9th SAPA-NE Annual Conference 2006

Advancement and Globalization of Drug Discovery and Development

Sunday, June 18, 2006

Wong Auditorium, Building E51, Sloan Business School
Massachusetts Institute of Technology, Cambridge, MA 02139

Organizer: SAPA-NE www.sapa-ne.org

Conference Chair:
Jun Han, Ph.D. Novartis Institutes for BioMedical Research; SAPA-NE, President-elect

Conference Co-Chairs:
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Bin Zhang, Ph.D. ArQule; SAPA-NE, Director
Kevin Q. Fang, Ph.D. Sepracor; SAPA-NE, Director/General Secretary
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Qing Huang Abbott Bioresearch Center; SAPA-NE, Director
Sue Ma, M.D. Novartis Institutes for BioMedical Research;
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Liping Zhou, Ph.D. Novartis Institutes for BioMedical Research; SAPA-NE, Director
Greetings from the Conference Chair

Dear SAPA Members and Friends:

Good Morning! Welcome to the Ninth Sino-American Pharmaceutical Professionals Association – New England (SAPA-NE) Annual Conference. The theme of this special event is “Advancement and Globalization of Drug Discovery and Development”.

Thanks to the great efforts of our conference organizing committee and the support of our distinguished speakers, we have the privilege to present to you a great program today. In the morning sessions, you will find exciting talks on the cutting edge of drug discovery for both small molecules and biopharmaceuticals. With pharmaceutical companies like Novartis and AstraZeneca starting significant research operations in China, it is appropriate and timely to center the afternoon discussions on the globalization aspects of drug discovery and development in China.

Recently Biogeneric drugs have attracted great attention with the approval of the first biogeneric hGH preparation (Omnitrope) from Sandoz (Novartis) by FDA last month. During our dinner reception, we will have the opportunity to hear Dr. Ajaz S. Hussain, Vice President and Global Head for Biopharmaceuticals Development at Sandoz, to speak on the story of Omintrope and it’s impact on the pharmaceutical industry.

Taking this opportunity, I invite you all to join, support and volunteer for SAPA, a member based non-profit organization. SAPA New England, Located in the “GeneTown” Boston/Cambridge area, has a member base of about 1000 professionals and students from both industries and academic research institutes. As an organization, we strive to

- Promote the advancement of pharmaceutical science and biotechnology
- Make contributions benefiting public health education
- Promote scientific exchange and business cooperation between the US and China
- Foster the career growth of pharmaceutical and biomedical professionals

For more details, please visit our website http://www.sapa-ne.org.

Finally I would like to thank our co-organizer - MIT Economics & Talent Forum. We are very grateful for the sponsorship provided by Novartis and other pharmaceutical companies listed in this program and on our website. It’s your support and generosity made this special event possible.

This is a day packed with exciting presentations, insightful panel discussions, extensive exhibits, and great network opportunities. Thank you again for your participation and enjoy the day!

Sincerely Yours,

Jun Han, Ph.D.
SAPA-NE 2006 Conference Chair
President-elect of SAPA-NE
Ninth Annual Conference SAPA-NE 2006

Advancement and Globalization of Drug Discovery and Development
Sunday, June 18, 2006

7:30 – 8:30 AM  Registration and Breakfast

Opening Remarks

8:30 – 8:40 AM  Jun Han, Ph.D.
9th SAPA-NE Annual Conference Chair, SAPA-NE President-elect

Session 1: Advances in Discovery Research and Development
Host: Bin Zhang, Ph.D., Conference Co-Chair

8:40 – 9:15 AM  Dennis France
Vice President, ArQule Institute for Biomedical Research

“Beyond Biomolecular Screening: A Multi-Paradigm Approach in Streamlining Early Oncology Drug Discovery”

9:15– 9:50 AM  Nick Terrett, Ph.D.
Chief Scientific Officer, Ensemble Discovery Corporation

“The Evolution of Drug Discovery - from Viagra to Variety”

9:50– 10:25 AM  Raymond Skwierczynski, Ph.D.
Director of Formulation, Millennium Pharmaceuticals, Inc.

