

Breakthroughs.

Partnerships.

Leadership.

# “Managing Technological Innovation in the New Era”

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## Discussion Overview

- Synthetic Biology as an Emerging Technology
  - Technology Trends and Drivers
  - Applications and Markets
- Integrated Tools and Technology Pillars
  - Host Systems
  - Parts/Devices: Synthesis and Assembly
  - Biological Design Software
- Technology Considerations and Managing Risk
  - Brief History of Synthetic Biology
  - Bio-Security and Screening Workflow
  - Bioethics

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# Synthetic Biology

- Engineering life for useful purposes
- A rapidly growing field of research & new approach to life sciences
- Multi-disciplinary: Engineering, biology & informatics converge
- Impacting a broad range industrial applications

**Standardized Parts**  
**Engineered Hosts**  
**Assembly Tools**  
**Computational Design Tools**  
**Analytical Tools**

**Healthcare**



**Energy**



**Chemicals**



**Agriculture**



**Bio-Remediation**



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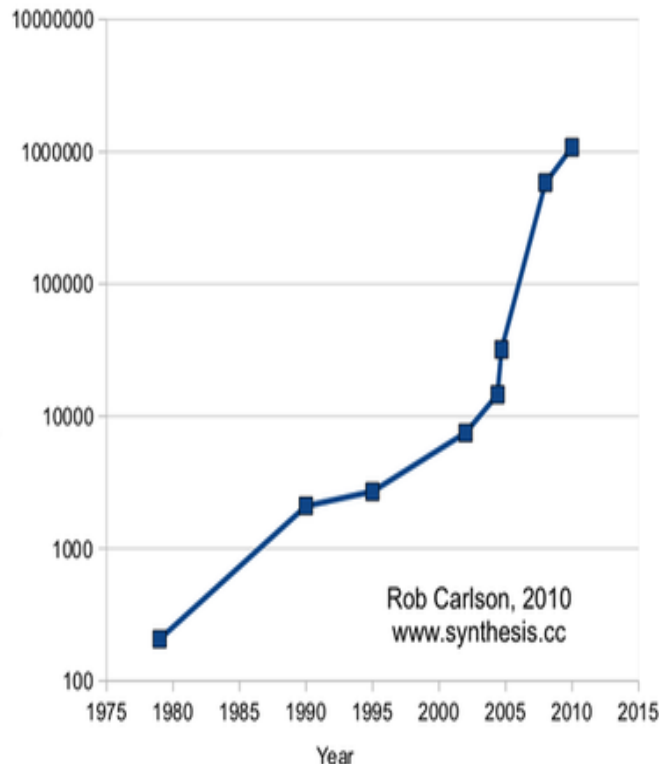
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# Technology Trends and Drivers

## Converging Technologies

### Understanding & Design Ability to Read & Write DNA

Longest Published Synthetic DNA



Molecular/Cell Biology  
Microbiology

DNA Sequencing  
Meta-Genomics

DNA Synthesis

### Tools Revolution

Engineering

Bioinformatics  
Systems and  
Computational Biology

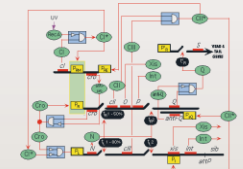
Industrial Microbiology  
Chemical Engineering  
Fermentation Science

