BioMADE

# Biosecurity Sequence Screening Training Course for Bioengineers

## BioMADE Perspective

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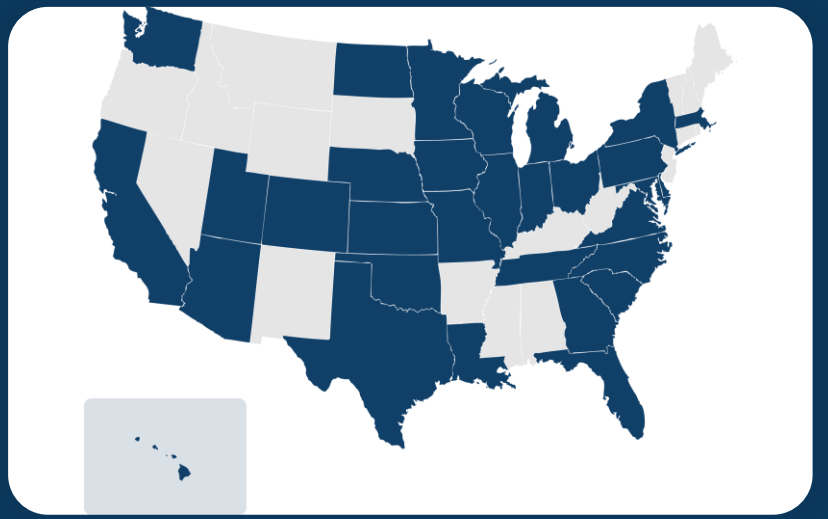
*Credit: Novozymes*

# BioMADE

## Bioindustrial Manufacturing and Design Ecosystem



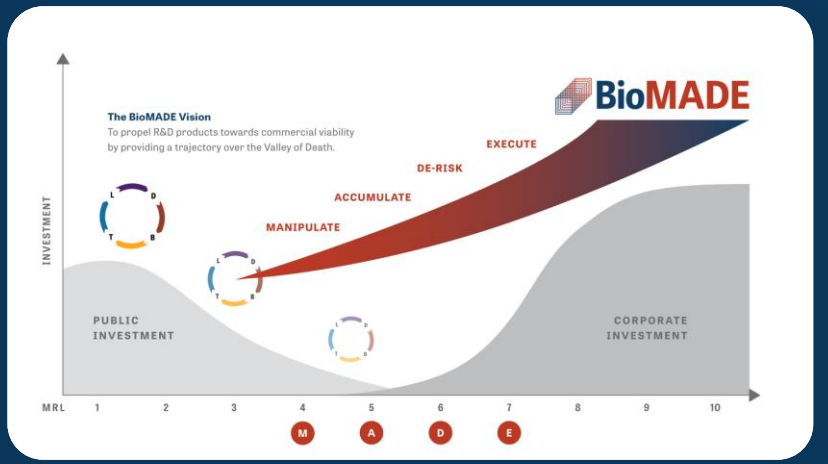
**BioMADE** is securing America's future through biomanufacturing innovation, education, and collaboration

## Mission

Enable domestic bioindustrial manufacturing at all scales, develop technologies to enhance U.S. bioindustrial competitiveness, de-risk investment in relevant infrastructure, and expand the biomanufacturing workforce to realize the economic promise of industrial biotechnology.

## Vision

To build a sustainable, domestic end-to-end bioindustrial manufacturing ecosystem.




