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Synthetic Biology: Creating Custom Organisms for Industry

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ABSTRACT

Synthetic biology represents a transformative interdisciplinary field that integrates biology, engineering, and computational science to design and construct new biological entities and systems. This paper examines the scientific foundations and historical emergence of synthetic biology, highlighting its technological advances in gene editing, DNA synthesis, metabolic engineering, and the design of custom organisms. It examines industrial applications across sectors such as pharmaceuticals, agriculture, and biofuels, illustrating how synthetic biology enables the production of tailored organisms for specific functions. Through detailed case studies, the paper emphasizes the growing industrial impact and commercialization potential of synthetic biology technologies. Additionally, it addresses the regulatory and ethical challenges posed by the creation and deployment of engineered organisms, calling for robust frameworks to manage biosafety, biocontainment, and equitable access. This synthesis underscores synthetic biology's potential to redefine biological production, while emphasizing the need for thoughtful governance as we shape the future of life itself.

Keywords: Synthetic Biology, Gene Editing, Metabolic Engineering, DNA Synthesis, Custom Organisms, Biotechnology, Industrial Applications, CRISPR, Bioethics.

INTRODUCTION

As a global society, we increasingly depend on biological systems, making the understanding and manipulation of these systems crucial. However, our grasp of biological components and their design is still developing. Synthetic biology aims to engineer biology from a foundational level by integrating chemical, molecular, and quantitative insights. As the field advances, it will facilitate the creation of novel organisms with unique traits not found in nature and enable the reprogramming of existing organisms to introduce new pathways or characteristics. Comparing this to computing, synthetic biology will eventually allow the generation of digital life from scratch or the modification of existing life forms. This engineering process may lead to the emergence of unforeseen life forms, sparking ethical discussions regarding their ownership and regulation. Synthetic biology encompasses the design and assembly of new biological parts and systems, incorporating molecular biology, biochemistry, bioinformatics, systems biology, and chemical engineering. Its significance is anticipated to grow in medicine, biotechnology, energy, and environmental sectors, leading to global synthetic biology initiatives, including bioeconomic and biomanufacturing platforms for producing new chemicals and biofuels. Examples include personal genome sequencers from a £5 billion start-up and a company founded by graduates valued at over $1.4 billion, aiming to transform our interaction with nature [1, 2].

Historical Background

The term 'synthetic biology' is used to designate a new area of science and engineering that considers biology as a raw material with which complex functional systems can be built in a rational, modular, and predictable way. The goal of synthetic biology is, on one hand, to create organisms with useful properties for biotechnology, medicine, or basic research, and, on the other hand, to understand the ensemble of interacting components and principles that enable biological systems to build up their complexity and

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functionality. Synthetic biology has emerged as a very interdisciplinary field that combines organisms, bioanalytical methods and biocomponents with engineering principles, electronic components, and computer-aided design tools. During the last decade, many microbial, yeast, and mammalian synthetic biology advances have been published and commercial software is increasingly being claimed to help design and build biocircuitry in a manner similar to electronic circuitry. Interest in synthetic biology had been growing, with increased funding available for synthetic biology projects, organizations, or start-up companies. The first major synthetic biology research project started in early 2000 with Chris Voigt, Drew Endy, and Tom Knight on genetically programmed behavior in bacteria. However, synthetic biology is in an earlier stage of development than DNA assembly and other synthetic molecular biology tools. Synthetic biology comprises the design and construction of new biological parts, devices, and systems, and the re-design of existing natural biological systems for useful purposes. The design of synthetic biological systems is based on a characterisation of biological organisms. An organism's biochemistry and genetics are essential as input for the design, construction and sources for biological components and biological mechanisms. Natural biological parts and devices are hardly perfected for applications, which leads to the need to design and characterise synthetic biology parts (also in organisms). Characterization includes specificity, throughput, and other parameters. This required understanding how every part works, both by itself and when combined with other parts and an organism (signal propagation, robustness, etc.) [3, 4].