“Developable Candidate Selection through the Eyes of a Development Scientist”

10:25 – 11:00 AM  Exhibition and Coffee Break
Session 2: Trend in Biopharmaceutical Research and Development
Host: Qing Huang, Conference Co-Chair (Sponsored by Blue Sky Biotech Inc.)

11:00 – 11:35 AM  Garvin Warner, Ph.D.
Senior Director, Drug Safety Metabolism, Wyeth Pharmaceuticals
"Nonclinical Safety Assessment in Biotechnology: What Can We Try and Do Better"

11:35– 12:10 PM  Tariq Ghayur, Ph.D.
Research Fellow (Volwiler Society Member), Abbott Laboratories
“The Science Behind Discovery & Development of Fully Human Therapeutic Monoclonal Antibodies at Abbott Bioresearch Center”

12:10– 12:45 PM  Edmund (Ted) Sybertz, Ph.D.
Senior Vice President, Scientific Affairs, Genzyme Corporation
“Genzyme Corporation’s initiatives in neglected diseases drug discovery and development”

12:45 – 1:40 PM  Lunch and Exhibition

Session 3: Challenges, Innovations, & Globalization of Medicine Development
Host: Min Dong, Ph.D., Conference Co-Chair

1:40 – 2:15 PM  En Li, Ph.D.
Vice President and Global Head of Models of Disease Center, Novartis Institutes for BioMedical Research
"Innovative Drug Discovery in China: Mission Possible?"

2:15 – 2:50 PM  Mark T. Goulet, Ph.D.
Executive Director of Chemistry, Merck Research Laboratories-Boston
“Building a 21st Century Research Laboratory”

2:50 – 3:25 PM  Bing Yu, Ph.D.
Chief Operation Officer, AstaTech Inc.
“A Case Study about Doing Business in China”

3:25 – 4:00 PM  Exhibition and Coffee Break
Session 4: Panel Discussion: All speakers and the invited panelists from China and US

Host: Jun Han, Junjun Wu, Sue Ma and Kevin Fang, Ph.D., Conference Co-Chairs

1. The future of drug discovery and development.
2. Strategies for US companies to benefit from the rapid growth of China and international pharmaceutical industry? Strategies for Chinese pharmaceutical industry to be competitive?

(Panelists from China may change due to the Visa issue and travel schedules)

XiaoJian Zhu  General Manager, Wuxi Mashan Biological and Pharmaceutical Industrial Park
Guozhong Rui  Director, International Technology Exchange and Transfer Center, SFDA
Amber Cai  Director, Strategic Alliance, Novartis Institutes for BioMedical Research
Wei Dong Yin  President and CEO, SinoVac Biotech Pharm,
Ling Su  Director, Medical and International Pharma Development, Roche Pharmaceuticals Ltd Shanghai
Ling Chen  M.D., Ph.D. Director-General, Guangzhou Institute of Biomedicine & Health, CAS

5:50– 6:00 PM  Closing Remark and Raffle
Host: Huimin Chen, SAPA-NE President and Bingli Ma, MD, Conference Co-Chair

6:30– 9:30  PM  Novartis Sponsored Dinner Reception
Host: Jun Han, SAPA-NE 9th Annual Conference Chair

Place:  MIT Faculty Club

Activity:
1. Keynote speaker: Ajaz Hussain, Ph.D., Vice President & Global Head of Biopharmaceutical Development, Sandoz
   The Evolving Omnitrope Story and Adam Smith's "Invisible Hand" Concept

2. SAPA-NE 2004 Outstanding Contribution Award Ceremony

3. Networking opportunity among speakers, sponsors, vendors and attendees.

Drinks and food will be served.

