Engineering Biology Metrics and Technical Standards for the Global Bioeconomy

Asia and Australia Workshop Report

Contents

1. Introduction

There is a pressing need to establish global technical standards and metrology for Engineering Biology. The lack of standardization in various areas of the bioeconomy innovation process may lead to significant challenges in data integration and interoperability, regulatory compliance, product quality, and consumer transactions. The result would be a delay in advancing the bioeconomy and the integration of biomanufacturing into industry practices.

The Engineering Biology Metrics and Technical Standards for the Global Bioeconomy workshop series aims to identify the community's needs for advancing standardization and metrology within Engineering Biology. Through the interactions and involvement of key stakeholders, this global initiative seeks to identify scientific, technical, operational, and semantic standards driven by the community. The goal is to enhance scalability, improve reproducibility in different locations and batches, and boost the performance of microbial factories and bio-products. Through these efforts, we can open voluntary standards for Engineering Biology which can be established and facilitate the growth and success of the bioeconomy.

This report summarizes the proceedings of the Asia and Australia Workshop held in Singapore on 29-31 August 2023. The workshop emphasized that identifying standards complements other supporting actions, such as recent regulatory changes and technological advancements. As previously highlighted in the America segment of the workshop series, setting standards is crucial for the biotechnology industry; it will determine the long-term success and growth of the research field and its ecosystems.

2. Asia and Australia Workshop Summary

In a global endeavor to advance the field of Engineering Biology, a series of workshops has emerged as a vital platform for establishing consensus on technical standards and metrology. Following the successful Americas Workshop, the Asia & Australia Workshop, brought together key stakeholders in the region at the Shangri-La Rasa in Sentosa, Singapore. From the 29th to the 31st of August 2023, nearly 40 attendees from 13 countries and various sectors, including industry, academia, and government, participated in dynamic discussions aimed at harmonizing metrics and standards in this rapidly evolving field.

Hosted by the National University of Singapore (NUS) and the Singapore Consortium for Synthetic Biology (SINERGY), the Asia & Australia Workshop on Engineering Biology Metrics and Technical Standards, marked a significant step in the global effort to delineate essential standards and metrics for Engineering Biology. This workshop shed light on the challenges and opportunities posed by these standards and metrics in Engineering Biology in the region. Participants overwhelmingly recognized the importance of establishing standards in Engineering Biology, despite the complexity of defining the problem space. A shared sentiment emerged: standards are the cornerstone of innovation though the precise route toward realizing this objective remains under formulation. As one participant aptly noted, "**We need to do something... pick a few things to start.**"

A key focus of the workshop was the collaborative dialogue among stakeholders about existing standards, which is vital for establishing a foundational framework. Moreover, there was unanimous agreement on the necessity to standardize the burgeoning volume of biological data produced globally. The success of standard-setting efforts in medical imaging, genomics, and genome editing served as a powerful example, illustrating the potential of community-driven standardization initiatives. Productive discussions led to several action items and collaborative initiatives. These include harmonizing data

formats under the potential leadership of the Global Biofoundry Alliance, promoting data sharing and collaboration between academia and industry, and emphasizing the roles of regional organizations like ASEAN in shaping the vision for Engineering Biology standards. In the coming months, we anticipate more regional initiatives with clear structures and objectives to further advance standardization.

As part of a broader series of workshops across the Americas, Asia & Australia, and Europe, the action items underscore the commitment to fostering cooperation and openness within the global Engineering Biology community. The outcomes of these workshops will contribute to a joint strategic report led by the Task Force on Engineering Biology Metrics and Technical Standards, comprised of representatives from EBRC, NIST, the National University of Singapore, Imperial College London, and Schmidt Futures. The Task Force aims to ensure that standards and metrics align with the specific priorities and needs of the Asia-Pacific and Australian regions, while also advancing the broader global dialogues on Engineering Biology standards.

The Engineering Biology Metrics and Technical Standards for the Global Bioeconomy project aims to identify scientific, technical, operational, and semantic standards driven by the community and stakeholders. These standards are intended to enable and drive scale-up capabilities, enhance reproducibility across batches and locations, and improve the performance of microbial factories and bio-products.

The objective of the Asia & Australia Workshop was to address the following pertinent points:

- Where are we now? What is the current regional ecosystem for Engineering Biology standards and metrology?
- What have we learned from past efforts?
- What standards and metrology are needed to promote innovation and market-growth regionally and globally?
- What local and global developments, technical and otherwise, are required to achieve the standards and metrology needed?

2.1 Abridged Agenda for Asia & Australia Workshop

Tuesday, 29 August 2023
Barnacles By the Sea Room
Shangri-La Rasa Sentosa

1830	**Welcome Dinner** An opportunity to build connections and begin discussions with fellow participants.