- Newest Manufacturing Innovation Institute, initiated by the U.S. Department of Defense
- Public-private partnership launched in 2021

**Sites in the Twin Cities, MN and Emeryville, CA**

**Learn more and subscribe to updates at www.BioMADE.org**





BioMADE

# What is Bioindustrial Manufacturing?

Bioindustrial manufacturing uses living organisms such as bacteria, yeast, and algae to make new products or replacements for current products that are more sustainable and environmentally friendly than current processes

By harnessing the power of biology, bioindustrial manufacturing can make myriad products that Americans use every day

Bioindustrial manufacturing is key part of the bioeconomy, which could have an economic impact of up to $4 trillion annually within the next 10–20 years

## Applications

- Novel and performance-driven chemicals, materials, catalysts, sensors, probiotics, and more
- Compounds that go into footwear, ink, and engine coolant
- Fibers that become coffee capsules, diapers, cups, and electronics
- Skincare products
- Growable concrete and on-site production of fuels, lubricants, and other critical materials

# BioMADE's Approach: M-A-D-E

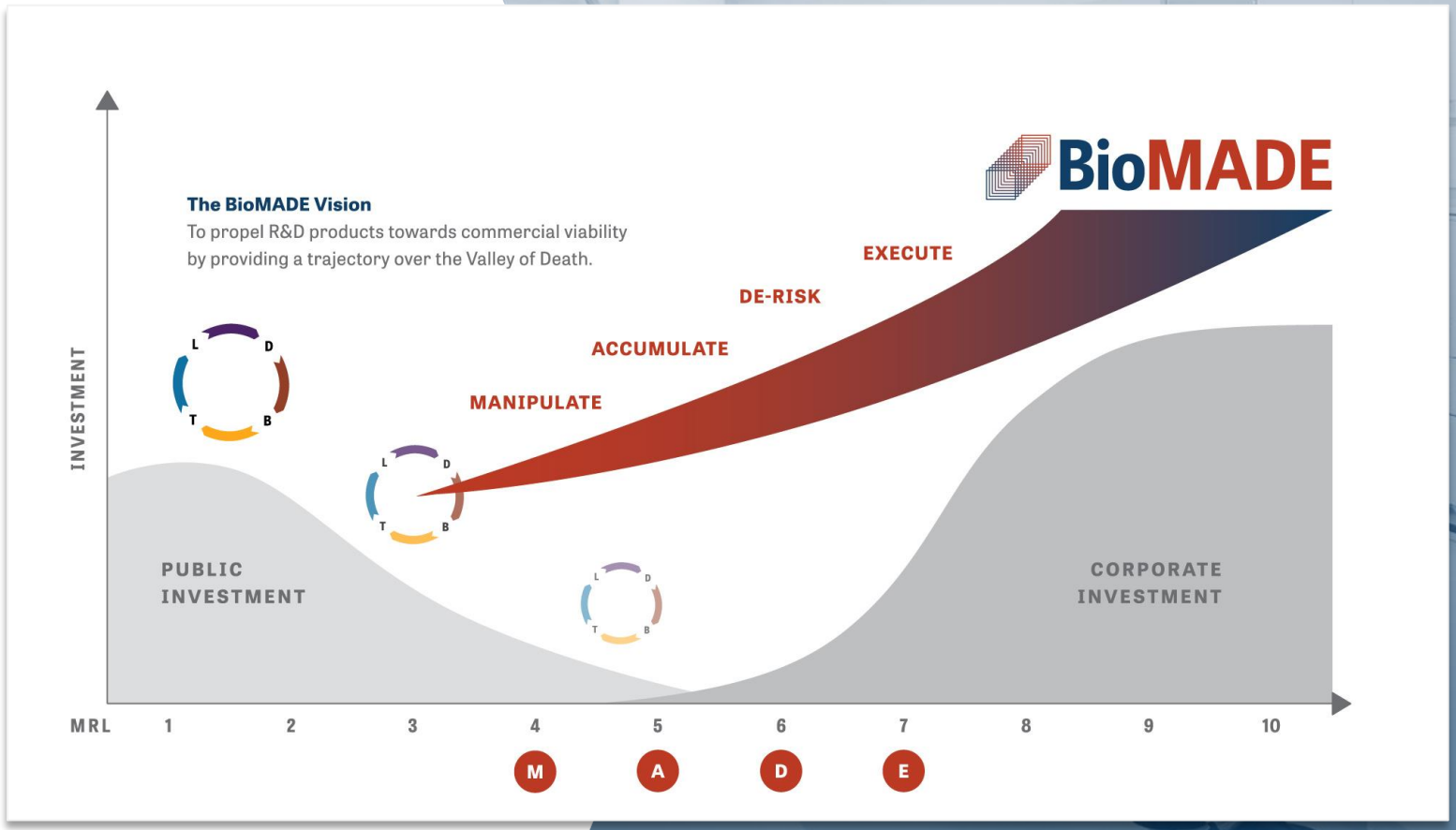
## M-A-D-E

**M**anipulate

**A**ccumulate

**D**e-Risk

**E**xecute

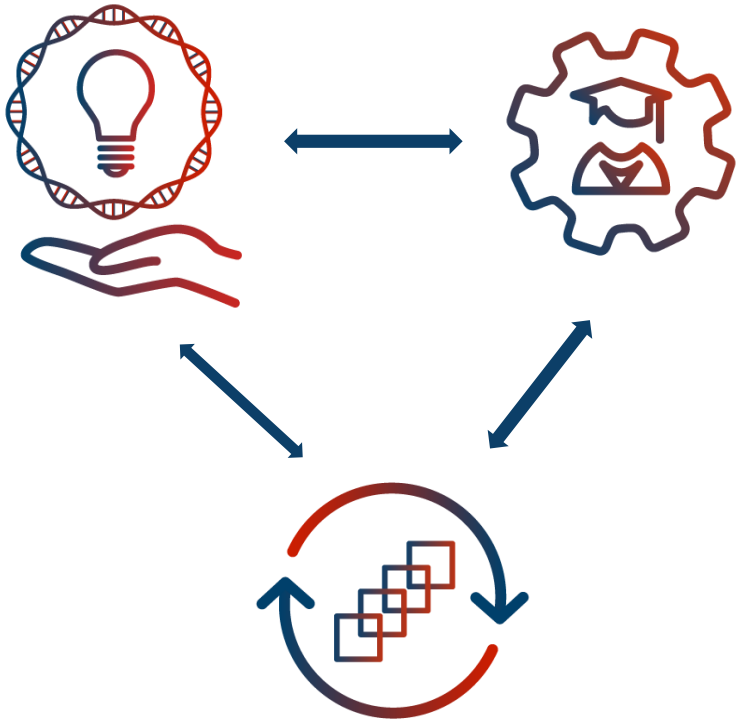



