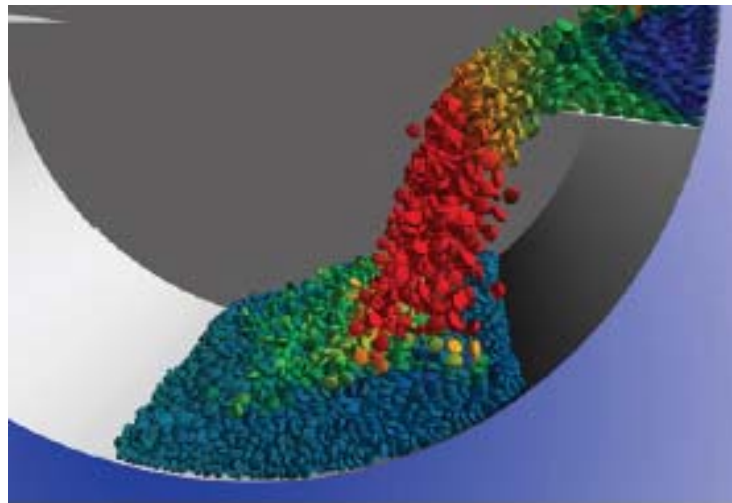


National Institute for Pharmaceutical Technology and Education (NIPTE)



Technology Roadmap



NIPTE The National Institute for
Pharmaceutical Technology and Education
Improving Quality and Lowering Costs of Pharmaceuticals

www.nipte.org

NIPTE Needs Strategic Plans

- **NIPTE mission** implies two interconnected components:
 - A **research agenda** leading to the development of necessary fundamental knowledge.
 - Development of a **strong human resource pool** to develop this knowledge and to implement it in the field.
- **Roadmaps** are needed for both education and research.



What is a Technology Roadmap?

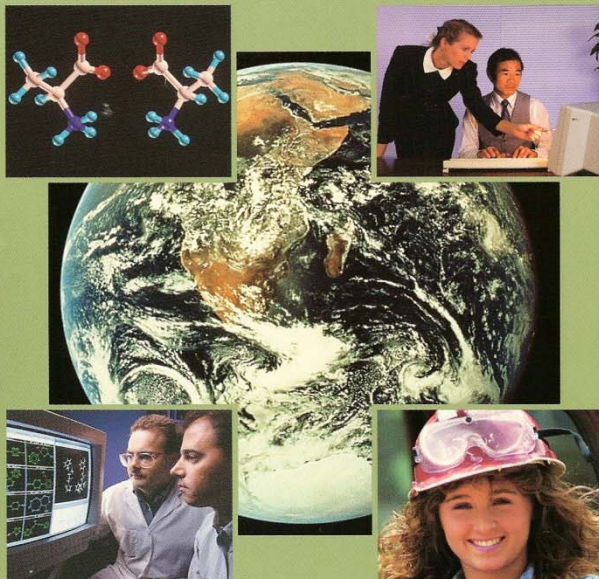
- **Strategic Plan** for Research in a given domain.
- **Blueprint of R&D tasks & milestones** necessary to achieve desired technology goals:
 - *Identify what should be done vs. what can be done.*
 - *Prioritize & set achievable timelines.*
 - *Establish rational basis for estimating resource needs & setting resource allocations.*
- **Key element: Participation of technology users & providers** to arrive at broad consensus.



Roadmapping Phases

- **Define scope & domains**
- **Current state**
- **Desired future state**
- **Barriers**
- **Research needs:**
 - **Core technologies**
 - **New capabilities**
 - **Improvements/enhancements**
 - **Time frame**
 - **Prioritization**
 - **Enabling technologies**
- **How to get there (resources, actions)**





TECHNOLOGY VISION

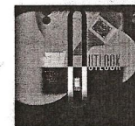
2020

The U.S. Chemical Industry

AMERICAN CHEMICAL SOCIETY
AMERICAN INSTITUTE OF CHEMICAL ENGINEERS
CHEMICAL MANUFACTURERS ASSOCIATION
COUNCIL FOR CHEMICAL RESEARCH
SYNTHETIC ORGANIC CHEMICAL MANUFACTURERS ASSOCIATION

SEMICONDUCTOR INDUSTRY

2001 Technology Roadmap for Semiconductors



The International Technology Roadmap for Semiconductors (ITRS) is a collaborative effort within the semiconductor industry to confront the challenges implicit in Moore's law. Representatives of the International Technology Working Groups for Design and Test outline some of the contributions made by 839 international experts as they sought to reach an industry-wide consensus on its R&D needs out to a 15-year horizon.

Alan Allan
Intel

Don Edensfeld
Intel

William H. Joyner Jr.
Semiconductor Research Corp.