Wednesday, 30 August 2023
Barnacles By the Sea Room
Shangri-La Rasa Sentosa

0800	Registration
0830	**Welcome to the Workshop** *Matthew Chang (National University of Singapore, NUS and Singapore Consortium for Synthetic Biology, SINERGY)*
0835	**Overview and Objectives of the Workshop** *Genevieve Croft (Schmidt Futures)*
0845	**Session 1: Engineering Biology Standards and Metrology: Opportunities and Challenges** *Chairs: Juliette Malley (Imperial College, U.K.) and Kostas Vavitsas (SINERGY)*
	0845: *Paul Freemont (Imperial College, U.K.)* Developing metrics and standards for Engineering Biology 0855: *Sheng Lin-Gibson (National Institute of Standards and Technology, U.S.A.)* Engineering Biology metrology and standards and current U.S. efforts 0905: *Ran Wang (BGI Group, China)* Opportunities and challenges in advancing Engineering Biology metrology and standards 0915: *Kanchana Wanichkorn (ASEAN, Indonesia)* Metrology and standards for bioeconomy policy 0925: *Makiko Matsuo (University of Tokyo, Japan)* Policy and regulation for metrology and standards 0935: *Ajay Perumal (Economic Development Board, Singapore)* Metrology and standards for bioeconomy 0945: Discussion
1000	Break

1030	**Session 2: Engineering Biology Metrology and Standards: Current State and Development** *Chairs: India Hook-Barnard (Engineering Biology Research Consortium, U.S.A.)* and *Wen Shan Yew (NUS)* 1030: *Celine Tan (Enterprise Singapore)* Engineering Biology metrology and standards in Singapore 1040: *Fan Jin (Shenzhen Infrastructure for Synthetic Biology, China)* Engineering Biology metrology and standards in China 1050: *Faisal Khan (Precision Medicine Lab, Pakistan)* Engineering Biology metrology and standards in Pakistan 1100: *Haseong Kim (Korea Research Institute of Bioscience and Biotechnology)* Engineering Biology metrology and standards in Korea 1110: *Sivinee Sawatdiaree (Office of National Higher Education Science Research and Innovation Policy Council and National Institute of Metrology, Thailand)* Engineering Biology metrology and standards in Thailand 1120: *Robert Speight (CSIRO, Australia)* Engineering Biology metrology and standards in Australia 1130: *Wataru Mizunashi (New Energy and Industrial Technology Development Organization, Japan)* Engineering Biology metrology and standards in Japan 1140: Discussion
1200	**Lunch** Silver Shell Café, Shangri-La Rasa Sentosa
1330	**Session 3: Metrology and Standards in Industry: Engineered Biology as the Product** *Chairs: Emily Aurand (Engineering Biology Research Consortium, U.S.A)* and *Wataru Mizunashi (New Energy and Industrial Technology Development Organization, Japan)* 1330: *Santanu Dasgupta (Reliance Industries, India)* Metrology and standards in the biotechnology industry 1340: *Laura Navone (EdenBrew, Australia)* Metrology and standards in the agri-food industry 1350*: Lei Dai (SynBiome, China)* Metrology and standards in the microbiome industry 1400*: Soichiro Tsuda (bitBiome, Japan)* Metrology and standards in the microbiome industry 1410*: Chionh Yok Hian (GenScript, Singapore)* Metrology and standards in the gene synthesis industry

	1420: *Jungjoon Lee (ToolGen, Korea)* Metrology and standards in the genome-editing industry 1430: *Ramon Gonzalez (Mojia Bio, Singapore)* Metrology and standards in the biomanufacturing industry 1440: Discussion
1500	Break
1530	**Session 4: Metrology and Standards in Industry: Engineering Biology as the Process** *Chairs: Cynthia Ni (Engineering Biology Research Consortium, U.S.A)* and *Ran Wang (BGI Group, China)* 1530: *Seokmyung Lee (CJ CheilJedang, Korea)* Metrology and standards in biomanufacturing processes 1540: *Tomohisa Hasunuma (Kobe University, Japan)* High-throughput analytics and automation for Engineering Bioology metrology and standards 1550: *Jianzhi Zhang (Chinese Academy of Sciences)* Biofoundry for Engineering Biology metrology and standards 1600: *Koichi Yoshioka (Bacchus Bio, Japan)* Metrology and standards in the biofoundry industry 1610: *Chueh Loo Poh (NUS, Singapore)* Metrology and standards in the bioimaging industry 1620: *Donghyuk Kim (UNIST, Korea)* Biological data management and sharing 1630: *Erhan Simsek (Agilent, Singapore)* Metrology and standards in the bioanalytics industry 1640: Discussion
1700	**Discussion and Summary** *Kostas Vavitsas (SINERGY)* Engineering Biology metrology and standards: Current state, opportunities, and challenges
1730	Adjournment
1830	**Banquet Dinner** Shangri-La Rasa Sentosa