Key Concepts in Synthetic Biology

The rise of synthetic biology exemplifies the notion that "Necessity is the mother of invention," driven by the aspiration to enhance our planet, environment, and health, as well as to foster renewable energy. This need spurs the human mind to devise a "pragmatic utopia." A profound scientific perspective posits that all life stems from the self-organization of biomolecules, shaped by physical and chemical laws, which generates complexity that mitigates the randomness of events. This philosophy aligns life with an operating system, much like New York City, suggesting that organisms function as innate machines using biological parts powered by biochemical and biophysical energies. This idea led to the development of artificial circuits in E. coli for regulating small molecule concentrations based on other molecules. Essential to this "surrogate environmental data logger" are small ribozymes and Ras family GTP-binding proteins, leveraging well-known oligomerization and allosteric mechanisms to transfer paradigms from physics to biology. This constitutes synthetic biology. Initially, the ability to design custom organisms was unimaginable until the advent of genome sequencing technologies. The first goal of the International Human Genome Project was to disseminate DNA sequencing technology globally, paving the way for the idea of synthetic genes and organisms, essentially engineering the genomes of model organisms. The first part of this review discusses fundamental concepts in synthetic biology, particularly pathways using prokaryotic organisms as templates. The second part will provide examples extending from simple elements to complex circuits or devices, including a project aimed at creating a paper-based cancer diagnostics tool utilizing DNA strands as unique biomarkers [5, 6].

Gene Editing Techniques

The discovery of restriction enzymes in the 1970s and subsequent sequencing initiated the genomic era, focusing on simpler viruses and bacteria. Genome-scale engineering for social organisms emerged, enhancing insights into social behaviors and producing useful features like biofilm and hydrogen. Early experiments engineered multicellular oscillating circuits, revealing population-level behaviors such as dominance and community interaction. Innovations utilized autoinducers to create engineered steady-state bacterial biofilms for pollution control. Since the advent of CRISPR in 2013, interest in DNA-editing techniques has surged, allowing any genetic circuit to be integrated into organisms, thus sparking engineering evolution experiments for industrial productivity. Advances have been made in gene-editing techniques, including hybrid CRISPR and single-base editors, alongside new genome-scale sequencing instruments. Developments range from large robotic systems to small benchtop sequencers, and techniques like liver-targeted Cas9 have created transgenic cell lines for better cellular behaviors. Rapid advancements in genome-scale design and DNA libraries have broadened applications across various fields, from microbes to macro-systems, and engineered biology, encompassing areas such as precision medicine and personalized microbiomes using DNA querying tools for engineered products [7, 8].

DNA Synthesis and Assembly

Deoxyribonucleic acid (DNA) is a polynucleotide made of nucleotides that store information. Nucleotides consist of a ribose sugar, a phosphate group, and a nitrogenous base. In DNA, the ribose is deoxygenated, making it more stable than ribonucleic acid (RNA). Synthetic Biology relies on DNA synthesis technology. Sequencing characterizes genomic DNA and assists in assembling informative DNA

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sequences from base pairs. Just as IT relies on storage and input devices, DNA synthesis requires assembling functional topologies with microbial organisms. Emerging biofoundries aim to automate and scale these processes while redefining life. DNA features four bases (adenine, guanine, cytosine, thymine) in complementary pairs A-T and C-G. Various methods exist for chemically synthesizing oligonucleotides, which are short DNA strands up to 200 bases long. Currently, automated phosphoramidite processes significantly reduce costs compared to earlier manual sequence writing. Deprotected oligos can be combined into a DNA assembly mixture for manipulation by molecular biologists or bioengineers. Each assembly condition aims to join oligos into longer strands using DNA polymerase, minimizing unwanted strand joining before deployment. Kits can efficiently conduct these DNA reactions in either microcentrifuge tubes or 96-well plates [9, 10].

Metabolic Engineering

The main goal of metabolic engineering is to create a microbe that efficiently produces a desired compound. Instead of starting from a genome sequence, pathways often redesign existing native pathways, sometimes adding synthetic components. Researchers scan genes from related organisms for pathway components. When multiple components exist in one genome, focus shifts to component clusters. Before synthesizing a pathway, strains must be prepared. Pathway assembly can involve generating a complete pathway from few components or stepwise exchanging non-native components into an existing pathway. In the first method, building blocks are assembled in a single plasmid in vivo or in vitro, then transformed into the host organism. The second method uses a destination plasmid with an intact pathway and replaces a single gene in the chromosomal location. Simultaneously, variants of targeted strains are produced to screen for pathway presence or output. Once established, tests assess strain performance, including pathway establishment and product yield. After successful strain screening, additional genetic modifications aim to enhance performance for industrial relevance. However, techniques, methods, and available genomes face compatibility and availability limitations across diverse organisms. Some techniques, like pathway design and strain screening, can be imprecise or inefficient. Addressing the influence of chassis choice on metabolic engineering results could identify important alternatives. More research is needed before reliable designer microbes for industrial applications can be developed [11, 12].

