

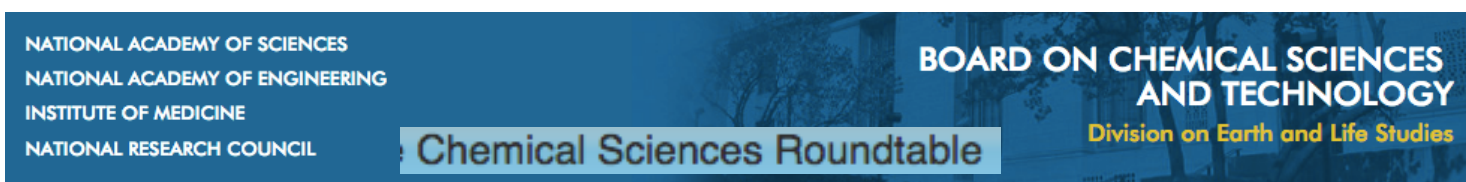


THE CHANGING LANDSCAPE OF PHARMA PROCESS R&D AND MANUFACTURING

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Background

- NAS-CSR (2013) discussions on the changing pharma landscape



- CCR Workshop (2013) on Pre-Competitive Collaboration



- NSF Workshop (2014) on Data-Rich Organic Chemistry



Changes in Pharmaceutical Paradigms



- Big Pharma is consolidating
- Pharma development and manufacturing are being viewed as a commodity
- Controlling quality is a major challenge as technical know-how is increasingly fragmented
- Pharma employment base is shrinking
- Changes in landscape have serious implications for education and academic research

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Pharma is Consolidating



- Big Pharma is relying on external partners
 - ▣ Mergers, outsourcing, contract manufacturing
- In-house expertise in process chemistry is disappearing
 - ▣ Increased reliance on low labor and capital costs
 - ▣ Decreased emphasis on good chemistry, well-engineered processes, mechanistic understanding, state-of-the-art process control
- Critical issues are kicked downstream

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Process R&D as a Commodity



- Implications of this fragmentation of supply chain:
 - ▣ External partners have a wide range of sophistication, technical capability, and resources (equipment)
 - ▣ Good process understanding is even more critical given this variability
- “New Complexity” in API supply:
 - ▣ Outsourcing the product
 - ▣ Outsourcing services:
 - R&D
 - Analytical
 - Regulatory

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Controlling Quality



- Heavy reliance on contract manufacturing organizations
- Changing regulatory and business landscapes in India and China
- Recent quality problems at prominent Indian firms highlight the seriousness of the situation
- Deep technical know-how (both chemistry and engineering) developed at Big Pharma in the 1990's is disappearing

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Shrinking Pharma Employment Base



- Disappearance of the Big Pharma base of technological competence means that outcomes from outsourcing can be hit-or-miss
- Downsizing leads to more contract/short-term workers
- Competing on a long-term basis will require modern manufacturing approaches:
 - ▣ Efficient syntheses
 - ▣ Efficient engineering and process control
 - ▣ Process analytical technologies

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Implications for Education



- Shrinking employment in Big Pharma may mean:
 - ▣ Scaling back graduate programs in synthetic chemistry?
 - ▣ Decreasing interdisciplinary efforts at the chemistry/chemical engineering interface?
 - ▣ Loss of deep knowledge/technical competency base?
- Shrinking government sponsorship of research may mean:
 - ▣ Loss of innovation in synthetic chemistry, catalysis, green chemistry, separation technology?
 - ▣ Loss of focus on novel engineering solutions?

Collaborative Efforts



- CCR Workshop on Pre-Competitive Collaboration
Enabling Technologies for the Pharmaceutical Industry
- NSF Workshop on “Data-Rich Chemistry”
Enabling and Innovating the Study of Chemical Reactions

Pre-Competitive Collaboration

- June 2013: Council for Chemical Research (CCR) workshop, U Penn, Philadelphia



- The growing need for rapid information collection in an era of shrinking resources provides a strong motivation for pre-competitive collaboration between companies themselves and between companies and academia.
- Goal: an integrated approach to data capture and interpretation.

