Engineering Biology Metrics and Technical Standards for the Global Bioeconomy

Americas Workshop Agenda

7-9 June 2023

Reception Event (7 June): Cosmos Club, 2121 Massachusetts Ave NW, Washington, DC, USA
Workshop (8-9 June): University of Maryland - Institute for Bioscience and Biotechnology Research, 9600 Gudelsky Dr, Rockville, MD, USA

Workshop Objectives:
Plenary presentations and discussions (plenary and breakout) will consider the following questions:

- Where are we now? What is the current 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 globally?
- What developments, technical and otherwise, are required to achieve the standards and metrology needed?

Participants will aim to identify regional priorities and define a strategy that will lead to a roadmap for developing global standards and metrics for engineering biology.

Please see last page for definitions of key terms and confidentiality guidelines.

Wednesday, 7 June 2023
Cosmos Club, Crentz Room
2121 Massachusetts Ave NW, Washington, DC, USA

4:15 PM	EBRC coordinating ride shares from Hilton Garden Inn to Cosmos Club (will depart promptly)
5:00 PM	**Welcome Reception** An opportunity to build connections and begin discussions with fellow participants. Please note the required dress code for the Cosmos Club (Business Casual). Heavy hors d'oeuvres and drinks will be served.
9:00 PM	EBRC coordinating return ride shares to Hilton Garden Inn

University of Maryland - Institute for Bioscience and Biotechnology Research
9600 Gudelsky Dr, Rockville, MD, USA

Thursday, 8 June 2023
Auditorium (except where noted)

8:00 AM	Registration and Check-in (Atrium) Breakfast available
8:30 AM	**Welcome to Day 1** *India Hook-Barnard (EBRC) and Andrea Hodgson (Schmidt Futures)* Dr. Hook Barnard and Dr. Hodgson will provide an overview and objectives of the workshop.
9:00 AM	**Developing Metrics and Setting Standards** *Paul Freemont (Imperial College) and Plenary Discussion* Prof. Freemont will present key definitions for the workshop, describe current, past and failed efforts, and the purpose for the current effort.

9:30 AM	**The Current State of Standards and Metrics** *Sheng Lin-Gibson (NIST) and Plenary Discussion* Dr. Lin-Gibson will present the current state of engineering biology metrology, metrics, and standards and NIST efforts.
10:00 AM	Break (Atrium)
10:30 AM	**Informal Standards are Barriers to Using Non-Model Organisms** - Sarah Richardson (MicroByre)
10:50 AM	**Panel 1: Upstream Processing and Feedstocks** *Moderator: Jane Romantseva* *Panelists:* Aaron Schaller (MeliBio), Jonathan Jacobs (ATCC), Marilene Pavan (LanzaTech), Sarah Richardson (MicroByre), Swami Srinivas (Ginkgo) *Discussion Questions:* ● What metrics are needed to assess and ensure the reproducibility of engineered organisms in diverse production environments? ● Would it be more beneficial to establish metrics and standards on the methodology of engineering organisms or on the resulting organismal genotype, phenotype, etc.? Are there cases where one or the other is better suited? ● What metrics are needed for feedstocks to improve reproducibility and comparability between batches and processes? ● What measurements and standards are missing from upstream processing that would enable reproducibility across batches and production environments?
12:00 PM	Lunch (Atrium)
1:00 PM	**Downstream Process Development for Precision Fermentation** - Stan Herrmann (Amyris)
1:20 PM	**Panel 2: Downstream Processing and Scale Up** *Moderator: Emily Aurand* *Panelists:* Elizabeth Onderko (Capra Biosciences), Sean Hunt (Solugen), Stan Herrmann (Amyris), Steve Evans (BioMADE), Vikramaditya Yadav (UBC) *Discussion Questions:* ● What are the biggest measurement challenges in downstream processing? ● What (unique) standards are needed for bioprocess/bioproduct purification or separations? ● What new measurements, metrics, and standards are needed to improve reproducibility along the scale-up process? ● What standard reference materials are needed to ensure biomanufacturing quality controls?
2:30 PM	Break (Atrium)
3:00 PM	**Standards and Benchmarks for Automated Experimentation** - Pete Kelly (Align to Innovate)
3:20 PM	**Panel 3: Process Development and Data** *Moderator: Cynthia Ni* *Panelists:* Dave Vance (BU DAMP Lab), Emiley Eloe-Fadrosh (LBL), Nathan Hillson (LBL), Pete Kelly (Align to Innovate) *Discussion Questions:* ● What reference materials and standards are needed throughout the workflow of biomanufacturing process development?

	• What aspects of automation for scale-up are amenable to standardization to ensure reproducibility across batches and production environments? • How could data reporting be improved to promote innovation and facilitate engagement with regulatory bodies?
4:30 PM	Recap of Day 1, Plans for Day 2
5:00 PM	Adjourn

Friday, 9 June 2023

Auditorium (except where noted)

8:30 AM	Arrival and Breakfast
9:00 AM	Welcome to Day 2: Overview and Objectives; Instructions for Breakout Sessions
9:30 AM	Breakout Session 1 A. Standards and metrics for **engineer*ed* biology as the product** (e.g., T-cells, crops) B. Feedstocks: components, consistency, and sustainability C. Standards and metrics for **engineer*ing* biology as the process** (e.g., organism, enzyme, strain platforms for biomanufacturing)
10:45 AM	Break
11:15 AM	Breakout Session 2 A. Standards that support regulations and biosecurity B. Translating and coordinating with existing standards and benchmarks C. Metrology: tools, platforms, and equipment
12:30 PM	Lunch (Atrium)
1:45 PM	Breakout Session 3 - *Subject to change based on Slido poll* {Informal Break during Breakout Session 3} A. Best practices for data sharing and platform interoperability B. Safety, sourcing, traceability, public perception C. Connecting capabilities and competencies of CMOs for scale up and DSP
3:00 PM	Plenary Discussion and Workshop Summary
4:00 PM	Adjourn

Definitions:

Standards: (1) A published document that provides specifications, guidelines, characteristics, or procedures that can be used consistently, and are designed to maximize the reliability or to ensure that materials, products, processes, and services are fit for their purpose. (2) Requirements that establish the fitness of a product for a particular use and may address product features, performance, quality, compatibility, or other product attributes.

Metrics: The measurements made towards assessing the (technical, economic, social, etc) viability of a product or process.

Metrology: The science of measurement and its application.

Upstream processing: The first phase of the bioprocess from cell line development, optimization, and cultivation to the fermentation process.

Feedstock: Raw material to supply or fuel a machine or industrial process.

Downstream processing: The part of a process where the upstream product is recovered, concentrated, and purified to meet quality requirements.

Scale up: The steps involved in transferring a manufacturing process or section of a process from laboratory scale to the level of commercial production.

Process development: The exercise of creating a means to manufacture a given product in a given quantity.

This meeting will run under Chatham House Rule and in accordance with the EBRC Antitrust Policy.