Thursday, 31 August 2023
Barnacles By the Sea Room
Shangri-La Rasa Sentosa

0830	**Welcome to Day 2** *Matthew Chang (NUS and SINERGY)* Overview and Objectives; Instructions for Breakout Sessions; Introduction of Discussion Leads
0835	**Breakout Session 1** ● Standards and metrics for engineered biology as the product o *Leads: Santanu Dasgupta (Reliance Industries) & Laura Navone (EdenBrew)* ● Best practices for data sharing and platform interoperability o *Leads: Chionh Yok Hian (GenScript) & Jungjoon Lee (ToolGen)* ● Metrology and Standards that support regulations and biosecurity o *Leads: Kanchana Wanichkorn (ASEAN) & Makiko Matsuo (University of Tokyo)*
0945	Break
1000	**Breakout Session 2** ● Standards and metrics for Engineering Biology as the process o *Leads: Seokmyung Lee (CJ CheilJedang) & Ramon Gonzalez (Mojia Bio)* ● Translating and coordinating with existing standards and benchmarks o *Leads: Ran Wang (BGI) & Erhan Simsek (Agilent)* ● International partnership and engagement o *Leads: Kostas Vavitsas (SINERGY) & Robert Speight (CSIRO)*
1110	**Discussion and Workshop Summary** *Matthew Chang (NUS and SINERGY)* Engineering Biology metrology and standards: Collaborative initiatives and action items for Asian and Australian communities
1200	**Lunch** Silver Shell Café, Shangri-La Rasa Sentosa
1330	**End of the Workshop**

3. Report Overview

As a workshop participant remarked, "… [now] we have discussed substantially, so where do we begin?" as we attempt to take more proactive actions in establishing regional and global standards and metrics in accelerating the bioeconomy. The Asia and Australia Workshop summarized the opportunities, challenges, and requirements that arise, all of which are important to consider when developing metrics and standards within this region. Efforts were also made during the workshop to pinpoint follow-up actions aimed at advancing standardization and metrology, focusing on specific areas with clear objectives. This report contains the following sections: (1) Metrics, (2) Technical Standards and (3) Recommendations. It aims to address the shared concerns and challenges faced by the various stakeholders in academia, industry, and regulatory bodies in advancing standardization efforts in the region.

3.1 High-Level Takeaways

- The participants unanimously recognized the utility of a comprehensive set of standards for the bioeconomy. However, the path to achieve this remains elusive. A problem articulated by one of the attendees was the difficulty in defining the problem space. There ought to be a consensus among the people when discussing standards and metrics for the bioeconomy. While the topic of setting standards for the bioeconomy has been actively discussed at great lengths within both the Americas and the Asia & Australia workshops, actionable steps are still absent. As one other participant emphasized, "We need to do *something* … pick a few things [to start] ...". The workshop yielded several actionable outcomes and proposed regional collaborations, all of which will be detailed later in this report.

- Several key discussion points related to the standard setting emerged from the workshop. (1) There is a need to develop a framework to educate stakeholders on existing standards (e.g., ISO/TC 276 Biotechnology). Surprisingly, a significant number of participants were unfamiliar with these existing standards. (2) With the increasing volume of biological data generated worldwide, there was a clear consensus on the need to set standards for data sharing. The success of standard-setting efforts in medical imaging, genomics, and genome editing, served as a powerful example, illustrating the potential of community-driven standardization initiatives. Existing standard-setting efforts, such as the medical imaging standard DICOM 3.0, exemplifies how industry players (even direct competitors) can come together to establish a set of standards for sharing medical images from different companies' imaging devices. By adopting and learning from existing standard-setting efforts, these pioneering efforts might provide useful directions and testbeds for setting data-sharing standards in the bioeconomy. Noteworthy collaborative initiatives discussed include promoting data sharing and collaboration between academia and industry and harmonizing data formats under the Global Biofoundry Alliance's potential leadership.

- For standardization to succeed, it must be inclusive. In the workshop context, while China remained a major player in the region for standard setting, Singapore, Japan, Korea, India, and other regional countries played significant roles in contributing to the regional consensus on standard setting. While acknowledging the regional differences between countries in the region, any standard-setting processes without buy-in from all or most of these players would fragment an already fragmented landscape for standard setting within the region. One possible effort is to further involve and engage regional organizations, such as ASEAN, to take on active roles of directing and facilitating standard-setting discussions for Engineering Biology.

4. Metrics

Metrics are defined as the measurements used to assess various aspects of a product or process, including its technical, economic, and social viability. Metrics play an instrumental role in process development, enabling researchers and companies to fine-tune and optimize processes. By identifying and tracking relevant metrics, bottlenecks and inefficiencies can be pinpointed and addressed, potentially accelerating innovations in Engineering Biology.

4.1 Diverse Needs for Metrics

At the Asia and Australia Workshop, participants acknowledged the importance of standardizing metrics, despite the challenges involved in reaching a consensus on which metrics to standardize. Ideally, metrics should be adaptable and context-specific. There is a need to identify a core set of universally applicable metrics while allowing flexibility for customization in the innovation pipelines. Participants underscored the critical importance of measuring uncertainties within biological systems and the need to develop methodologies for predicting and managing these uncertainties effectively. Additionally, it's essential to incorporate controls, including reference materials and design strategies, to address the intricate nature of biological measurements.

