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## TIP Project Brief – 10067/11H008

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### **Manufacturing** **Volatile Reporters for Biomanufacturing of Protein Therapeutics**

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*Develop genetically engineered measurement technologies for real-time monitoring of cellular health and production capacity during the manufacturing of therapeutic proteins.*

**Sponsor: Ginkgo BioWorks, Inc.**

7 Tide Street

Unit 2B

Boston, MA 02127-0000

- Project Performance Period: 2/1/2011 - 7/31/2013
- Total project (est.): \$2,300 K
- Requested TIP funds: \$1,000 K

Ginkgo BioWorks aims to develop genetically-engineered tools for in-line, real-time monitoring of the fermentation processes used in the production of pharmaceutical proteins. The company's novel "reporter technology," intended for integration and use with analytic equipment already in place in biomanufacturing operations, will facilitate the monitoring, control, and optimization of fermentation processes used to produce monoclonal antibodies, vaccines, and other biologic compounds for medical and industrial applications.

Made in cells, biologics constitute one of the fastest growing segments of the pharmaceutical industry. Yet, determining and maintaining fermentation process conditions that yield acceptable levels of these compounds can be exceedingly challenging. Slight variations in process conditions can stress cells, suppress expression of genes that code for desired proteins, or interfere with the folding and post-translational modification of proteins as they are being assembled inside cells. Existing process-monitoring methods only make periodic measurements of many sample variables—akin to taking multiple photographs. With the tools of synthetic biology, Ginkgo BioWorks proposes to fashion the biomanufacturing equivalent of real-time video monitoring. By inserting so-called reporter genes at strategically located sites in the production cell's genome (the cell's hereditary information) the company will create the means to continuously track the health of cells and the growth conditions in fermentors. Changes will trigger the reporter genes to initiate production of volatile reporter compounds that can be detected with gas chromatography-mass spectrometry instruments, which are standard in biomanufacturing. With this capability, manufacturers could make real-time adjustments to maintain optimal production conditions. In-line monitoring would also simplify steps required to demonstrate conformance with regulatory requirements, thereby facilitating further innovation in manufacturing practices.

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