



Massachusetts Institute of Technology

MASSACHUSETTS INSTITUTE OF TECHNOLOGY
PROGRAM ON THE PHARMACEUTICAL INDUSTRY PRESENTS:

ADDRESSING 21ST CENTURY GMPS

Merging New and Existing Technology with Process Automation
to Deliver Science-Based Manufacturing

Wednesday, November 16, 2005 • Massachusetts Institute of Technology
Sloan School of Management • Wong Auditorium • Cambridge, MA



Rockwell
Automation



Massachusetts Institute of Technology

November 16, 2005

Dear Colleague,

On behalf of the Massachusetts Institute of Technology Program on the Pharmaceutical Industry (POPI), I am privileged to welcome you to our biennial POPI Symposium on the Future of the Pharmaceutical Industry. This year's theme is, "Addressing 21st Century GMPS: Merging New and Existing Technology with Process Automation to Deliver Science-Based Manufacturing."

We are grateful to the distinguished group of speakers and panelists who will discuss current developments that are ongoing within this area. We are pleased to offer the opportunity to join in the examination of some of the major technological advances that have the potential to revolutionize pharmaceutical development.

We are grateful to our co-sponsors, IBM Healthcare and Life Sciences, Rockwell Automation, the Consortium for the Advancement of Manufacturing of Pharmaceuticals (CAMP), as well as the Engineering Systems Division (ESD) and the Industrial Liaison Program (ILP) here at MIT for facilitating today's event.

Thank you for your participation! We hope you enjoy the symposium!

Sincerely,

A handwritten signature in black ink, appearing to read 'Stan Finkelstein'.

Stan N. Finkelstein, M.D.

Co-Director of MIT POPI

Senior Research Scientist

Engineering Systems Division & Harvard-MIT Division
of Health Sciences and Technology

SYMPOSIUM AGENDA

8:00 a.m. Registration and Continental Breakfast

8:30 a.m. Event Introductions and Event Overview

Charles L. Cooney, Ph.D.

Professor of Chemical & Biochemical Engineering;

Faculty Director, Deshpande Center for Technological Innovation;

Co-Director, Program on the Pharmaceutical Industry (POPI), Massachusetts Institute of Technology

9:30 a.m. 21st Century Pharmaceutical Manufacturing

**Achieving the Advanced Automation to Manage Product Risk, Reduce Operational Costs
and Increase Supply Chain Responsiveness**

James Bradburn

Americas Pharmaceutical Manufacturing Solution Executive, IBM Business Consulting Services

10:30 a.m. Break

11:00 a.m. PAT and the Manufacturing Science Opportunity

G. K. Raju, Ph.D.

Executive Director, Pharmaceutical Manufacturing Initiative (PHARMI),

Program on the Pharmaceutical Industry (POPI), Massachusetts Institute of Technology;

Chairman & CEO, Light Pharma Incorporated

12:00 p.m. Lunch – Walker Memorial (Building 50), Morss Hall

1:00 p.m. Manufacturing: A Strategic Asset Throughout the Drug Development Cycle

Bob Honor

Vice President, Life Sciences, Rockwell Automation

2:00 p.m. Process Improvement as a Catalyst for Innovation, Examples from
High Throughput DNA Sequencing

Robert Nicol, M.B.A., M.S.

Director of Sequencing Operations, The Broad Institute of MIT & Harvard University; Ph.D.

Candidate, Engineering Systems Division (ESD), Massachusetts Institute of Technology

3:00 p.m. Break

3:30 p.m. Innovations and Strategies in Supply Chain Management

David Simchi-Levi, Ph.D.

Professor of Civil & Environmental Engineering & Engineering Systems Division (ESD),

Co-Director, Leaders For Manufacturing (LFM), and System Design & Management (SDM),

Massachusetts Institute of Technology

4:30 p.m. Speaker Roundtable

5:30 p.m. Event Close

SESSION ABSTRACTS

21st Century Pharmaceutical Manufacturing

James Bradburn

Product evolution, market dynamics and regulatory transformation are causing significant disruption in the pharmaceutical industry. The case for change is impossible to ignore. Moving from today's static production to tomorrow's scientific manufacturing requires data sharing and process collaboration between development and manufacturing.

PAT and the Manufacturing Science Opportunity

G. K. Raju, Ph.D

A "PAT and Manufacturing Science" perspective will be used as an overall theme in this presentation to:

- Highlight the strategic role of pharmaceutical manufacturing
- Describe its current state ("Here")
- Envision its desired future state ("There")
- Identify real and perceived barriers in getting from "Here" to "There"
- Identify how PAT can help overcome some of these barriers

Examples of how PAT technologies (such as LIF) together with a "science" perspective can fundamentally transform the way medicine is made will be described. Some of the current momentum towards capturing this rare window of opportunity will be described in some detail.

Manufacturing: A Strategic Asset Throughout the Drug Development Cycle

Bob Honor

Science-based trends and economic pressures are driving significant changes in life sciences manufacturing. Learn about opportunities to leverage manufacturing as a platform for shortening time-to-market and reducing costs within today's regulatory environment.