Precompetitive Collaborations

Enabling Technologies for the Pharmaceutical Industry

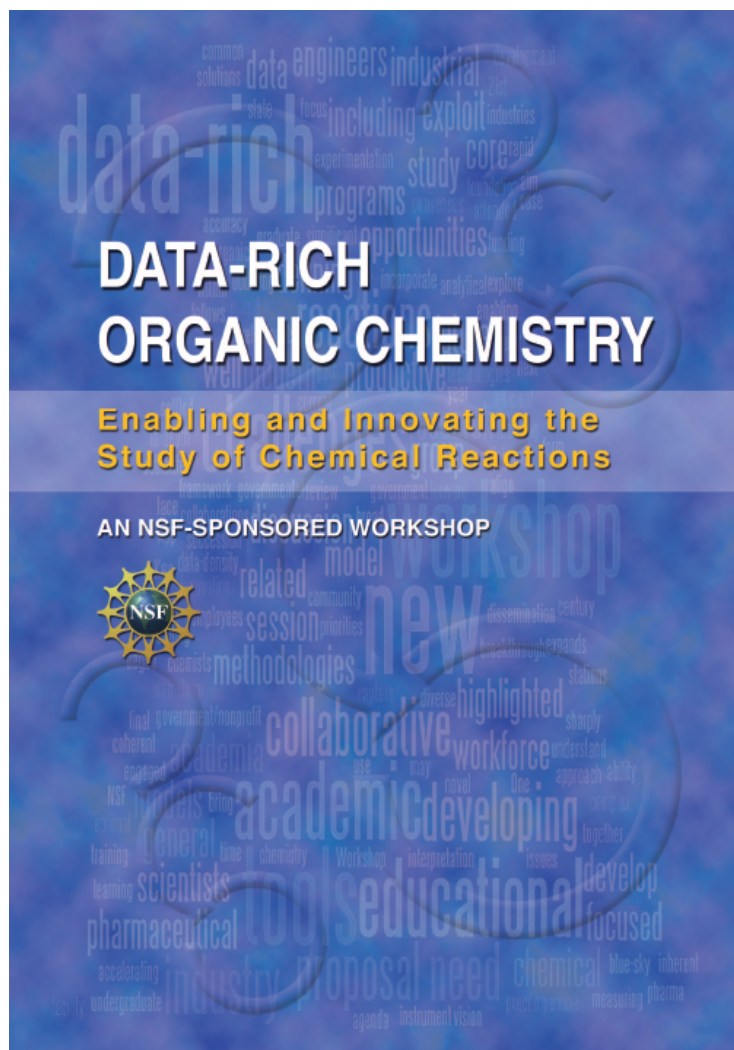
Wednesday-Thursday
June 12-13

On June 12 & 13, 2013, the Council for Chemical Research (CCR) will be hosting a New Industrial Chemistry & Engineering (NICHE) workshop on the topic of "Precompetitive Collaborations on Enabling Technologies for the Pharmaceutical Industry" on the University of Pennsylvania Campus in Philadelphia, PA.

The meeting, chaired by Christopher Welch (Merck), Joel Hawkins (Pfizer) and Jean Tom (Bristol-Myers Squibb) will feature lectures, panel discussions and breakout discussion sessions with leaders in industry, academia and government exploring new approaches to cross-pharma collaborations on precompetitive chemistry and chemical engineering technologies. Join in the discussion with key opinion leaders from Merck, Pfizer, Bristol-Myers Squibb, Amgen, Boehringer Ingelheim, University of Pennsylvania, Mettler-Toledo, Waters, Johns Hopkins University, National Institutes of Standards and Technology (NIST), National Science Foundation (NSF) and others.

This symposium will provide unparalleled opportunities to network and exchange information in an informal setting. NICHE workshops often sell out, so mark your calendar now and watch for future emails from us about registration instructions.

Data-Rich Chemistry Workshop



National Science Foundation
WHERE DISCOVERIES BEGIN

- September 11-12, 2014, Washington, DC
- Broad aim of the workshop is to drive sustainability of the US economy and workforce through:
 - dissemination of data-rich tools across industry and academia
 - building of new collaborative funding models across academia, industry and government
 - implementation of ideas for the further development of our workforce

Acknowledgments



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