The metric requirements in Engineering Biology can vary significantly depending on the specific context. For instance, key metrics for cell growth and viability are crucial for understanding and optimizing fermentation processes, while downstream processes may require metrics related to product purity and yield. This diversity highlights the challenge of developing a comprehensive set of metrics that can accommodate various applications. Furthermore, metrics play an integral role in scaling up technologies from laboratory-scale experiments to industrial production. Metrics related to scalability assess the feasibility of transitioning processes to larger scales while maintaining performance and efficiency. Ensuring these specific metrics are properly defined is essential and remains a challenge for the successful commercialization of biotechnology products.

Further, metrics are relevant in a regulatory context. Regulatory agencies are increasingly seeking well-defined metrics that can provide a basis for assessing product safety and efficacy. Specifically, standardized metrics can facilitate regulatory approval processes, streamlining the path to market for bio-based products.

4.2 Data-Driven Decision-Making

Metrics are identified to be increasingly critical to data-driven decision-making in Engineering Biology. They provide quantitative insights that guide researchers in making informed choices throughout the research and development process. Participants reiterated the importance of collecting high-quality data and aligning metrics with a project's objectives. The standardization of metrics is closely tied to data sharing and interoperability. This interoperability can significantly enhance the efficiency and impact of research efforts. There is a consensus on the importance of developing common metrics and data formats, allowing for seamless collaboration and data exchange among laboratories, organizations, and biofoundries. This interoperability can significantly enhance the efficiency and impact of research efforts. One potential action item from the workshop discussion was harmonising data formats under the potential leadership of the Global Biofoundry Alliance.

5. Technical Standards

Numerous topics were discussed in detail at the Asian and Australian Workshop. These key summary points have been elaborated and remain top considerations for the workshop participants.

5.1 Regional Developments in Standard Setting

At the workshop, open discussions revolved around the current state of standards in Engineering Biology and the challenges and opportunities they present within the region. Participants stressed the importance of balancing standard-setting to support innovation while maintaining safety and quality. The paramount importance of standards as enablers for translating innovative concepts into tangible applications was a recurring theme throughout the workshop.

Participants engaged in a comprehensive discussion regarding the critical role of establishing standards within the biotechnology industry. The discourse commenced with a fundamental query concerning the feasibility of a growing biotech sector without standardized protocols. While the pharmaceutical domain enjoys a well-defined set of standards, the nascent Engineering Biology sector faces a noticeable lack of such guidelines for standardization. The need for metrics and benchmarks specific to bioprocesses and products was highlighted. Participants recognized that while these standards provide a base foundation, they may not fully align with the unique aspects of biotechnology, in which technologies evolve rapidly over time. Further, there are constant challenges in matching new technologies and platforms with existing standards.

The standardization of feedstock materials emerged as a pivotal facet of the growth and success of the bio-based industry. Participants delved into the differentiation between petrochemical feedstocks and bio-based feedstocks. Petrochemical feedstocks were characterized as relatively homogeneous and amenable to standardization, whereas bio-based feedstocks were perceived to necessitate more concerted standardization efforts. Emphasis was directed on biomass feedstock and its relationship with sustainability, focusing on ASEAN and its initiatives to harness biomass opportunities to drive economic development. It is important to note that ASEAN operates on a consensus-driven model, requiring unanimous agreement from all 10 member nations for any proposed activities in this domain. In the same vein, regulations were identified as a pivotal driving force in the bio-based sector, particularly within Europe, where regulations mandate minimum percentages of sustainable aviation fuel (SAF) in traditional jet fuels. These regulatory mandates not only stimulate demand but also contribute to enhanced profit

margins within the industry. Regional organizations, such as ASEAN, can ideally take the lead in driving innovations in the Engineering Biology sector.

In the United States and Australia, the concept of distributed manufacturing through bio-based processes was suggested. This model had not been widely explored in Asia regions. Questions arose regarding the feasibility and economic viability of large-scale biomass processing, as well as the potential advantages of harnessing the decentralization of biomanufacturing in the bio-based industry in this region.

In China, there was an emphasis on the development of a standards roadmap aimed at ensuring the safety and regulatory compliance of biotech products in the country. This endeavor stemmed from the recognition of the need to establish a regulatory framework capable of accommodating the rapid advancements occurring within the Engineering Biology sector. The discourse also touched upon the design of biofoundries, whether biofoundries should be designed to be identical or customized and how data integration across various processes and vendors could be achieved. While some participants emphasized the concept of "soft integration" and shared data repositories in biofoundries, concerns were expressed regarding the absence of standardized data interfaces from vendors. Nonetheless, participants conveyed their willingness to collaborate towards data standardization to promote greater interoperability.

In Japan, as part of the Engineering Biology process, the country was committed to introduce mandatory Life Cycle Assessment (LCA), with ongoing initiatives aimed at standardizing the LCA process. Notably, concerns were raised regarding the quality of LCA data, particularly in the realms of bioeconomy and Engineering Biology, highlighting the need for significant improvement in this area.

The discussion further addressed the adoption of standards from initiatives like the iGEM (International Genetically Engineered Machine) foundation. While acknowledging the historical utility of these standards, there was a shared recognition that standards should remain purpose-driven. If they become obsolete or less relevant, a willingness to evolve and adapt is paramount. The iGEM platform was acknowledged as valuable for countries like Thailand and Pakistan, and there was interest in establishing similar initiatives in other regions.