**Manufacturing Readiness Levels 4-7**, BioMADE's focus, correlate with advancing a pilot-scale manufacturing process through at-scale-production-representative environments.
[Bioindustrial manufacturing readiness levels (BioMRLs)]

# BioMADE Work Across 3 Areas

BioMADE biomanufacturing work is closely integrated across:

- **Technology & Innovation**
- **Education & Workforce Development**
- **4S (Safety, Security, Sustainability and Social Responsibility)**



› This Biosecurity Sequence Screening Training Course for Bioengineers integrates all 3 areas and is relevant across the Biotechnology and Bioindustrial Manufacturing ecosystem

# Technology and Innovation

- BioMADE is moving the bioindustrial manufacturing industry forward by funding innovative research, reducing barriers to scaling-up and commercialization, and de-risking investment in relevant infrastructure
- Focus on strengthening capabilities at Manufacturing Readiness Levels (MRLs) 4-7

## Focus Areas

- Data and Design
- Scale up
- Downstream Processing
- Testing and Evaluation
- Resilient Bio-Manufacturing Ecosystem
- Commercial Readiness

# Education and Workforce Development

The bioindustrial manufacturing sector is poised for significant growth in the coming decade and will need a trained and prepared workforce.

BioMADE is building the workforce of the future by partnering with K-12 schools, community colleges, universities, and professional development organizations.