Ticket is required for Reception, which is available in front registration desk.
SAPA-NE Previous Annual Conference (1998-2005)

06/06/1998 First Annual Conference “Interface of Biochemistry, Biomedicine and Drug Development”, Yenchin Library, Harvard University

06/29/1999 Second Annual Conference “A Blue Print of Biotechnology/Biopharmaceuticals for 21st Century”, Medical School, Boston University

06/24/2000 Third Annual Conference “Molecular Medicine and Drug Discovery in the New Millennium”, Sloan Business School, MIT


06/18/2005 Eighth Annual Conference “Advancing Drug Discovery & Development”, Sloan Business School, MIT

Dennis France
Vice President, Oncology Lead Discovery, ArQule Biomedical Institute

Dennis France joined the ArQule Institute for Biomedical Research as Vice President of Oncology Lead Discovery, located in Woburn, MA in July 2004. Dennis’ role focuses on molecular targeted approaches to cancer from target selection to IND submission. Before joining ArQule, Dennis rose through the ranks over a span of 17 years at Novartis, most recently as an Executive Director in the oncology disease area where he was responsible for early target-based oncology lead discovery. Prior to joining the pharmaceutical industry in 1987, Dennis worked at leading medical research labs, including the Dana-Farber Cancer Institute (DFCI), the Mt. Sinai School of Medicine and the NYU Medical School. At Novartis, he served as a key liaison for the collaboration between Novartis and the DFCI and was also a co-investigator for several natural product drug discovery grants sponsored by the National Cancer Institute. Dennis was also the Executive Chairman of the Laboratory Robotics Interest Group for over ten years and was recently recognized for his leadership in growing this group from 200 members to over 8,000 worldwide. Dennis has also been Chairman of the MipTec Conference for nearly a decade, a leading European conference on drug discovery. Dennis has received a number of awards, including the ISLAR Pioneer Award in Laboratory Robotics, The Association for Laboratory Automation Achievement Award, and the Novartis Pharmaceuticals Corporation Pioneer Award. Dennis has co-authored over 30 peer-reviewed scientific papers during his career ranging across such diverse areas as oncology, atherosclerosis, and drug discovery technologies.

“Beyond Biomolecular Screening: A Multi-Paradigm Approach in Streamlining Early Oncology Drug Discovery”

Traditional HTS campaigns have been somewhat variable in providing suitable hits for further lead optimization for oncology targets with compelling epidemiologic and pathophysiological rationales. We have explored alternative opportunistic approaches to initiate the lead discovery process for highly attractive oncology targets. In the case of Hsp90 inhibitors, we assembled available structural information and generated a number of hypothesis-driven compound sub-libraries. One sub-library yielded an initial hit with high micromolar potency that was subsequently optimized to low nanomolar biochemical and cellular potency after iterative rounds of hit explosion. For mutant BRAF kinase, a target implicated in melanoma and other cancers, a unique scaffold was identified from an archival kinase sub-library with micromolar activity against c-raf-1 kinase. The subsequent optimization of this series against mutant BRAF yielded selective, potent, and cell-active compounds. Finally, the chemistry space was expanded around known HDAC inhibitors using available structural data and compounds were synthesized with picomolar activity against certain HDAC isoforms and exhibited cell kill against cancer cells at low nanomolar
concentrations. The unique features and accelerated timelines of these and other discovery programs will be discussed in detail.

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**Nick Terrett, Ph.D**  
*Chief Scientific Officer, Ensemble Discovery, Cambridge, MA*

Dr. Nick Terrett was born in London and educated at Pembroke College, Cambridge (BA in Natural Sciences) and Corpus Christi College, Cambridge (PhD in Organic Synthesis with Dr Ian Fleming). He worked at Glaxo Group Research from 1979 to 1981, at Pfizer Central Research (Pfizer Global R&D now) from 1984 to 2006.

Dr. Terrett’s Pfizer work was initially in Sandwich, UK as a medicinal chemist in cardiovascular disease, working on ACE and NEP inhibitors, and as inventor on patents for candoxatrilat (NEP inhibitor for heart failure). Subsequently worked on cGMP PDE inhibitors for angina and erectile dysfunction, inventor on patents for sildenafil (Viagra®). Dr. Terrett established Pfizer’s combinatorial chemistry group and published several related publications and textbook (Combinatorial Chemistry, Oxford University Press, 1998). From 1998 to 2003 he managed high throughput screening and materials management groups in Sandwich. From 2003 to 2006 Nick was Senior Director and Head of Chemical Sciences at the Pfizer Research Technology Center in Cambridge MA, USA.

Currently Dr. Terrett is the Chief Scientific Officer for Ensemble Discovery, a biotech company applying novel methods for drug discovery using DNA-programmed chemistry and screening.