Lastly, the role of social interactions and societal acceptance within the biotechnology field was also examined. Participants from diverse countries displayed varying approaches to risk and acceptance of genetically modified (GM) products, leading to divergent tolerances for a wide array of GM products. Importantly, the regulatory frameworks and public perception surrounding GM and genome-edited products were acknowledged as substantial determinants of a country's competitiveness in the biotechnology arena.

5.2 International Partnerships and Engagement

A pivotal theme that emerged is the need for fostering global collaboration and engagement within the biotechnology field. An active, comprehensive discussion covered various facets of international cooperation, the imperative for standardized practices, and the roles played by different stakeholders. A key discussion point was determining whether existing global engagement mechanisms could effectively serve as platforms for standard practices, or if the establishment of new ones was necessary. It was proposed that commencing from existing organizations and forums was a pragmatic approach, as creating entirely new mechanisms from scratch can be challenging. The importance of establishing consensus and shared values in informal settings before formalizing them in standards development

processes was strongly emphasized. While existing dialogue platforms exist in our region, they seldom focus on standardization. A suggestion was made to harness the expertise of these existing groups by redirecting their efforts toward standardization initiatives. It was noted that certain representations were required in these potential consortia, such as experts from standardization bodies and other diverse backgrounds.

To adeptly navigate the international landscape, participants advocated for the creation of a comprehensive map encompassing stakeholders, processes, areas of focus, and forums. Such a map would serve to identify gaps and opportunities for international collaboration effectively. Stakeholder analysis was recommended to align stakeholders with specific themes and areas of interest. The discussion further touched upon existing international working groups and organizations relevant to biotechnology. While the bioeconomy was an initial focal point, participants noted that some parallel sectors, such as food industries, already possess established frameworks. Enhanced coordination between organizations, such as the Organization for Economic Co-operation and Development (OECD) and the International Organization for Standardization (ISO), was also emphasized, which can potentially lead to translating scientific evidence into standards.

Lastly, it was recognized that no single group or country could comprehensively cover all aspects of biotechnology, necessitating better definitions and categorizations of topics to guide collaboration effectively. Building trust among partners and having shared objectives were identified as critical factors for successful international partnerships, in accelerating the bioeconomy. However, the balance between international engagement and country-specific focus was considered crucial. Participants acknowledged that regulatory landscapes differ among countries and regions, necessitating a nuanced approach to navigate this diversity effectively.

5.3 Setting Standards: Engineered Biology as the Product

Workshop participants identified two primary categories for engineered biology products: materials and services. Materials encompass tangible products such as engineered organisms and biomaterials, while services include offerings like microbiome data analysis, gene synthesis, and personalized dietary prescriptions. There are complexities in regulating and standardizing products in the field of engineered biology. The discussion underscored the complexity of services such as DNA synthesis and strain engineering, which involve intricate upstream biological processes. In such cases, having a standardized framework can enhance reliability and consistency, benefiting both service providers and consumers. Moreover, regulatory oversight can protect consumers, particularly in contexts involving microbiome-related products, by ensuring that safety and quality standards are upheld. Beyond the categories of materials and services, participants acknowledged that some engineered biology products may not neatly fit into these distinctions. This led to a discussion on the challenges associated with regulating novel products like cultured meats, bio-leathers, engineered bacteriophages, and engineered gut bacteria.

One of the significant challenges identified was evaluating the safety of these novel products. Defining what constitutes a safe product, especially when dealing with novel offerings, proved complex. Participants highlighted the importance of demonstrating comprehensive safety data and addressing complex safety matrices. The concept of "Generally Regarded as Safe" (GRAS) was also discussed, with participants considering the need for equivalent GRAS strains for novel products and impurity quantification. There is a need to reshape public perception regarding engineered biology products. Early-generation GMO foods have left negative connotations in the public's mind, making it essential to engage with the public, highlight present successes in improving food security, and redefine the language used to

communicate the benefits and safety of these products. In the same vein, standardized labeling emerged as another prominent topic. Participants emphasized the importance of proper labeling, including accurate information about a product's safety and efficacy. The discussion addressed concerns about misleading labels, particularly those claiming environmental friendliness, without proper life cycle assessments (LCA) and techno-economic analyses (TEA) to objectively quantify a product's green credentials.

With regards to the metrics and standards for AI in the context of Engineering Biology, there was a consensus that the standardization of large biological datasets is crucial. While genomic data has seen some standardization, phenotypic data, which involves various variables such as incubation time and temperature, remains challenging to standardize. This process often requires substantial manual curation, making it unfeasible for academic laboratories but possibly manageable for companies. However, a significant bottleneck in AI applications in biology arises from data collection and cleansing, as many companies are reluctant to share their data, even though the consensus is that data sharing is essential for advancing AI-driven solutions.

