

Biopharmaceutical Operations

Developing the science

Drawing parallels with the semiconductor industry, the authors argue that biopharmaceutical firms are finally reaching a point where efficient operations are becoming critical, thus necessitating advanced research in biopharmaceutical operations. The arguments are based on preliminary investigations at the University of California, Berkeley, identifying key needs in a variety of areas.

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Thirty years ago, the semiconductor industry was a growing technology-focussed industry and for the first time was beginning to face cost pressures. For years, the focus had been on superior technology, and manufacturing was an afterthought. As long as the products were manufactured as they were envisioned by their inventors, there was little need to pay attention to capacity utilisation, operational efficiency, inventory levels, or risk management—if you made them, profits would come. However, as the semiconductor industry matured and competitive pressures grew, firms began to focus on operations—utilising resources effectively and efficiently, optimising systems and dealing effectively with uncertainty and risk. However, significant advances in the science of operations were required to bring about these changes. Working together with each other as well as with academia through organisations such as SEMATECH and the Center for Competitive Semiconductor Manufacturing at UC Berkeley, semiconductor firms were able to make great strides, pushing the state-of-the-

art in semiconductor operations to new heights.

Biopharmaceutical firms now find themselves at a similar crossroads. Over the last several decades, billions of dollars have been invested in the research and development of medicines, leading to ground breaking advances in the treatment of many severe illnesses from arthritis to cancer to haemophilia.

There has been significantly less research focus, however, on operational issues, in spite of the fact that the biopharmaceutical supply chain presents a unique set of operational challenges—demand is highly uncertain and dependent on the results of clinical trials and competitors' actions; supply is highly uncertain due to complex and incompletely understood biological processes; the regulatory demands of agencies in multiple jurisdictions add untold layers of complexity to operations; and capacity is extremely expensive and requires long lead times to build or acquire. Adding to the complexity, mechanisms for drug production are typically not standardised even within firms, technologies continue to change, and generics are

perhaps poised to dramatically impact the industry.

Key operational issues

Over the past three years, a variety of workshops at the University of California Berkeley, have focussed on biopharmaceutical operations, and have provided a forum for interaction between operations managers from many large and small biopharmaceutical firms, and operations experts in academia. The goal of these sessions was to discuss, characterise, and prioritise operational problems faced by the industry, as a precursor to an organised effort to address these issues. Through panel discussions, industry talks and breakout discussions, it became apparent that there are a number of key operational issues on the minds of biopharmaceutical operations executives.

Risk management tools and approaches: Almost every firm is focussed on identifying and working to hedge or manage the risk associated with their operations. In spite of this, there is a lack of basic research on the nature of risk in biopharmaceutical operations, and a lack of tools, techniques, and approaches

for managing this risk.

Long-term capacity planning tools: Most firms have efforts in place to constantly reevaluate long-term capacity requirements, and to ensure that the right amount of capacity will be available in the future. There is a need, however, for standardised tools to address this issue in an analytically rigorous way. Although each firm is facing a similar set of questions, many firms have developed their own ad hoc approaches to answer them. Managers perceive a need to design and implement new, effective, and analytically sound tools to assess the long-term capacity picture.

Operational supply chain management decision support tools: In the short term, firms need to make the most effective and efficient use of their available capacity. However, this is typically done using general purpose tools that don't adequately address the specialised requirements of the biopharmaceutical supply chain. There is a need for advanced and specialised tools, approaches and algorithms that effectively address day-to-day supply chain decisions.

Approaches to assess lean supply chain and operational excellence efforts: Many firms are currently engaged in operational excellence or lean supply chain efforts. There is a lack of tools and techniques to assess the impact and cost-effectiveness of these efforts.

Tools for inventory management: More and more firms are focussing on inventory levels throughout the supply chain. However, there is a lack of approaches and theories that take the specialised nature of biopharmaceutical operations into account when determining what these inventory levels should be, and a lack of benchmarking data with which to assess supply chain inventory performance.

An understanding of the impact of personalised medicine and supply chain fragmentation: Most experts expect that the biopharmaceutical industry will increasingly focus on a larger set of more specialised products, each of

which will have relatively smaller demand than today's blockbuster drugs. There is a need for research into how this will impact supply chains in the future.

Strategies for process improvement and the integration of new technologies in the face of regulation: One of the unique challenges faced by the industry is the regulatory implications of process improvements, and many firms are struggling with appropriate strategies for introducing process improvements for existing products.

Research projects at UC Berkeley have already started to address some of these issues. With a major biopharmaceutical firm, we have developed a planning tool that integrates with SAP to plan production of a complex multi-step product. The firm currently uses this tool daily to plan production at one of their biggest plants. With another firm, we have developed a series of simulation tools to help the management fully understand the impact of introducing new technologies into existing production facilities. This tool has proved to be so successful that the technology invented for this project is currently being utilised in the development of an advanced supply network simulator so that the firm can fully understand the impact of rare high impact events on the supply network, and assess the effectiveness of intended responses to these events. Working with a large biopharmaceutical firm, we have also developed a capacity planning tool to help strategic planners understand more completely the cost and value of delaying costly decisions.

The need for a centre

The results of many of these projects were presented at the recent 2008 UC Berkeley Center for Biopharmaceutical Operations Workshop. The participants of that workshop agreed that the impact of these projects, and others like them could be dramatically increased with the establishment of a centre of excellence focussed on improving operations. There is a compelling need for such a centre as the industry matures and shifts its focus from discovering new process technologies towards cost-efficiency and robustness.

Indeed, faculty at UC Berkeley are currently working to establish such a centre, the UC Berkeley Center for Biopharmaceutical Operations, with the mission of bringing together academic researchers with diverse expertise and industrial experience and biopharmaceutical professionals to advance the state-of-the-art of biopharmaceutical operations with focus on cost-effective, reliable biopharmaceutical production systems and supply chains.

The centre will work to facilitate collaboration between multiple firms and academia for pre-competitive research addressing the issues listed above, provide firms with a forum to share ideas and best practices, provide world-class students with exposure to and training in biopharmaceutical operations ultimately providing the industry with world-class employees, and develop data-driven tools, techniques, and approaches that help the biopharmaceutical industry address its most pressing operational problems.



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