## Synthetic Biology

Standardized Genetic  
Parts/Devices

Engineered Hosts

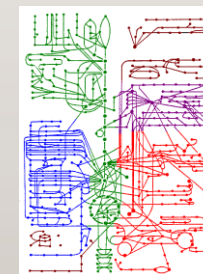
Gene/Chromosome Assembly/Transfer Tools



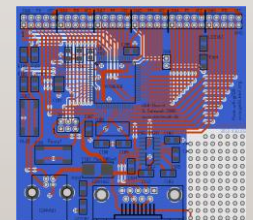
Engineered  
Genetic Circuits



Predictive  
BioCAD/FAB  
Optimized Applications



Genetic/Biochemical  
Pathways



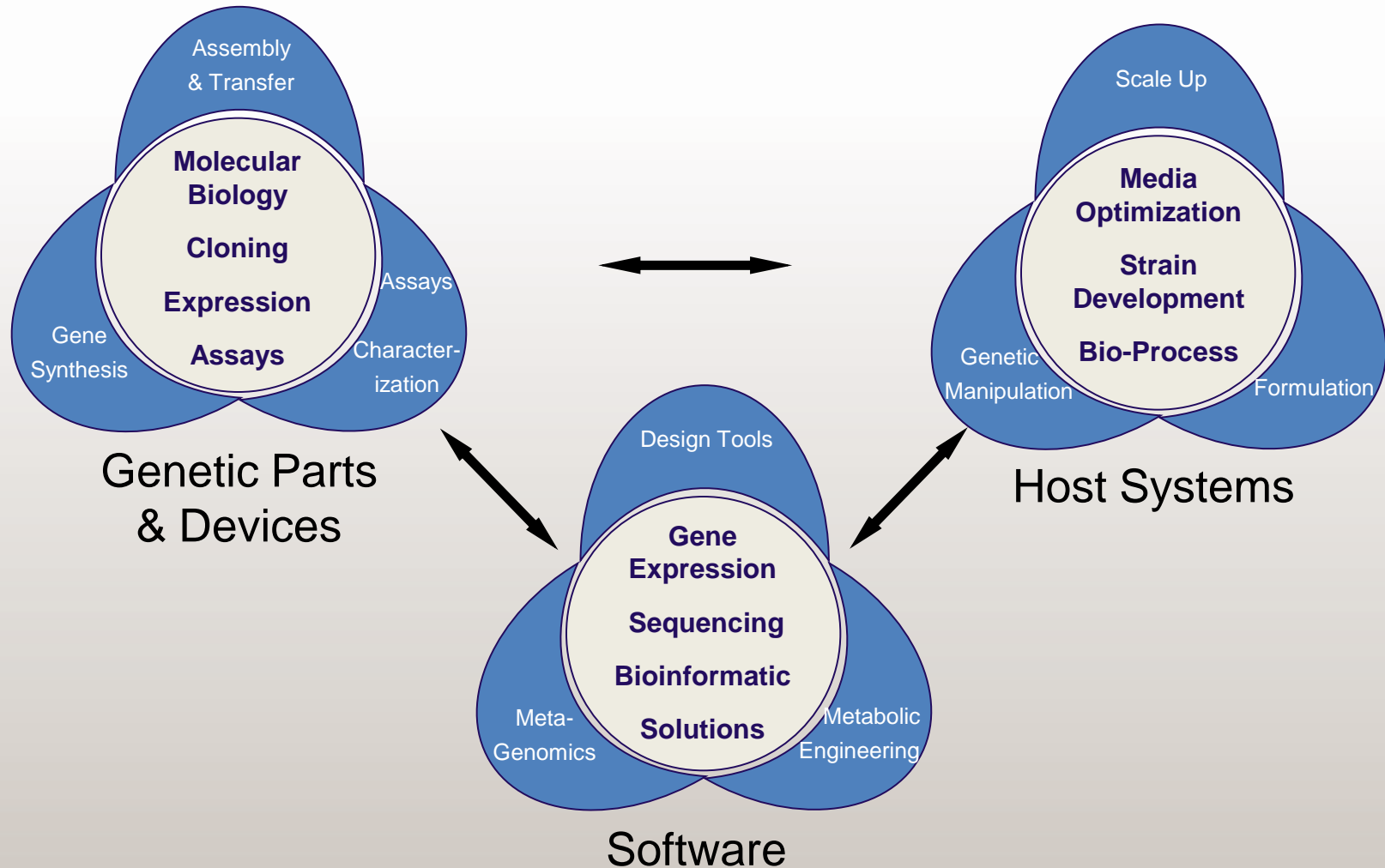
Design Engineering

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# Synthetic Biology Technology Integration



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# Managing Synthetic Biology Risk and Opportunity

Issues in synthetic biology common among many emerging technologies

## Bio-Safety

- Safe use, containment & disposal for laboratory practitioners, developers & the public