Applications in Industry

Synthetic biology is the engineering of biology to produce organisms not found in nature. As an emerging technology platform, it is being applied across a wide variety of fields, including medicine, fuel production, and food production. Alongside planting crops, producing food through microbial fermentation is one of the oldest industry sectors. This panel discusses the present state of the art in using synthetic biology to produce specialty foods and flavour compounds in yeast and bacteria, prospects for progressing to mechanism design and creating custom production organisms, upsides to merging bioreactor and fermentation modelling with grapevine research for improving wine production, and the use of synthetic biology to engineer perennial monocot crops for better regional adaptation and performance. Synthetic biology is an interdisciplinary field encompassing molecular biology, biochemistry, biophysics, computer science, and engineering. The fundamental principle of synthetic biology is the engineering of biology to produce new biological systems, circuits, and organisms that are either not present in nature or are significantly altered versions of naturally occurring systems. Applications range from producing specialty biocontrol agents in microbes to fighting disease through cell engineering in T cells. The scale of investment in advancing this new capability is enormous across industry, academia, and private capital. It is often suggested that synthetic biology represents “a new industrial revolution”. Each particular application of synthetic biology is generally at various stages of maturity, ranging from ideas without prototypes to working prototype systems [13, 14].

Designing Custom Organisms

Synthetic Biology (SB) is a continually emerging area of research with the potential to engineer a new architecture of biological circuits and systems to direct biology to produce useful products. One of the ambitious goals of SB is to design and construct custom organisms, and so far, there has been significant progress toward this goal. This section discusses the elements required for assembling custom organisms and highlights research developments in these fields. Currently, five key elements are known to be involved in designing custom organisms and are rudimentarily available for engineering applications. The first component is the basic biomolecules, including natural or synthetic nucleic acid sequences, proteins, or auxiliary cofactors of proteins. The second is engineered scaffolds used for the assembly of basic biomolecules. The third is digital design tools, which computationally run through algorithms to create effective genetic circuits or systems. The fourth is automated assembling devices, which physically realize

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the digital designs, such as synthesizing and cloning nucleic acids or constructing polypeptides. The fifth is assemblages of the constructed biomolecules into active biological processes or systems that achieve applications. DNA is one of the three basic biomolecules of life. A genome is an assemblage of all DNA molecules. A genome has two essential functions: it packages all coding and non-coding information concerning the maintenance and replication of life; it is transcribed, translated, and directly functions in biochemical processes such as metabolism, replication, and cell division. All these functions are achieved through the collaboration of two different molecules, DNA and proteins. SB is investigating how to design and construct organism genomes with unique target properties, ranging from microorganisms to higher organisms, such as bacteria, yeasts, plants, and mammalian cells. The current understanding of the basic biosystems and their engineered applications is mainly from microbes, while investigations regarding the genomes of more complicated organisms, like eukaryotic or higher multicellular organisms, have much space for improvement [15, 16].

Case Studies

Using the toolbox available from subcontractors, cutting-edge synthetic-biology methods can be developed and evaluated to the proof-of-concept stage. Pre-commercial partners could either use a demonstrated custom method in-house or, after detailed negotiation, simply outsource implementation of the concept. Exact roles would be defined subsequently, but would typically involve a hands-on project for the first method, followed by exclusive rights for implementing the methods and additional projects for developing protocols for a wider range of potential methods. CW can assess the risks associated with biofortification because a transformation of yeasts allows the export of further metabolites into the growth medium. European partners bring additional institutional expertise to the separation and analytical and structural identification of the desired products from a bulk of other metabolites. An Industrial Advisory Board composed of representatives from a range of companies will ensure that the needs of industry are better served by the Synthetics concerning validated methods and products than would otherwise be the case. Chemist Martin Burkart is investigating the value of using synthetic biology techniques to develop active ingredients in the pharmaceutical industry, together with academic partners. This technology has the potential to revolutionize biocatalysis and has also proved its worth in the production of fragrances. A new generation of cosmeceuticals based on genetically modified yeast to produce fragrances has reached large-scale application and generated annual revenues of 30 M. Andrew McPherson is striving to develop new-generation antibacterial agents based on bacteriocins, lipopeptides produced by Bacillus spp., and active against Gram-positive pathogens. Other biocides produced by phages and bacteriophages are also being evaluated as potential agents against Gram-negative pathogens. A business model is under development to evaluate proposed agents for safety and biocontainment before further industrial evaluation. Esteve Marti is assessing the market for biocontrol agents. He is profiling potential targets and convincing clients of the validity of the experimental approach. He is also interested in biosecurity and biosafety issues about some of the proposals. Synthetic Biology is often nominated as "The Next Big Thing" for the biotechnology industry, and investment pours into this sector. But what is Synthetic Biology? What do these Big Ideas encompass? Who is involved, and where should investors focus their money? This paper will outline where Synthetic Biology is headed, what some of the main players in the field are, and offer insight on where potential investors may find the greatest opportunities [17, 18].

