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Use of standards for digital biological information in the design, construction and description of a synthetic biological system – Guide

Innovate UK
Technology Strategy Board

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Publishing and copyright information

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Foreword

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Acknowledgement is also given to the members of a wider review panel who were consulted in the development of this PAS.

This PAS is not to be regarded as a British Standard. It will be withdrawn upon publication of its content in, or as, a British Standard.

The PAS process enables a guide to be rapidly developed in order to fulfil an immediate need in industry. A PAS may be considered for further development as a British Standard, or constitute part of the UK input into the development of a European or International Standard.

Use of this document

As a guide, this PAS takes the form of guidance and recommendations. It should not be quoted as if it were a specification or a code of practice and claims of compliance cannot be made to it.

Presentational conventions

The guidance in this PAS is presented in roman (i.e. upright) type. Any recommendations are expressed in sentences in which the principal auxiliary verb is "should".

Commentary, explanation and general informative material is presented in italic type, and does not constitute a normative element.

Spelling conforms to The Shorter Oxford English Dictionary. If a word has more than one spelling, the first spelling in the dictionary is used.

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a PAS cannot confer immunity from legal obligations.

Innovate UK statement

Innovate UK – the new name for the Technology Strategy Board – is the UK's innovation agency. We fund, support and connect innovative businesses to accelerate sustainable economic growth.

Timely, consensus-based use of standards plays a vital role in ensuring that the knowledge created in the UK's research base is commercialised and brought to market and plays an important part in driving innovation.

Innovate UK is working with BSI, the Research Councils and Catapults to establish new standards earlier in the development of technologies. We are collaborating in four areas of innovation to define standards that will accelerate the development of technologies and services to provide UK businesses with a competitive "first mover advantage", including the subject of this document that will enable computer-aided design, manufacture, and verification using digital biological information.

We have also joined with the Engineering and Physical Sciences Research Council and Biotechnology and Biological Sciences Research Council to create SynbiCITE, a pioneering Innovation and Knowledge Centre dedicated to promoting the adoption and use of synthetic biology by industry. The centre is focused at Imperial College, London and will help turn academia and industry-based research into commercial success. For more information see **http://synbicite.com/**

More widely, health and care is a key priority area in our work – with major innovation programmes to stimulate the development of new technologies, products and services, building on the UK's world-class science and technology base and its global presence in the biopharmaceutical and health technology sectors.

Read more about Innovate UK and our plans in health, care and other areas here: **www.innovateuk.gov.uk** or contact **support@innovateuk.gov.uk**

Introduction

Synthetic biology has been identified by the Synthetic Biology Roadmap [1], Eight Great Technologies report [2] and the Davos Global Risks 2015 report [3] as one of the key emerging technologies with the potential to provide solutions to many of the social, technological and environmental problems of the coming decades. Several areas where immediate attention is required include:

- food security;
- energy security;
- economic security; and
- wealth creation.

Synthetic biology offers a new way to approach such issues. This new approach, based on the use of engineered biology, is likely to be more sustainable than current methods and might offer renewable solutions to such problems.

Synthetic biology is the term given to the conceptual framework surrounding the systematic design and engineering of biological systems. At present the major thrust of effort within synthetic biology is focused on the genetics of biological systems and improving the ability to design and build at the genetic level in order to produce products for a range of applications. The objective of this technology is to enable the formation of a biomanufacturing industry where it will be possible to rapidly design and build new biological systems and organisms for a diverse range of applications. In order for this to happen, improvements to the engineering of biology are required to bring it in line with the rational design used in other engineering disciplines. In particular, this requires the development of the capability to apply the design-build-test cycle to synthetic biological systems and subsequent improvement in the predictive power of the designs. To achieve this, a standards framework is required.

Standards enable effective engineering by establishing both good practice and the necessary framework of tools and processes required to ensure compatibility and interoperability for those working with the technology. At present there are no formalized standards within synthetic biology. There are however community-led projects to standardize various processes within synthetic biology, with particular focus on the transfer of digital biological information between institutions and individuals and the methods for the assembly of genetic constructs. These projects are generally focused on developing openly accessible resources for various groups to use with their own tools and projects. This open nature serves the responsible research and innovation (RRI) framework by providing transparency, evidence and data in the development of technical standards. The adoption and further development of the most useful of these standards will be advantageous for synthetic biology as they will:

- enable the transfer of information between tools and designers;
- improve the reliability and reproducibility of designs; and
- allow the sharing of good practice such as the latest developments in prevention of DNA release to the environment [1)].

In the longer term, formal standardization has the potential to foster the generation of a new digital biomanufacturing industry and accelerate research and innovation within academia.

[1)] MANDELL D. J., LAJOIE M. J., MEE M. T., TAKEUCHI R., KUNZETSIV G., NORVILLE J. E., GREEG C. J., STODDARD B. L. and CHURCH G. M. Biocontainment of genetically modified organisms by synthetic protein design. *Nature.* (2015) and ROVNER A. J., HAIMOVICH A. D., KATZ S. R., LI Z., GROME M. W., GASSAWAY B. M., AMIRAM M., PATEL J. R., GALLAGHER R. R., RINEHART J. and ISAACS F. J. *Recoded organisms engineered to depend on synthetic amino acids. Nature.* (2015).

1 Scope

This PAS gives guidance on the systematic approach to the use of standards for digital biological information in the design, construction and description of a synthetic biological system.

This PAS provides guidance on:

- how digital biological information can benefit the process of designing, constructing and describing biological systems (Clause **3**);
- standards in development for the transfer of digital biological information (Clause **4**);
- metrology requirements for digital biological information (Clause **4**); and
- development of standards for constructing biological systems with digital biological information (Clause **5**).

It does not give specific technical requirements about how to construct such processes, but contains reference to what standards are available and in development, and guidance on their use.

It does not cover:

- specific details of the methods for generating digital biological information;
- how to utilize digital biological information within an existing manufacturing process;
- specific details regarding the design of new manufacturing processes around digital biological information; and
- the utilization of digital biological information and its implementation within the responsible research and innovation (RRI) framework.

It is intended for use by companies, academics and institutions looking to innovate using digital biological information or intending to develop commercially acceptable manufacturing processes.

2 Terms, definitions and abbreviations

For the purposes of this PAS, the following terms and definitions apply.

2.1 Terms and definitions

2.1.1 abstract level

conceptual rather than physical level

2.1.2 biological product

product produced by a living organism

NOTE *Biological products can include, for example, enzymes or chemicals.*

2.1.3 component

DNA object within the synthetic biology open language (SBOL) data model

2.1.4 device

combination of parts that carry out a task

NOTE *This term originated with the BioBrick-based abstraction hierarchy.*

2.1.5 DICOM-SB

data system developed from the existing DICOM standard data model, specifically designed for synthetic biology

NOTE *This incorporates the full range of characterization data (including colour images, where appropriate) and metadata, for a given characterization protocol.*

2.1.6 digital biological information

functional design characteristics of a synthetic biology system

NOTE *This also applies to the end use and includes the behavioural properties, the characteristics of the system implementation and the contexts within the system.*