The sharing of information and workflows among companies remains a complex challenge, as the need for companies to maintain proprietary assets often clashes with the transparency needed for standardized practices. From an industry viewpoint, it is evident that not all companies require comprehensive community standards, as many have internal standards in place. Resistance to adopting new standards might arise due to potential cost increments, which might deter industry players. As such, engaging these organizations and highlighting the merits of adopting new standards remains a challenge. Tangible benefits that align with industry profit motives, such as facilitating market access through compliance with different regulatory structures, could serve as incentives for industry-wide adoption of standards. Nevertheless, there is growing recognition of the importance of standardization in synthetic biology, and initial steps toward transparency can emerge through mechanisms like internships and collaborations. Participants also considered the nature of standards, with some highlighting the potential for proprietary standards that could be licensed to others. This approach allows companies to retain some level of control and potentially generate revenue from their standards while still contributing to standardization efforts.

5.4 Setting Standards: Engineered Biology as the Process

There are inherent complexities in regulating and standardizing the multifaceted processes within the domain of Engineering Biology. What defines a process in this context? The participants collectively agreed that a process encompasses everything that occurs between input and output. This expansive definition covered a wide array of elements, including the standardization of Research and Development (R&D) cycles, the optimization of process flow, measurement processes, and the intricate world of Life Cycle Assessment (LCA). Some distinct process categories include medical, food, pharmaceuticals, and R&D workflows for discovery and process creation.

Within these categories, discussions delved into the nuances of standardization, highlighting the need to redefine the concept of Design-Build-Test-Learn (DBTL). This redefinition was deemed essential to encompass the multiple DBTL cycles that can be encapsulated within a larger DBTL framework. The process of developing R&D workflows, transitioning from upstream to downstream, was examined. The journey from R&D to pilot and then to production was outlined, with a specific focus on DBTL and the need for standardized assays to accelerate this critical cycle. While participants acknowledged the necessity of standard data at the forefront of DBTL to drive consistent testing, variables stemming from

starting biomaterials, such as raw feedstocks with inherent variabilities, posed challenges that called for innovative metrology methods to drive standardization.

There is also a crucial task of optimizing process flow. Participants recognized the significance of imposing standards to achieve efficiency and reliability. They highlighted the role of Standard Operating Procedures (SOPs) in the biological process workflow, which were seen as vital for quality control and process consistency despite being predominantly kept in-house. Equipment standards, exemplified by companies such as Agilent's standards, were acknowledged as influential in shaping processes. Moreover, the consensus was that industry leaders and regulatory bodies, exemplified by the US-FDA, often set the standards for processes and drive innovation within specific technological fields. Engaging the regulatory authorities earlier in the R&D pipeline is therefore encouraged.

The timing of standard development within the Engineering Biology process was also discussed. The consensus was that its development should depend on the needs of either the customer or the broader research and industry community. Ideally, standards should serve a purpose and fulfill a specific need, whether it is for improving interoperability, ensuring data consistency, or enhancing the overall quality of processes and products. A parallel was drawn to the DICOM (Digital Imaging and Communications in Medicine) standard, commonly used in the medical field to facilitate the exchange of medical images and related information. Identifying both the providers and end-users of standards is crucial. In this case of the DICOM standard, the end-users are the companies or organizations that want to use the data, while the vendors provide the necessary tools and infrastructure. However, it was also noted that abundant metadata might not always be necessary for the end-users although valuable for certain applications. The focus should be on determining what data annotations and information need to be collected.

On the topic of process regulation, regulatory efforts varied significantly across regions. While some sectors, like biotechnology laboratories, had established regulations, others, such as in Japan, reported limited efforts in this aspect, while other fields, such as medical devices and food manufacturing, were recognized for their regulatory frameworks, often complying with ISO certification, and adopting Six Sigma methodologies.

Unique challenges exist in standards development in the field of Engineering Biology. Unlike health data standards, which are often organized around the patient, the organization of data in this field is still an open question. This raised discussion about whether data should be organized at the strain level, which is a fundamental unit in Engineering Biology. However, there was no definitive answer, emphasizing the need for further discussions in the Engineering Biology community. There was also an absence of a clear framework for developing standardized processes, particularly in the novel food industry. Participants acknowledged the potential to draw insights from existing food products as guides for standardization and regulatory frameworks.

5.5 Setting Standards: Regulations and Biosecurity

There was a strong consensus that understanding the expectations and preferences of regulators concerning the integration of biotechnology processes and products is crucial for the industry's success. Divergent regulations for domestic and international markets across countries were identified as a significant challenge. The industry expressed the need for well-defined guidelines, especially for the emerging Engineering Biology field, which often falls into regulatory gray areas. Environmental impact assessments were noted as a key aspect of regulatory evaluation. It was suggested that the industry, armed with technological expertise, should take a proactive role in educating regulators, whereby most

companies have developed their own internal standards, and often align and fall back on existing genetic modification regulatory frameworks. Thus, coordinated efforts between industry and regulatory bodies were highlighted as essential for effective regulation. Standards and metrics for biosecurity were also highlighted, involving safety by design principles, traceability, barcoding, and the differentiation between natural and synthetic DNA.