Process Improvement as a Catalyst for Innovation, Examples from High Throughput DNA Sequencing

Robert Nicol, M.B.A., M.S.

The exponential efficiency increases in high throughput DNA sequencing that made the human genome project possible have been largely attributed to technology advances. But process improvement in the organizations responsible for this technology has contributed in equal measure. The use of statistical process control, design of experiments, supply chain optimization, and other techniques from industry has enabled these technologies to form robust, efficient, and adaptable systems. Beyond the benefits in efficiency, process improvement enables innovation by deploying the trouble-shooting, analysis, and control methods needed to rapidly integrate new ideas and technologies. The benefits can be very significant, as demonstrated by examples from the Broad Institute Genome Sequencing Platform.

Innovations and Strategies in Supply Chain Management

David Simchi-Levi, Ph.D

The presentation will describe a new approach to positioning inventory in the supply chain in a way that increases service levels and reduces supply chain costs. The focus is on replacing the traditional approach for inventory management, which is based on locally optimizing inventory levels within one facility, with a globally optimized supply chain strategy. The approach is based on identifying the optimal location of the Push-Pull boundary in the supply chain taking into account the entire network, forecast error, variability in transportation and processing times as well as supplier characteristics. We review a variety of field studies that illustrate that the new approach reduces inventory costs by 20-30% and sometimes even more, while maintaining or increasing service levels.

Speaker Roundtable

You will have the opportunity to ask the speakers questions regarding topics from this event, topics you would like to see addressed during future events and/or topics on which you would like additional information.

ABOUT THE MIT PROGRAM ON THE PHARMACEUTICAL INDUSTRY (POPI)

The MIT Program on the Pharmaceutical Industry (POPI) is a unique university-industry-government collaboration based at MIT's Sloan School of Management. It was founded in 1991 to both perform multi-disciplinary research on the factors which drive, constrain and enhance the performance and competitiveness of the pharmaceutical/biotechnology industry, and to educate future scientific and management leaders for the industry and for those of the organizations which supply it, regulate it or use its products.

Among its research and educational accomplishments, POPI continues to contribute activities to areas including drug development, pharmaceutical manufacturing and the pharmaceutical marketplace. It has been supported by more than 30 faculties of MIT Schools of Engineering, Science and Humanities and Social Sciences, the MIT-Harvard Division of Health Sciences and Technology and the MIT Sloan School of Management.

ABOUT THE SPONSORS

IBM

The goal of IBM Healthcare and Life Sciences is to rapidly bring real-life business and information technology solutions to customers in the fields of pharmaceutical research and development, compliance, biotechnology, genomics, information-based medicine, biomedical imaging, healthcare delivery and other specialties. IBM is a proven leader in data integration, supercomputing, high-performance storage and on demand information technology services.

Long-term projects at IBM Research Centers and the IBM Deep Computing Institute foster collaboration with life science and healthcare companies — bringing domain expertise and innovative technologies to the development of its solutions. Together with its Business Partners, IBM can provide customized, effective solutions that include hardware, software, services and the brightest ideas in the business. To learn more, visit ibm.com/lifesciences, or contact an IBM Life Sciences specialist at LS@us.ibm.com.

Rockwell Automation

Rockwell Automation, Inc. (NYSE: ROK), is a leading global provider of industrial automation power, control and information systems and services that help manufacturers achieve a competitive advantage in their businesses. The company brings together leading brands in industrial automation, including Allen-Bradley controls and services, Dodge mechanical power transmission products, Reliance Electric motors and drives and Rockwell Software factory management software. Headquartered in Milwaukee, Wisconsin, the company employs about 22,000 people serving customers in more than 80 countries.

ABOUT THE SPONSORS (CONT.)

The Consortium for the Advancement of Manufacturing of Pharmaceuticals (CAMP)

CAMP is a non-profit consortium of pharmaceutical companies that conducts research focused on decreasing new product time-to-patient, increasing quality and lowering product costs by enhancing pharmaceutical manufacturing performance. Its mission is to identify, research and develop new technologies that can dramatically enhance pharmaceutical manufacturing performance.

MIT Engineering Systems Division (ESD)

The Engineering Systems Division of MIT creates and shares interdisciplinary knowledge about complex engineering systems through initiatives in education, research and industry partnerships. ESD broadens engineering practice to include the context of each challenge as well as the consequences of technological advancement.

ESD has a dual mission: to define and evolve engineering systems as a new field of study and to transform engineering education and practice. As a division, ESD establishes an intellectual home for key programs and centers, engages faculty across departments and disciplines and fosters discourse about engineering innovation.

MIT Industrial Liaison Program (ILP)

The Office of Corporate Relations' Industrial Liaison Program promotes MIT/industry collaboration, encouraging the flow of knowledge and resources between the Institute and innovation-driven companies for their mutual benefit.

The exchange of ideas and capabilities resulting from ILP-facilitated interactions often speed the incorporation of new technologies into products and services — helping MIT research make its way to the marketplace and out to the global community.

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