrology and Standards. The Institute will create and provide dedicated metrology infrastructure and reference standards defined by industry challenges and will convene other components of the UK RDI and Eng Bio ecosystem including professional development and skills, policymakers and regulators.
13. The National Vision for Engineering Biology recognises that the US and China, as the world's largest economies, lead on the scale of investment in Eng Bio. Continued investment that keeps pace with the leaders in Eng Bio is vital if the UK is to realise the full benefit of Eng Bio driven growth and ensure that UK innovations are realised at manufacturing scale in the UK.

On applications

14. The National Vision for Engineering Biology noted that the majority of engineering biology companies fall within the healthcare sectors, and this is where we see the most commercially advanced applications. However, as a platform technology, Eng Bio is widely recognised as having the potential to deliver solutions to other major challenges, including food and energy security, defence and national security, and management of the environment.

⁷ <https://www.ingenza.com/>

15. NPL collaborates with industry, supporting research, development and innovation activities and the growth of SMEs involved in the delivery of Eng Bio solutions by providing access to specialist measurement and metrology expertise, capability and infrastructure. NPL is currently supporting SMEs developing Eng Bio solutions in areas as diverse as bioremediation, regenerative medicine, drug discovery and continuous bioprocessing. Specific examples include:
- a) Supporting a sustainable healthcare system through the development of innovative antimicrobial treatments which benefit from applying Eng Bio principles to creating artificial bacteriophages targeting pathogenic bacteria.
 - b) Enabling high-quality DNA manufacturing for applications ranging from gene therapy and vaccine development to data storage.
 - c) Realising the significant potential of Eng Bio to enable bioprocessing applications which turn waste products into new useful and valuable products, or into more readily managed alternative waste streams.

On Government policy to support the development of engineering biology

16. The National Vision for Engineering Biology builds effectively on recommendations from the Prime Minister's Council for Science & Technology report on Engineering Biology and the recommendations published by the Engineering Biology Leadership Council. The National Vision for Engineering Biology identifies the requirement for metrology and technical measurement standards and infrastructure to drive growth in Engineering Biology enabled solutions⁸.
17. The measurement infrastructure and standards that NPL and other laboratories across the UK's National Measurement System have already developed to support Eng Bio includes biological reference materials, calibrants, measurement tools, standardised processes and methods, using agreed upon language which is the foundation for the development of standards in the area. This is challenging, owing to the complex nature of biological systems and the variety of variables at play which are not always easily controlled. NPL takes an integrated approach to the problem, bridging the intricate complexities of biological systems with the precision of data-driven methodologies.

⁸ <https://www.gov.uk/government/publications/national-vision-for-engineering-biology>: "Standards will also be key to speeding up innovation by increasing the reproducibility and comparability challenges experienced when working with biological systems. The UK is committed to leading the development of responsible and fair standards. The National Physical Laboratory and the National Measurement Laboratory [at LGC] are spearheading UK efforts to improve engineering biology metrology."

18. This enduring measurement infrastructure can serve as a catalyst for collaboration among R&D teams, not only within the UK but also on a global scale. Collaboration is necessary to translate research out of the laboratory and enable manufacturing at scale. Measurement is key to test, validate and quality assure the products, processes and systems for Eng Bio, ensuring that products and services meet stringent standards of safety, efficacy and suitability.
19. Measurement infrastructure and technical standards play a crucial role in enabling the scale-up of companies which use new and emerging foundational or platform technologies such as Eng Bio, enabling both investors and customers have confidence in the efficacy of Eng Bio products and processes. Additionally, they underpin the UK's positioning within the global supply chain for biological components, such as cells, nucleic acids, bioprocesses, and feedstocks.
20. As such, measurement infrastructure and technical standards are critical to ensuring recent investments made by HMG and UKRI realise tangible benefits to the economy. It is essential that measurement infrastructure, such as nomenclature, tools, references, standards, test, validation and quality control processes, are embedded in national programmes from the outset. This approach has been a success is within the National Quantum Technologies Programme (NQTP) where NPL is providing the underpinning metrology, developing the measurement capabilities to test and validate quantum technologies across all of the quantum hubs in partnership with universities and industry.

On maximising the economic potential of developments in engineering biology

21. To maximise the economic potential of Eng Bio, the UK needs to be able to support companies to scale up and get their products to market quickly. Investment in, and access to, the measurement infrastructure required to test, validate and quality assure products, to agreed standards in order to provide consumers with confidence, is essential to accelerate the commercialisation and uptake of Eng Bio products.
22. A specific example of supporting economic potential in Eng Bio is NPL's Measurement for Business (M4B) programme, which gives UK SMEs access to specialist measurement science and engineering experts and facilities, at no charge, in order to support scale-up and business growth. Measurement expertise can accelerate products or services getting to market by, for example, giving innovators vital feedback during development, and also giving potential investors confidence in performance.

On regulation

23. Measurement and technical standards are a flexible accompaniment to regulation and, by working alongside best practice, can accelerate innovation through enabling the essential testing of novel technologies, empowering regulators to deliver proportional responses which assure safety, without hampering rapid development.
24. Eng Bio, as a platform technology, has applications across a wide range of sectors, where its products and processes may have different regulatory requirements and considerations the safety and efficacy of the products, processes and reactants and products.

On possible barriers and limitations to good and effective use of engineering biology

25. The skills required to support the growth of Eng Bio as a platform technology are also in demand in other sectors. It therefore remains essential that the UK invests in training and skills development for its workforce, at all career stages and as the UK's National Metrology Institute and a national laboratory, NPL supports a range of STEM skills development initiatives, from apprentice to doctoral training to professional development. Technical expertise in measurement skills will also be key in supporting the scale up of Eng Bio products and processes.
26. There is a need to develop and deploy new measurement infrastructure to characterise system inputs to ensure optimised bioprocesses able to deliver standardised and easily regulated products both for end use and for incorporation into global supply chains. Just a few examples of the process parameters and specific measurements which require measurement infrastructure to enable standardisation and control include:
 - a) DNA synthesis efficiency and efficacy - Purity, size, structure, sequence and edit integrity.
 - b) Nucleic acid delivery - Transfection efficiency and measures of DNA and other nucleic acid delivery to target cells.
 - c) Cell characterisation and efficiency - Cell number measurements, metabolite production, protein synthesis, feedstock utilisation.
 - d) Bioprocessing and fermentation systems - enzyme production, metabolic outputs, feedstock utilisation.
27. There is also a significant requirement for the development of standardised approaches at the interfaces between Eng Bio and other technologies and where Eng Bio products will work as a system with other products. For example, a data standards infrastructure for the systems which underpin artificial intelligence algorithms that enable the modelling, design and characterisation of the complex biological systems

exploited in engineering biology technologies would support
reproducibility accelerate technology development.

07 May 2024