Regulatory and Ethical Considerations

As synthetic biology applies engineering principles to biological systems to create new life, it raises societal implications surrounding these innovations. Global researchers report developing engineered microbes for drug production in human guts and releasing black rot bacterium into oceans. While some applications are not entirely new, recent advancements have ignited debates on the engineering of complex bacteria and their public release. Current discussions lack formal guidance on content, length, and structure. Establishing a regulatory landscape could help frame engagement among scientists, industry, and the public regarding future synthetic biology applications. This piece outlines the current challenges and landscape of regulations in synthetic biology, emphasizing the need to address future applications. Any regulatory guidelines for novel live organism releases assume these organisms are engineered within incompatible frameworks. Inspired by chemical regulation models, EGF members suggest collaborative round table discussions among scientists, industries, and regulators to create a unified epistemology for assessing the risks and potentials of engineered biological systems. The piece provides an overview of existing and potential regulatory frameworks to encourage creative discussions and include relevant participants from both scientific and regulatory sectors, aiming to foster brainstorming around this topic for future developments [19, 20].

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Future Trends in Synthetic Biology

The next decade will witness a rise in products leveraging engineered biology for enhanced performance and cost-effectiveness, especially in agriculture to combat evolving pests and weeds. Insightful companies highlight opportunities in this sector, where products are projected to generate ~$2 billion annually, with a steady increase in non-medical applications. Beyond the initial six examples of integrating engineered biology with software, many innovations could emerge each decade, including alternatives to Horseradish Peroxidase for bioassays and chemical detection in food and water, simplifying result delivery. By 2030, we expect an exponential increase in product-related information, indicating a transformative future. As the population grows and fermentation-derived products rise, using sugar as a feedstock will become less viable. Instead, new microbial chassis are needed to convert carbon from sources like plastic waste or CO2 via fixation or synthetic pathways. The reliance on fresh water in fermentation calls for halophilic chassis that can thrive in ocean water, and cell-free manufacturing methods could utilize condensates as co-solvents, avoiding traditional solvents. Ultimately, focus will shift towards system arrangements within cellular chassis to achieve desired functions, exemplified in agriculture by engineered plants and bacterial symbioses designed to work together seamlessly [21, 22].

Challenges in Implementation

As synthetic biologists reverse-engineer organisms for various applications, challenges to broader implementation will arise. Creating organisms that perform desired functions requires understanding both their operation and the features giving them a competitive advantage. The success of reverse-engineering hinges on collective knowledge of the appropriate parts and their assembly into modules. Though challenges in closed industrial settings are significant, some agencies utilize systems that integrate safety features with strict containment controls. To foster public acceptance, synthetic biology must demonstrate tangible benefits, ensuring that new tools align with safeguards against misuse and potential negative outcomes. It is essential to examine the social implications and reshape goals related to synthetic biology practices. Increased public concern necessitates developing open systems for implementing synthetic organisms. Accidental releases into the environment could provoke unique public fears compared to issues associated with engineered microbes in controlled environments. Open systems pose greater challenges in supervision and enforcement. Combining environmental screening, biopolicing, and virtualization is vital for a robust safety plan. There is a need for biosafety mechanisms tailored to prospective threats. Public dialogues regarding specific projects and containment methods should evaluate community values and guide implementation. Broader discussions comparing the merits of open versus closed systems are also crucial [23, 24].

CONCLUSION

Synthetic biology is redefining our capacity to engineer life at the molecular level, enabling the creation of custom organisms that fulfill industrial and societal needs. From programmable bacteria to yeast strains producing pharmaceuticals and fragrances, the field is rapidly transitioning from theoretical constructs to real-world applications. As demonstrated by successful case studies, synthetic biology holds immense promise in addressing global challenges in healthcare, agriculture, and sustainability. However, this promise is accompanied by significant ethical and regulatory considerations. As the boundaries between natural and synthetic blur, clear guidelines and public discourse are essential to ensure safe, equitable, and responsible development. The future of synthetic biology hinges not only on scientific innovation but also on our ability to govern its power with foresight and integrity.

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