## Bio-Security

- Prevention of nefarious use

## Bio-Ethics

- Ethical development & use of engineered biological systems



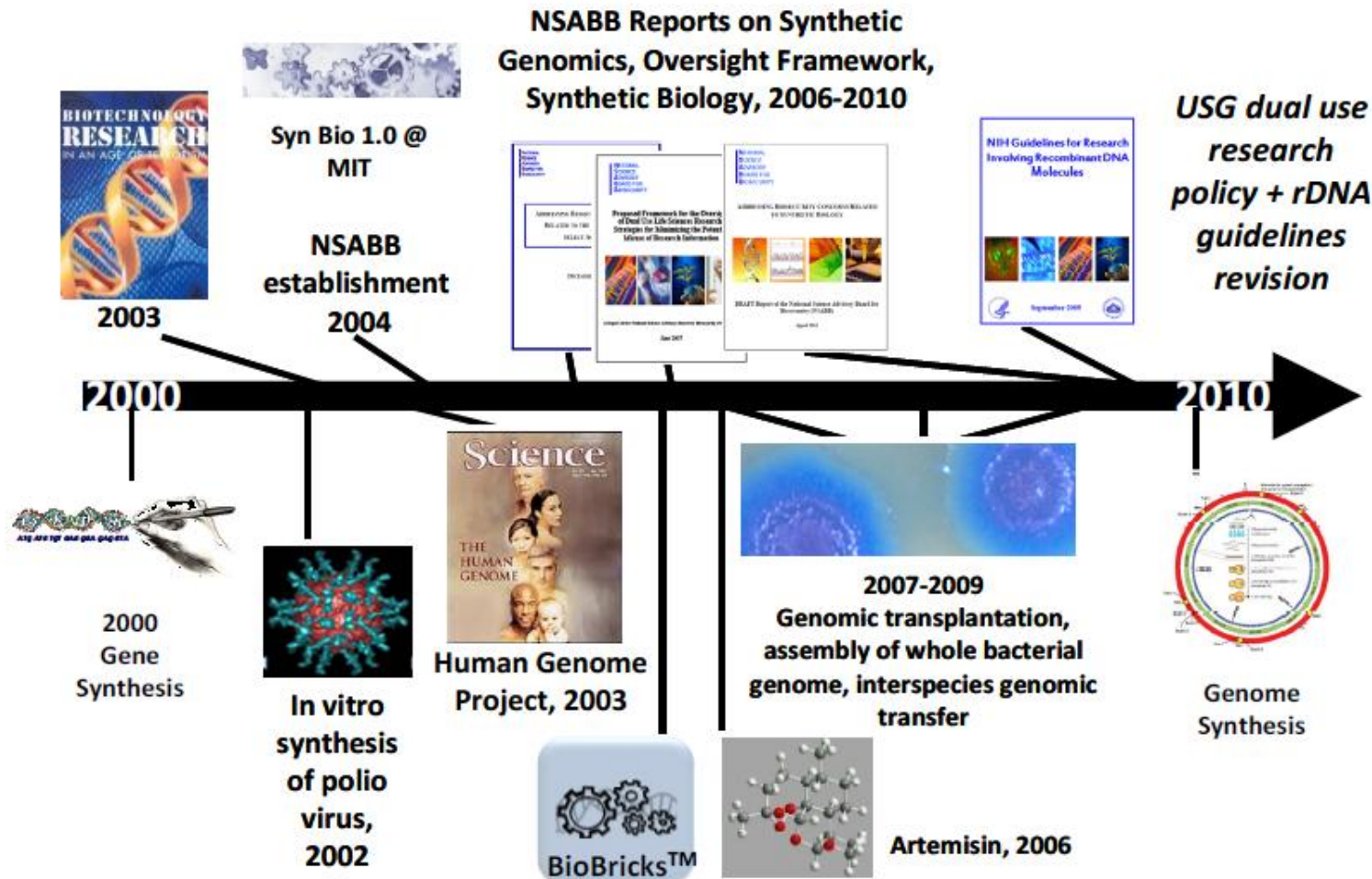


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# Key Events in Synthetic Biology



## Bio-Safety and Bio-Security

- Important regulatory and compliance areas for life sciences researchers and companies involved in synthetic biology
- Assessing the safety risks (known/unknown) inherent in re-design of genomes or creation of new organisms.
- Use of synthetic biology products/technologies and possible risks to lab personnel
- Lab containment and proper disposal to protect against accidental release potentially impacting communities and the environment
- Active surveillance and protection against nefarious use
- Assessing the risks of engineered organism release into the environment whose behavior or properties may not be fully understood



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# Implementation of Gene Synthesis Bio-Security

## Proactive Gene Synthesis Consortium:

- GENEART/Life Technologies, Integrated DNA Technologies, DNA 2.0, Blue Heron Biotechnology (Origen) and Genscript
- Culture of cooperation, responsibility and engagement
- Continuous improvement, sharing and use of best screening practices
- IGSC Harmonized Protocol: <http://www.genesynthesisconsortium.org>



INTERNATIONAL GENE SYNTHESIS CONSORTIUM (IGSC)