“The Evolution of Drug Discovery – From Viagra to Variety”

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**Raymond D. Skwierczynski, Ph.D**  
*Director, Formulation Science, Millennium Pharmaceuticals*

Dr. Raymond D. Skwierczynski is Director of Formulation Science at Millennium Pharmaceuticals, where he is responsible for preformulation and formulation development for oral-dosage forms. He has worked in parenterals development in Baxter Healthcare (1984-87), materials characterization at Hoffmann-LaRoche (1994-96), and the Pharmaceutics and Analytical R&D Departments at 3M Pharmaceuticals (1996-2003). In his previous position at 3M, he was responsible for drug substance analysis, exploratory pharmaceutics, degradation chemistry, solid-state characterization, and spectroscopy. Dr. Skwierczynski received B.S. degrees in chemistry.
and mathematics from the University of Wisconsin – Eau Claire (1984) and M.S. (1989) and Ph.D. (1992) degrees in pharmaceutics from the University of Wisconsin – Madison. He received a postdoctoral training in physical organic chemistry at UW-Madison as a PhRMA Foundation Fellow. He teaches courses in pharmaceutical stability and preformulation at the University of Minnesota, where he is Adjunct Associate Professor in the Pharmaceutics Department, and through the University of Wisconsin Extension Services in Pharmacy.

“Developable Candidate Selection through the Eyes of a Development Scientist”

The progression of an active molecule through Lead Optimization is determined, in part, by its biological properties. Although desirable biology is absolutely necessary, it is not sufficient for identifying developable molecules. The biopharmaceutical and physicochemical properties of the active molecules and their route of delivery also must be considered. Key decisions in late Lead Optimization should be made from biological data obtained from formulated molecules administered using the intended route of delivery. A useful tool to ensure efficient progression of molecules and objective decision making is a process map that defines the tasks and tests performed by multiple disciplines. The map, which should be developed by the Discovery team, essentially defines how business will be done. The map indicates what tests will be done and when, how much material is needed, who is responsible and accountable for completing for the tests, what are the advancement criteria, and, most importantly, how data-driven decisions will be made.

A case study that illustrates the biological and physical chemical tests performed during Lead Optimization for an oncology project will be presented. A multi-tiered process was used to funnel desirable molecules through Lead Optimization. All molecules entered the first tier, which consisted of a series of simple material-sparing biological and physical chemical tests. Molecules that met predefined criteria, advanced to the second tier of testing that included additional, somewhat more involved, in vitro biological testing and physical chemical testing. Again, only molecules that met pre-defined criteria advanced to the third tier, which included in vivo testing of formulated molecules and, hence, was more labor intensive. The ultimate decision on candidate selection was made by the lead representatives from Pharmacology, Drug Metabolism and Pharmacokinetics, and Drug Safety Evaluation Departments by using in vivo data obtained from formulated molecules and the intended route of delivery.

Garvin L. Warner, Ph.D
Director, Drug Safety and Metabolism, Wyeth Research

Dr. Warner received his BA in Biology from Colgate University and a Ph.D. in Microbiology and Immunology in 1986 from Albany Medical College. Following a post-doctoral fellowship and an appointment as a Research Assistant Professor in the Immunology Division at the University of Rochester Cancer Center, Garvin joined Drug Safety Evaluation, Bristol-Myers Squibb, Syracuse, NY, in 1991 and expanded the immunotoxicology and exploratory
toxicology group there as part of the department of Biologics Evaluation. His responsibilities included drug safety and development programs for a number of immunomodulatory, oncology, and therapeutic protein programs, including the nonclinical safety assessment of the recently approved novel immunosuppressant Orencia (abatacept, CTLA4Ig). In 1997 he moved to Genetics Institute, Andover, MA, and was responsible for a number of development programs including Nuemega (IL11), BeneFIX (Factor IX), and ReFacto (Factor VIII). When Genetics Institute was fully incorporated into Wyeth Research Garvin was responsible for various development programs (both large and small molecules) in Immunology, Cardiovascular and Metabolic Disease, and Hemophilia, and also managed the Exploratory Drug Safety group, Wyeth Research, Andover, MA. Currently Garvin is a Therapeutic Area Head and is responsible for the Immunology and Vaccine programs, as well as the Alzheimer’s Immunotherapy programs, within Preclinical Development, Drug Safety and Metabolism. Garvin has over 25 publications and several books chapters in the fields of immunology and drug safety evaluation.

