AGILE BIOMANUFACTURING CENTER

INDUSTRY LISTENING DAY

DoubleTree Hotel Berkeley Marina :: March 15, 2016

THE PROBLEM

The bioeconomy is poised to expand with current market and policy factors that encourage renewable products to be considered for transportation, clothing, chemicals, polymers, fragrances, and thousands of other products. However, the current state of the art typically relies on a process where companies develop a one-off technical design for each new product, optimize it, and scale it for commercial production in an ad hoc manner. This approach means it can take decades for a new product to come to market, during which time its value proposition may change drastically in response to external market factors. There are few public case studies of the overall cost to bring a product to market, but for renewable chemicals, anecdotes and back-of-the envelope calculations suggest that a company will have to invest at least $150 million and 15 years of development time before commercial introduction of each new product. From an enterprise perspective, this implies that hundreds of millions of dollars are expended annually by industry. A few public case studies exist for biomanufacturing of pharmaceuticals; estimates for bringing a new product to market are upwards of $1 billion (this figure includes the costs of the regulatory process). These estimates highlight the challenges associated with funding commercial scale research: the high price tag of investment and the time needed to reach the market price out companies without access to significant resources, massive capital, and very patient investors and shareholders.

Over the last forty years, the revolution in DNA technology has opened the door to cheaper and quicker production of certain bio-based products. While there have been significant and rapid advances in biological engineering, much of the work to create these products relies on the knowledge of individual scientists, incompatible data management, and the inability to learn from successes and failures. Industry has realized the value of biological engineering tools and some companies have built their own in-house platforms to better engineer production strains for advanced biofuels and bio-based products. However, since these tools are proprietary, the benefits of these advanced engineering techniques are inaccessible to the broader community. Even with advances in computing and automation, these tools may not capture learnings or relevant process considerations for future products.

Bioenergy and bio-product feedstocks

Processing feedstocks to bioproducts

These challenges and others have been identified in recent reports from the White House Office of Science and Technology Policy and the National Research Council. Both reports call for developing tools that advance our ability to engineer biology and confidently scale processes to expand and accelerate the bioeconomy. These tools would lower the barrier to market entry for startup and small companies, allow large companies to be nimbler in response to market drivers, and broadly enable the entire bio-based industry to expand the bioeconomy to meet the goals of the Department of Energy (DOE) and other federal agencies.

THE APPROACH

Lawrence Berkeley National Lab, Ames National Lab, Argonne National Lab, Idaho National Lab, Los Alamos National Lab, the National Renewable Energy Lab, Oak Ridge National Lab, Pacific Northwest National Lab, and Sandia National Lab seek to build an agile biomanufacturing platform for biological approaches to produce advanced biofuels, renewable chemicals, and materials that represent low greenhouse gas alternatives to everything we currently derive from petroleum. The DOE National Laboratories have built deep and unique capabilities that can be brought to bear to build powerful infrastructure and scientific engineering activities that will render design and implementation of new bio-

based products scalable, predictable, and more cost-effective. An agile biomanufacturing platform will enable companies, national labs, and universities to develop biological processes efficiently and with reduced risk to create products with better performance than their predecessors. This effort also addresses DOE's goals to develop manufacturing platforms that increase deployment of advanced biofuels that lower the carbon and energy intensity of fuels and products, improve domestic energy security, and ensure U.S. competitiveness in a variety of markets.

Researcher operating liquid handling robot to build new strains

To build the agile biomanufacturing platform, the labs envision a consortia-based center that will focus on building this platform with key industry partners to develop technologies, business models, and paths to commercialization. The development of an agile biomanufacturing platform would unite the labs' unique capabilities in biological process design, biological engineering, biological measurement, computation, chemical separations, catalyst design, technoeconomic analysis (TEA), and life cycle assessments (LCA). The platform would also address process integration and scaling challenges by designing biological pathways that consider downstream chemistry and separations and to develop predictive scaling tools that allow users to move quickly from bench to pilot scale. The national labs included in this proposal have core and enabling capabilities that span DOE's portfolio for biological engineering and process development for biofuels and bio-based chemicals.

HOW WILL WE WORK WITH INDUSTRY TO SOLVE THESE CHALLENGES?

- Develop platform technologies to rapidly iterate the design-build-test-learn cycle for biological engineering
- Develop and onboard industrially relevant host organisms, new genetic tools, new assays to understand and optimize biological processes, and statistical methods to learn how and why new biological processes succeed or fail
- Incorporate learnings from process integration and scaling, technoeconomic analysis, and life cycle assessments so that upstream and downstream process and market considerations are incorporated into designing new pathways
- Develop routes to "targets of opportunity," beachhead molecules in biological organisms that can provide access to nearly all of the current chemical space through further biological and/or chemical transformation
- Cooperative and sponsored research with companies to address their pressing challenges
- License technologies to companies to build their own platforms in house

INDUSTRY FEEDBACK AND ENGAGEMENT IS KEY

The national labs have been developing these concepts internally, but are relying on critical feedback and engagement from industry to develop a platform that solves challenges for companies that produce renewable fuels, chemicals, and materials. On March 15, 2016, the labs will be holding a workshop with industry stakeholders to solicit input on the R&D challenges facing industry, management and interactions with the proposed agile biomanufacturing center, and metrics to understand the platform's success. The labs hope to use the workshop to build collaborations with industry that lead to successful technology development and deployment into the private sector. The success of the agile biomanufacturing platform lies in our ability to establish industry partnerships and the growth of the bioeconomy.

For more information and to register for the workshop, visit ***agilebio.lbl.gov***

The Ames Laboratory — Creating Materials & Energy Solutions — U.S. Department of Energy
Argonne National Laboratory
Berkeley Lab
Idaho National Laboratory
Los Alamos National Laboratory — Est. 1943
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Oak Ridge National Laboratory
Pacific Northwest National Laboratory
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16-PB-2604