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Award Abstract #0951845

Commercializing of Continuous Pharmaceutical Manufacturing Technology

NSF Org: [EEC](#)
[Div Of Engineering Education and Centers](#)

Initial Amendment Date: November 25, 2009

Latest Amendment Date: November 25, 2009

Award Number: 0951845

Award Instrument: Standard Grant

Program Manager: Lynn Preston
EEC Div Of Engineering Education and Centers
ENG Directorate For Engineering

Start Date: December 1, 2009

End Date: November 30, 2013 (Estimated)

Awarded Amount to Date: \$1,800,000.00

Investigator(s): Marianthi Ierapetritou mgj@udel.edu (Principal Investigator)
Rajesh Dave (Co-Principal Investigator)
Fernando Muzzio (Co-Principal Investigator)
James Litster (Co-Principal Investigator)
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Sponsor: Rutgers University New Brunswick
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NSF Program(s): EEC Innovation Awards

Program Reference Code(s): 0000, 124E, 128E, 130E, OTHR

Program Element Code(s): 7960

ABSTRACT

This project will enable a vigorous commercialization effort for continuous pharmaceutical manufacturing technology developed by C-SOPS. This manufacturing approach can enable significant improvements in product quality, process robustness and productivity, and overall economic performance of the manufacturing process. A high level of interest exists at the present time in this technology, both by the US FDA, and by large pharmaceutical manufacturers, many of which are C-SOPS members. Many technology suppliers that are also members of C-SOPS have also indicated a keen interest in addressing this market need. The key missing element needed for successful commercialization is that, at the

present time, no single technology supplier has all the necessary capabilities required to address this commercial opportunity. Thus, the main goal of this proposal is to assemble a coalition of technology suppliers, led by a systems integrator, and to enable them, by knowledge transfer and technical support, to commercialize fully integrated "turn key" manufacturing systems.

The Intellectual Merit of this proposal has three main components. (1) This project will bring to the market place commercial-grade integrated technology for continuous manufacturing that is designed and optimized based on an in-depth understanding of the main components of the manufacturing system. (2) This project will expand the existing scope of continuous manufacturing at C-SOPS, which currently comprises uncoated tablets manufactured either via direct compression or dry granulation. We will add capabilities to enable the continuous manufacturing of both coated and uncoated tablets and capsules manufactured by direct blending, dry granulation, and wet granulation. (3) This project will demonstrate the impact of engineering methods for pharmaceutical product and process design and optimization, helping promote adoption of modern methodologies across an essential industry that at the present time uses empirical methods and batch processes as its main development and manufacturing paradigm.

The Broader Impact of this project is also manifold: (1) Based on projected sales, we anticipate creation of 80 direct jobs, devoted to the commercialization, design, and implementation of continuous manufacturing systems, and perhaps twice as many indirect jobs by the end of the third year of this project. (2) The project will also create seven full time technical positions at center sites. (3) This project will demonstrate the capabilities of our ERC to develop innovative commercial-grade manufacturing technology, helping establish it as the premier worldwide center of academic research in pharmaceutical product and process design, setting the foundation for the long term viability and sustainability of our ERC. (4) Availability of commercial sources of integrated continuous technology will lead to its rapid adoption and implementation, and will lead to improved product quality, higher productivity rates, and lower cost of manufacturing, likely resulting in price reductions for the patient population.

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