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.
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

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