## Focus Areas

- Building awareness of bioindustrial manufacturing careers
- Preparing the future workforce with innovative education
- Supporting the growth of the current workforce with world-class professional development

# Safety, Security, Sustainability & Social Responsibility (4S)

BioMADE is facilitating responsible bioindustrial manufacturing, addressing safety, security, and sustainability considerations, and increasing public communication around bioindustrial manufacturing.

Areas of 4S Action:

- Integration across all BioMADE ecosystem activities
- Member engagement and empowerment
- Public engagement and communication pathways

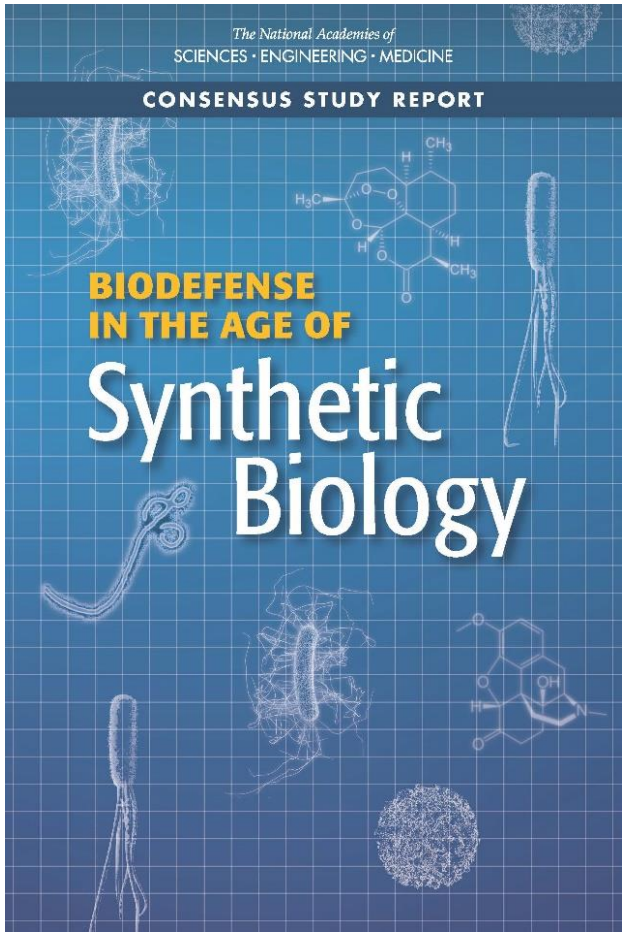
## 4S Landscape

- Worksite, public & environmental safety
- Securing against potential threats or loss of property
- Environmental & economic sustainability
- Responsible distribution of benefits & social engagement

# What do we mean by biosecurity in bioengineering?

- Safety and security include proactive identification of potential biorisk
- Biorisk: potential of a bioagent to cause harm to living organisms:
  - Known or novel
- Responsible biosecurity for bioengineering ought to:
  - Recognize how biorisk can be introduced
  - Proactively identify potential biorisk
- Science is moving fast, and biosecurity must keep pace

# Biorisk Applicability to Bioengineering Biosecurity




- Provides a framework for evaluating new technologies such as genome engineering
- Highlights limitations of current list-based risk classification e.g., Select agent list
- To assess biorisk, what an organism can do is more important than what it is
- Sequence screening needs to move beyond ‘bad bug’ to ‘predicted function of concern’

# Biosecurity is Highlighted in OSTP Bold Goals for US Biotechnology and Biomanufacturing

- Priorities related to Safety, Security, Sustainability, Societal Impact, and Responsible use of our biotechnology for biomanufacturing are highlighted in the multi-agency report: Bold Goals for US Biotechnology and Biomanufacturing.
- Biosecurity and Biosafety included in Education and Workforce Development
- Need to proactively predict the safety risk of any synthetic sequence, part, or organism
- Points to the strength of the BioMADE ecosystem and the power of collaboration