Andrew B. Kabng
University of California, San Diego

Mike Rodgers
Intel

Yervant Zorian
LogicVision

For the past 40 years, the semiconductor industry has distinguished itself by the rapid pace of improvement in its products. This growth has resulted principally from the industry's ability to decrease exponentially the minimum feature sizes it uses to fabricate integrated circuits, commonly referred to as Moore's law. The most significant trend for society is the decreasing cost per function, which has led to significant improvements in productivity and quality of life through proliferation of computers, electronic communication, and consumer electronics.

Over the past two decades, the phenomenal increase in research and development investments has motivated industry collaboration and spawned many partnerships, consortia, and other cooperative ventures. The International Technology Roadmap for Semiconductors (ITRS) is an especially successful worldwide cooperation that presents an industry-wide consensus on the "best current estimate" of its R&D needs out to a 15-year horizon. As such, the Roadmap provides a guide to the efforts of companies, research organizations, and governments to improve the quality of R&D investment decisions made at all levels, and it has helped channel efforts to areas that truly need research breakthroughs.

Excerpts from the Executive Summary and three chapters of *The International Technology Roadmap for Semiconductors, 2001 edition*, International Sematech, Austin, Texas, 2001.

Since its inception in 1992 as the *National Technology Roadmap for Semiconductors* (NTRS), the Roadmap's basic premise has been that scaling of microelectronics would continue to reduce the cost per function by 25 percent and promote market growth for integrated circuits by 15 percent annually. Thus, the Roadmap is put together in the spirit of a challenge: What technical capabilities does the industry need to develop to continue to follow Moore's law?

The semiconductor industry is increasingly sharing its research efforts via mechanisms such as consortia and collaborations with suppliers in a precompetitive environment. The ITRS identifies the principal technology needs to guide this shared research. It does this in two ways: by showing the targets that technology solutions currently under development need to meet and by indicating where there are no "known solutions" (of reasonable confidence) to continued scaling in some aspects of semiconductor technology. Because they clearly warn where historical progress trends might end if the industry doesn't achieve some real breakthroughs in the future, these latter indicators highlight serious and exciting challenges.

As the "Overall Roadmap Process and Structure" sidebar indicates, the 2001 Roadmap is notable because it was developed with truly international representation. The contributions outlined here represent but a small portion of this immense undertaking over the past two years.



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Chemical Industry Vision 2020

- The Vision2020 Roadmap was an industry-led partnership/ process among public and private sector stakeholders in the chemical and allied industries.
- Stakeholders identify common problems and leverage technical expertise and financial resources to develop the critical enabling technologies of the future.
- Through collaborative efforts among industry, national laboratories, and academia, the Vision2020 fosters step-change technology innovation, which may be beyond the risk threshold of individual companies.
- Vision2020 has helped to maintain U.S. leadership as the world's largest chemical producer.

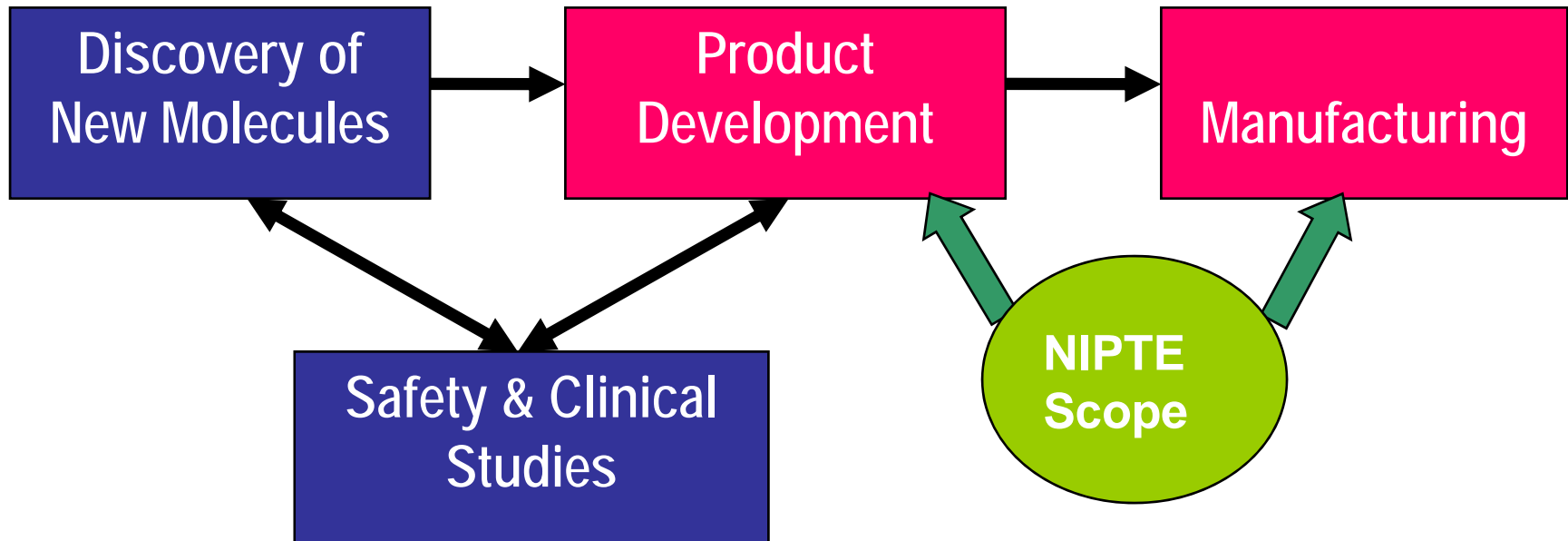
[From Vision 2020 Website](#)