The timing of raising biosecurity as a public policy issue was further contemplated, with recent developments, such as concerns related to gene synthesis, elevating biosecurity to a prominent position in policy discussions, particularly in the United States. Further into the topic of biosecurity, a multifaceted concept that encompasses various scenarios, from detecting viruses in wastewater to safeguarding against the deliberate creation of harmful pathogens, participants emphasized the necessity of collectively defining biosecurity within the context of biotechnology as a starting point. The intertwining of biosecurity regulations with biosafety laws and the evolution of GMO regulations over time were noted. The impact of the COVID-19 pandemic on the distinction between biosafety and biosecurity was debated and from the discussion, the concept of "bio-surveillance" was proposed as a more comprehensive framework addressing both safety and security aspects.

Across the world, the regulation of Engineering Biology products and processes also differs, with regions like the UK moving toward product-based regulation while Asia maintains stringent GM regulations integrated into biosafety laws. Singapore's pragmatic regulatory approach was highlighted, exemplified by its approval of cultured meat and its aspirations to become an innovation hub for the food industry.

5.6 Best Practices for Data Sharing and Platform Interoperability

There is a need to critically examine what types of data should be shared. It was emphasized that academia often advocates for the consolidation and sharing of most data. However, the boundaries between what data can and cannot be shared by the industry entities were recognized as far less clear-cut. While public funding often enforces data sharing through public databases, there was a recognition that a systematic mechanism to incentivize researchers and companies to share data is essential. Without such mechanisms, various stakeholders may be inclined to withhold their data. A key consideration was determining what types of data should be shared and ensuring that stakeholders on the ground are actively involved in this decision-making process.

The need to establish a clear definition of 'data' was highlighted to ensure a common understanding among stakeholders. Moreover, data quality was underscored as a critical factor before sharing, with expectations placed on data creators to ensure high quality. However, it was noted that there is currently no standardized system in place to maintain public domain databases, raising questions about data longevity and reliability. Regulatory bodies like the FDA often mandate data registration, allowing data to become shareable after a set period. The stringency of data sharing requirements also varies across industries; the food industry, for instance, is stricter about sharing data related to product and process safety.

Questions were also asked about additional components needed alongside data, such as metadata, and whether these too should be shared. Completeness was emphasized as an essential aspect of data quality, with discussions delving into the broad scope of data within the bioeconomy. The issue of data protection, particularly regarding intellectual property was raised. It was noted that even companies under the same corporate umbrella may be reluctant to share data with each other due to knowledge leakage concerns. It was pointed out that data on failures should be shared to prevent others from encountering

similar challenges. It was acknowledged that companies often remain hesitant to share failures due to competitive concerns and potential reputational damage. In contrast, academia may be more inclined to share failures as part of the research process.

There is also a call for best practices in data sharing, especially concerning issues related to sharing personal human data. Discussion pertained to alternative approaches, such as relying on machine learning to create high-quality data. For companies, data sharing primarily occurs with clients, often under Non-Disclosure Agreements (NDAs). Establishing common language and standardization principles for data sharing was thus essential. A shift in mindset and heightened corporate responsibility were identified as potential catalysts for behavior change in data sharing practices. Additionally, privacy-enhancing technologies that offer anonymity were explored as potential solutions for encouraging the sharing of failures while preserving privacy.

Policy choices in standards development can further have a significant impact on the adoption and implementation of standards. While there may not be a one-size-fits-all answer to this question, it highlights the importance of considering incentives for data sharing and collaboration among stakeholders. In terms of driving other countries to follow the standards developed in biofoundries, one approach discussed was sending standards to other organizations for validation, while another was obtaining government permission for the public release of standards. Building consensus and collaboration among various stakeholders, including academia, industry, and governments, is crucial in promoting the adoption of standards across borders.

6. Recommendations

The Asia and Australian Workshop concluded with several recommendations for follow-up actions and initiatives. The workshop created a positive momentum and sparked interest within the community, a momentum that can be harnessed to achieve significant progress in the standardization and metrology of Engineering Biology.

6.1 Leadership and Coordination

Establishing leadership and coordination within the Engineering Biology communities among stakeholders in the region is paramount to the success of standardization efforts. This requires identifying a central coordinating body or organization that can effectively oversee and guide standardization initiatives. To ensure these efforts are well-directed, clear leadership roles may be established, possibly through the formation of steering committees or working groups. These leadership entities would be responsible for setting priorities, defining goals, and engaging experts and institutions leading in specific standardization areas. A cohesive leadership structure will streamline the standardization process and provide a unified vision for advancing Engineering Biology standards. One recommendation is to engage regional organizations, such as ASEAN, in shaping this vision and forming specialized consortia that include regulatory authorities and stakeholders to frame standards and regulatory guidelines.

