Synergizing efforts to accelerate the development of materials and manufacturing enabled by synthetic biology

Sheng Lin-Gibson, Ph.D., Chief
Biosystems and Biomaterials Division, NIST
Materials and Manufacturing Enabled by Synthetic Biology/NMMB
May 1, 2019
• Learn and adopt from adjacent industries, particularly emerging cell and gene therapy

• Coordination of a network of “infrastructures” (Design, Build, Test, Production-tools and platforms as well as supporting ecosystem and standards) is required to accelerate discovery and delivery of synthetic biological materials

• Early development and adoption of standards can ensure interoperability and compress lead time from R&D to translations

• NIST efforts in Synthetic Biology, Biometry, and coordination
Diverse CGT product portfolio requires new manufacturing paradigm

Cell and Gene Therapy (CGT)

Diversity of product types, pipeline of capabilities
Will not be “One size fits all”
Learnings from CGT industry

- Rapid advances in science and technology (Immunology, virology, molecular biology, sequencing technologies, single cell measurements, automation, ML/AI, etc.)
- Clear targets (disease and comparison with existing treatment options)
- Cost of Good (CoG), can it be economically viable
- Risks (including regulatory, environmental, social acceptance, etc.)
- Manufacturing innovation: scale up and/or scale out
  - Process technology
  - Fully automated facility
  - Modularity and Mobility
  - Knowledge management
  - Supply chain management
- Quality of consistency (product as well as raw materials and reagents)
Multidisciplinary / Strategic Partnerships for CGT

Early TRLs
- NIH funded consortia
- NSF ERCs
- Academia
- & many others

Clinical
- Government
  - FDA
  - NIST + others

Growing industry
- Manufacturers
- Suppliers
- Equipment makers
- etc.

Mid TRLs
- Armim Advanced Regenerative Manufacturing Institute
- BioFabUSA
- NIMBL
- & many others

Communication, coordination, & advocacy
- Professional societies
- SCB
- MATES

Standards
- ISO
- IEEE
- ASME
- IEC
- ASTM
- US TAG
- others
Sec. 3036 Standards for Regenerative Medicine and Advanced Therapies

- defines “regenerative medicine and advanced therapies” products
- requires FDA to **consult with stakeholders and NIST to establish standards**, to support the development, evaluation, and review of regenerative medicine and advanced therapy products
Coordination of standards (tools, platforms)
Standards coordination for cell and gene therapy

- ISO TC/276: Biotechnology
- American National Standards Institute (ANSI) accredited SDOs: CLSI, ATCC, PDA
- Professional organizations: ISCT, ISSCR
- Accreditation bodies: AABB, FACT
- WHO
- Industry consortia, USP

Coordination is required to avoid conflict and duplication
Translation and Manufacturing: What does it take??

“n of 1” → Repeatedly producing defined quality

- Good **measurements**
- Vibrant “eco-system” with appropriate supporting **technologies**
- **Standards**

NIST mission
Good measurements – Biometrology

Nucleic acids: oligos, genomes, metagenomics, edited genomes, DNAs, RNAs,

Proteins:

Cells: microbial, mammalian, human

Tissues

Other biological entities

Measurement confidence
- “Accuracy”
- Precision
- Sufficient metadata to enable comparison
Public-private partnerships (PPP) focused on standards and pre-competitive solutions

Documentary Standards:
- Promote common understanding in business transactions
- Ensure interoperability
- Reduce time to market by leveraging industry and government efforts
- Accelerate regulatory approval
Each institute is a public-private partnership that focuses on promoting robust and sustainable advanced manufacturing research and development; providing workforce training and education; each has a standards emphasis:

**DOC-funded Institute**: accelerate biopharmaceutical manufacturing innovation

**Technical Scope**: Product focus areas include cell and gene therapy as well as existing biopharmaceutical products

**DoD-funded Institute**: make practical the large-scale manufacturing of engineered tissues and tissue-related technologies

**Technical Scope**: *engineered* tissue-based products

https://www.manufacturingusa.com/institutes
Example of PPP: NIST Genome Editing Consortium

NIST Genome Editing Consortium addresses the measurements and standards needed to increase confidence and lower the risk of using genome editing technologies in research and commercial products.

Recurring public workshops inform the work of three WGs (terminology, measurements, and data).

NIST leads measurement WG, build upon highly successful NIST Genome in a Bottle (GIAB) standards.

30 member organizations; coordinates with ISO and other SDOs for rapid tech transfer.
Engineering Biology @ NIST

High-Throughput Exp’t (HTE)
Unprecedented measurement capabilities to quantify complex living systems and processes

Design-Build-Test-Learn
Tools, platforms, and data/knowledge to predictively engineer biological systems to accelerate innovation in R&D to advance biomanufacturing

Standards & Living RMUs
Standards and technologies to ensure responsible biotechnology innovations
Materials and Manufacturing Enabled by Synthetic Biology

- Researchers are making new discoveries and gaining new knowledge
- Manufacturing institutes are working to advance manufacturing technologies
- Standards developing organizations (SDOs) and other communities efforts are underway to develop standards
- IAWG Synthetic Biology Working Group (SBWG) under NSTC Subcommittee on Biological Sciences - Ensure responsible innovation and significant advances in research in synthetic biology by identifying common challenges and synergies in design, construction, and implementation of this technology.
Laboratory collaborations via CRADA, consortia, etc.
Participate in NIST workshops
Participate in standards development efforts
Learn more @ www.nist.gov/mml/bbd or search NIST Advanced Therapies

Contact:

Sheng Lin-Gibson, Ph.D.
Chief, Biosystems and Biomaterials Division
NIST

slgibson@nist.gov