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NIPTE Scope



Components of NIPTE Technology Roadmap

Technology Road Map

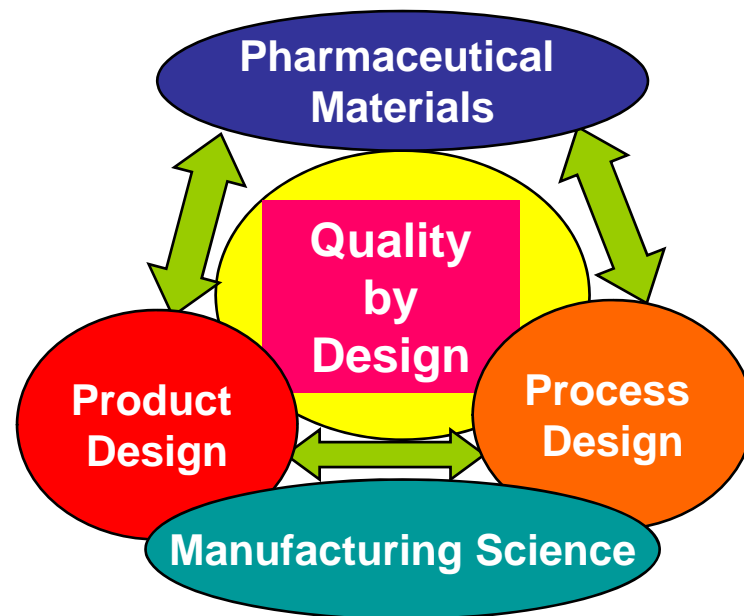
Domains:

- *Pharmaceutical Materials*
- *Product Design*
- *Process Design*
- *Manufacturing Science*



Technology Roadmap Progress

- NIPTE faculty team developed technology roadmap draft January-August 2006
- NIPTE commenced soliciting feedback from scientists and engineers in industry & FDA:
 - Sept 2006 Workshop at FDA attended by over 80 professionals from industry & FDA
 - Post-workshop Feedback received from several major companies & 20+ individual experts
 - Information & feedback sessions held at ISPE, AAPS & AIChE Fall 2006 meetings



**Key Weakness:
Solid oral dosage
form emphasis**



Technology Roadmap Progress

- **NIPTE Response**
 - Dosage oriented workgroups formed Nov- Dec 2006 & teleconferences initiated
 - Workgroup domains
 - Parenterals (including biotech)
 - Pulmonary, nasal & related
 - Topicals, dispersed, ophthalmic
 - Devices & Packaging
 - Solid oral dosage form
 - Planning support from GSK staff
- **Workshop (Jan 24-25 2007, Gaithersburg)**
 - To insure that roadmap addresses research needs of all principal dosage forms
 - To review roadmap draft to identify technology gaps & research needs
 - GSK facilitators



NIPTE Roadmapping

	Parenterals (including biotech)	Solid Oral Dosage Forms	Devices/ Packaging	Pulmonary, Nasal and Others	Topicals, Dispersed, Ophthalmics
Pharmaceutical Materials and Products					
Analytical Methods and Enabling Technologies					
Prediction of Properties					
Design to Achieve Desired Properties					
Process Development & Design					
Process Understanding					
Reliable Scale-up and Scale-down Methodologies					
On-Line Sensing and PAT-Based Unit Management					
Manufacturing Science					
Integrated Process Operations					
Innovative Manufacturing Systems					
Informatics-Based Model Development and Data Integration					

Matrix Approach to insuring completeness with regard to product domains & technology components



Technology Roadmap Progress

- **NIPTE Integration Workgroup assembled all inputs into next draft of roadmap & revised selected sections**
- **Workshop (Feb 21-23, 2007; Caguas, PR (Pfizer host))**
 - Presented draft & obtained additional feedback from manufacturing experts in PR (Feb 21)
 - NIPTE Executive Committee initiated prioritization & identification of theme projects (Feb 22-23)
 - GSK facilitators
- **Post workshop actions**
 - Aggregation of highest priority research needs into 14 research areas
 - Distillation of three theme projects
 - Updating of Roadmap document