6.2 Task Groups

Forming task groups is a potential practical approach to addressing specific aspects of standardization. These groups, composed of experts and stakeholders within specific focus areas, can be responsible for defining standards, reviewing existing ones, and setting clear timelines for the development of new standards. Assigning specific mandates to task groups ensures that they remain focused on key areas of

standardization A targeted and systematic strategy is recommended for the creation and refinement of standards. By establishing committees or working groups within well-established regional organizations like ASEAN, for example, the Science-Technology Innovation (STI) committee, standardization efforts can be expedited. These groups can specialize in specific areas of standardization, fostering in-depth exploration and development. Encouraging collaborations among experts, institutions, and organizations ensures a diverse range of perspectives are considered in standards development. One action item is that the Global Biofoundry Alliance assumes a potential leadership role and serve as a collaborative platform for biofoundries worldwide. This would enable the sharing of data, best practices, and standards, ideally serving as a pioneer model for international collaboration and standardization. Furthermore, engaging with biofoundries across regions not only fosters a sense of community and cooperation but also promotes greater transparency, knowledge exchange, and innovation in the field of Engineering Biology.

6.3 Regulatory Framework

Collaboration with government agencies to develop a comprehensive regulatory framework is essential. This recommendation entails defining guidelines for data sharing, safety protocols, and compliance mechanisms within the framework. Such a framework complements standardization efforts by providing a systematic approach to regulation. Leveraging collaboration platforms can facilitate communication between the standardization community and government agencies, ensuring that regulatory requirements are met while promoting efficient data sharing and compliance.

6.4 Timelines and Disclosure

Clear and definitive timelines for standards development are crucial for accountability and progress tracking. This recommendation emphasizes the importance of setting deadlines for the development and publication of standards. Additionally, sharing the progress of standards development with the wider community promotes transparency and fosters confidence in the standardization process. Making standards accessible to all stakeholders and providing comprehensive documentation ensures that standards are well-understood and can be effectively implemented.

6.5 Information Sharing

Information sharing lies at the core of successful standardization efforts. An active promotion of open dialogues and collaborations that transcend national boundaries is imperative. Creating dedicated platforms and forums for knowledge exchange is crucial for sharing information, experiences, and insights related to standards. Encouraging stakeholders from academia, industry, and government to actively participate in these platforms fosters a culture of openness and cooperation. Effective information sharing is recommended to ensure that best practices and lessons learned are disseminated widely, leading to more informed and efficient standardization efforts.

6.6 Catalog Expansion

As part of information sharing, expanding the catalog of standards is essential for comprehensive standardization efforts. This action item aims to include standards for a wide range of products and processes in Engineering Biology, such as laboratory protocols, data formats, safety procedures, and more. It is crucial to make the catalog accessible, searchable, and adaptable to various contexts. By

expanding the catalog, the Engineering Biology communities can ensure that standards are available for various aspects of their work, fostering consistency and best practices.

6.7 Biosecurity Considerations

In the pursuit of standardization, biosecurity must remain an important consideration. This action item calls for rigorous standards and practices incorporating robust biosecurity measures. These standards must address the potential risks of products inspired by Engineering Biology, including accidental releases and data security breach. It is important to establish guidelines for secure data sharing, laboratory safety protocols, and measures to prevent the unintended release of bioengineered organisms. Furthermore, promoting awareness and education on biosecurity within the community is essential to ensure that stakeholders are well-informed and can implement biosecurity measures effectively.

6.8 Interconnected Workshops

Lastly, forging close collaborations with other regions, such as the Americas and Europe, is vital to pinpoint shared challenges and solutions in standardization efforts. The recommendation emphasizes the need for consistent definitions, lexicon, and language across regions to facilitate global standardization efforts. Sharing large datasets, exploring the role of enabling regulations, developing assessment methods, and addressing economic challenges in unison fosters a cohesive global approach to standardization. This synergy in workshop discussions, action items and best practices ensures that standards are not developed in isolation but are part of a larger, coordinated effort to advance Engineering Biology worldwide.

7. Conclusion

Establishing robust standards and metrics is both a challenging and exhilarating endeavor for Engineering Biology. While standards can be perceived as cumbersome, their indispensable role in fostering innovation, ensuring safety, and facilitating technology transfer cannot be overstated.

One central theme that emerged from the Asia and Australia Workshop is the need for global harmonization in the inherently dynamic field. Unlike traditional industries, the ever-evolving nature of engineered biology introduces unique complexities. The challenge lies in striking a balance between standardized practices and the adaptability required to accommodate continuous change. The bioeconomy thrives on data-driven insights, and the harmonization of data formats emerged and remains as a key action item. It is encouraging to observe various regions such as the ASEAN states and broader Asia already actively working towards data standardization, bridging the gap between data silos, facilitating data interoperability, and amplifying the impact of shared knowledge.

The role of stakeholders in shaping the trajectory of Engineering Biology standards remains integral for the region. Engaging with industry and government stakeholders is pivotal in promoting the adoption of standards. Such standards are increasingly becoming the foundation for more Engineering Biology products and services in the regional market.

In all, the Asia and Australia Workshop provided a platform for meaningful dialogue with key stakeholders from the region. The nexus of collaboration between academia, industry, and regulators is a recurrent theme, through the establishment of a roadmap comprising global alliances, harmonized data formats

and data sharing. As the field of Engineering Biology continues to advance, this shared commitment to standards and metrics will drive the responsible and sustainable growth of the global bioeconomy.