# Scope of Bioengineering in Biotechnology and Bioindustrial Manufacturing

**Application Areas**

- Strain engineering; focus on downstream processes
- Metabolic and pathway engineering
- Metagenomic sequence analyses; bioprospecting
- Protein engineering
- Protein/biomolecule production

**Bioindustrial manufacturing offerings that involve bioengineering**

- Custom engineered strains
- Products of microbial genome engineering: proteins, biomolecules
- Oligonucleotides (eg.CRISPR repair templates)
- Supporting software: design prediction, data analyses
- DBTL platforms
- more

Biomanufacturing includes a range of products and services that involve or impact bioengineering at the sequence level

# SeqScreen Meets Industry Sequence Screening Needs

- Help demonstrate safety of bioengineered products
- Help meet regulatory guidance criteria
- Evaluate potential biorisk of novel sequences
- Predict biological function of bioengineering

FunGCAT

- Rapidly screen 100,000s variants simultaneously
- Variable length input sequences
- In-house sequence screening
- Minimal cost

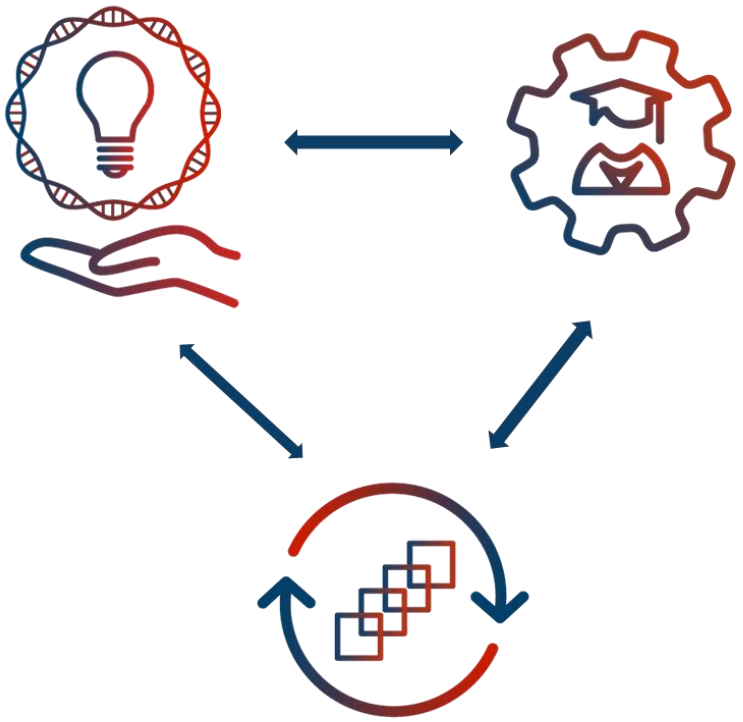
Office of the Director of National Intelligence
Intelligence Advanced Research Projects Activity
IARPA
Creating Advantage through Research and Technology

SEQSCREEN
Sequence of Interest Screening

- For industry buy-in, biosecurity sequence screening must be accessible, affordable, and reliable

# Biosecurity is a Shared Responsibility

- BioMADE activities are collaborative, community-driven, and built on partnerships across industry, academia, and government.
- Biosecurity training enables bioengineers to work together and take ownership of the safety of their engineered molecules.
- Sequence Screening needs to be considered at all stages of biomanufacturing lifecycle involving bioengineered organisms or products.
- BioMADE is building and empowering the bioindustrial manufacturing workforce of the future
- Innovative, accessible Biosecurity training is key!



# Future Directions for Bioengineering Biosecurity Sequence Screening

## Ongoing Challenges

- Context impacts: Genomic/organismal/environmental
- Relevant test sets
- Chimeric sequence
- Adaptable biorisk annotation
- Scale up continues
- Support evolving business models

## Let's Work Together!

- Awareness
- Resource building and sharing
- Crowd-sourcing
- Community efforts
- Collaborative problem solving
- Ongoing Biosecurity in Education and Workforce Development