

PAT and Process Understanding: A Call to Arms

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During the past three years, a consensus has grown regarding the need to achieve a higher level of scientific understanding of pharmaceutical products and processes. The US Food and Drug Administration's process analytical technology (PAT) guidance and the new GMPs have prompted the creation of dozens of discussion forums about developing and implementing analytical methods, using multivariate analysis, and incorporating information technology into pharmaceutical development and manufacturing. These actions are a desirable step forward. To further advance pharmaceutical product and process understanding and bring it to a level of development that is standard in other industries, a structured plan for long-term development and implementation is needed, followed by realistic resource allocation and the formation of a broad partnership among industry, government, and academia.

In direct response to this need, in October 2004, Rutgers University and its core partners Purdue University, New Jersey Institute of Technology (NJIT), and the University of Puerto Rico (UPR)—Mayagüez submitted a preliminary proposal to the National Science Foundation (NSF) to establish an engineering research center for Structured Organic Composites (C-SOC) for pharmaceutical and nutraceutical applications.

If funded, C-SOC would receive \$37.5 million in direct NSF funding over 10 years, in addition to attracting substantial contributions from other federal and state programs, the participating institutions, and industry to reach a total funding level greater than \$100 million. These resources will be devoted to implementing a long-term plan for achieving true product and process understanding. A coherent scientific foundation will be developed based on a predictive understanding of structure–function–performance relationships for the optimal design of biocompatible structured organic composites (e.g., tablets, capsules, gels, powders) with advanced drug-release functionality.

In early March 2005, NSF invited Rutgers and its partners to participate in the final round of the competition and to submit a full proposal for the C-SOC. As part of the preparation of the full proposal, the C-SOC team must develop a network of

committed industrial partners who will participate in the direction, execution, and evaluation of research and educational activities.

Thus, the time to stand up and be counted has arrived. By getting actively involved in the proposed center, companies can help the academic team make the proposed center a reality. Many forms of industrial participation have been articulated, including:

- broad involvement in the core research program using the multi-tiered memberships as promoted by NSF;
- participating in project-specific industrial teams sharing specific research goals;
- entering partnerships in educational activities;
- implementing internship programs open to employees from industrial companies pursuing degrees;
- participating in short-course training programs, short research residencies, and industrial sabbaticals;
- donating equipment and research materials.

The full proposal with all documented partnerships is due at NSF on 16 June 2005. Thus, we urge industrial representatives to take immediate action. To get involved in this effort, please contact Professor Fernando Muzzio, who serves as the principal investigator of the C-SOC team (see contact information at left).

In a related program, the C-SOC team has already achieved a significant success. On 11 March, the NSF contacted Professor Muzzio and announced its decision to fund a related collaborative effort among Rutgers University, NJIT, and UPR-Mayagüez to develop an Integrative Graduate Education and Research Traineeship program on Nano-Pharmaceutical Engineering and Science. The proposed program anticipates total funding of approximately \$8 million from NSF, industry, and participating universities, and will serve as a model of integrative training for scientists and engineers in organic nanotechnology applications. This program will train 50 PhD students to enhance the scientific basis underlying nanopharmaceutical materials, products and processes. Companies are invited to get involved in this effort as well. **PT**