HARMONIZED SCREENING PROTOCOL

*Gene Sequence & Customer Screening to Promote Biosecurity*

Federal Register / Vol. 74, No. 227 / Friday, November 27, 2009 / Notices



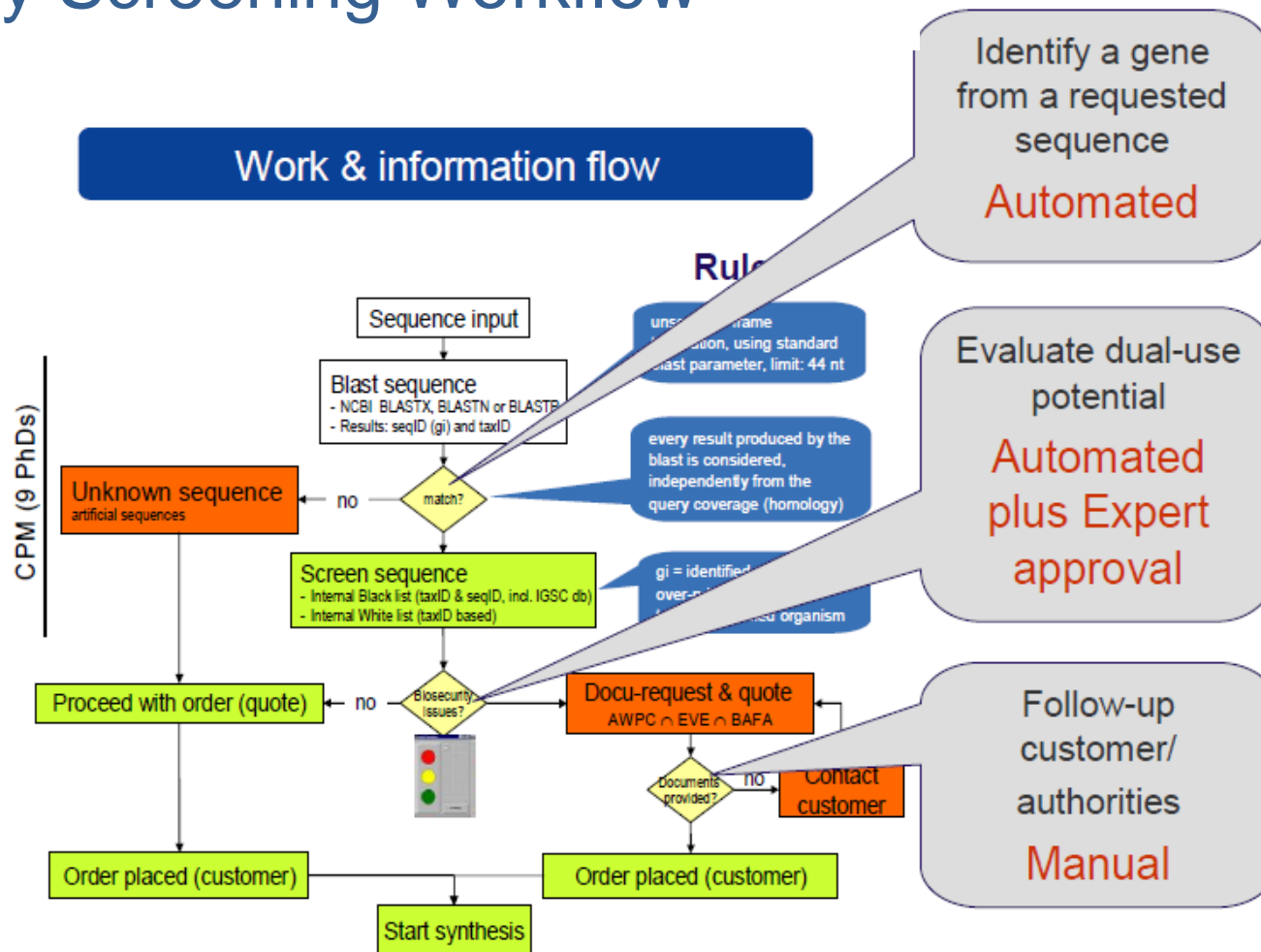
## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the Secretary

### Screening Framework Guidance for Synthetic Double-Stranded DNA Providers

**AGENCY:** Department of Health and Human Services, Office of the Secretary

# Bio-Security Screening Workflow



## Bio-Ethics

- Sufficiency of existing bioethics frameworks as for emerging technologies?
- Synthetic biology as “another level” of genetic engineering, generally not constrained by the natural genomes
- Like traditional biotechnology, synthetic biology:
  - Use of science to manipulate nature, "enhancing" human beings or other organisms
  - Distributive justice issues for who will benefit from technological advances
- Particular ethical issues related to synthetic biology:
  - Is it appropriate for humans to re-design the natural world to our benefit?
  - If so, should there be any limits on our power to do so?
  - Would answers to these questions change if ramifications of a "mistake" are unclear?
- Current public opinion polls suggest a lack of understanding that may impede public acceptance and technology development
- Public acceptance requires greater understanding and awareness of the technology and its benefits from the scientific and business communities
- Broad engagement and discussion of the issues is key to the management of risk and the balance required for further development