“Nonclinical Safety Assessment in Biotechnology: What Can We Try and Do Better”

The nonclinical safety assessment of all therapeutic molecules can be a challenging task. Novel platforms and/or targets, whether they are small or large molecules, protein or DNA/RNA, or vaccines requires a thoughtful approach in terms of assessing nonclinical safety prior to entry into clinical studies. The fundamental challenge in the early stages in this nonclinical safety assessment is to assist in the selection of the candidate least likely to fail in clinical studies due to safety/metabolism issues, to identify a safe starting clinical dosage, and to identify potential target organs of toxicity so that the clinicians can adequately assess safety in the clinical studies. To that end, a thorough understanding of the pharmacology of the candidate molecule is essential in understanding potential “on-target” toxicities, regardless of whether the compound being developed is a small molecule, large molecule, protein, DNA/RNA, or something in between. At the same time one must remember that “off-target” toxicities are important, whether they be due to metabolites or truly unpredictable based on the known pharmacology. As a regulator once stated to me as I tried to make an argument that a specific nonclinical study was not needed because we knew the answer based on the pharmacology, “We do toxicity studies to look for unexpected toxicity, not for expected toxicity.” In addition, a thorough understanding or the nonclinical safety model being used, whether in vivo or in vitro, or traditional tox/path or molecular/biomarker endpoint, is important in understanding the adequacy of the nonclinical safety assessment. Recent experiences with adverse events following the initial dose of TG1412 (a T-cell agonist, monoclonal anti-human CD28 antibody) clearly illustrate the need to understand the nonclinical model used to assess toxicity prior to first dose in humans. The primary goal of the nonclinical safety expert is to ensure patient safety. A thorough understanding of the pharmacology, metabolism, and the relevancy nonclinical model(s) being used is extremely important in understanding the nonclinical toxicity of any therapeutic compound.
Tariq Ghayur, Ph.D  
Senior Principal Scientist & Research Fellow, Abbott Bioresearch Center, Worcester, MA

Dr. Ghayur received a Ph.D (1986) in Immunology from McGill University, Montreal, Canada. He did his post-doctoral training at McGill (1986-'88) and Dana Farber Cancer Institute (1988-'90). He joined BASF Pharma (1990), which was acquired by Abbott Laboratories in 2000. He has worked on several small molecule and therapeutic antibody discovery programs, mainly defining the biology/pathology of selected targets (target validation) and assays development for high throughput screening and/or candidate selection. More recently, he has worked on developing novel forms of antibody-based therapeutics. Since 1996 he has initiated and/or worked on several therapeutic antibody programs for treatment of immunological, neurological, and metabolic diseases. From 1998-2004, he led two therapeutic antibody discovery project teams and delivered 2 drug development candidates. During this period, he was also responsible for establishing and maintaining several academic and industrial collaborations. He received Abbott’s “President’s Award” in 2004. Currently, he serves as a Senior Principal Scientist and is a Research Fellow in the Volwiler Society whose membership consists of accomplished Abbott Scientists. He is also a member of a team at Abbott Bioresearch Center (ABC) that encourages and enables scientists, at all levels of the organization, to explore novel ideas and initiate new drug discovery programs and/or develop novel technologies.

He holds several patents and is the author of many peer-reviewed scientific publications. In addition to therapeutic antibodies and antibody generation technologies, his areas of expertise are inflammation, lymphocyte biology, cytokine biology and transplantation rejection.

“The Science Behind Discovery & Development of Fully Human Therapeutic Monoclonal Antibodies at Abbott Bioresearch Center”

Since the publication of methodology for generating monoclonal antibodies (mAb) in the mid-1970s, mAb generation technologies have advanced at a breath-taking pace and several mAb-based therapeutics have reached the market place for a variety of disease indications. Antibody-based therapeutics has revolutionized treatment of certain diseases. According to some estimates 2004 sales of antibody-based therapeutics exceeded US $ 5 billion – with sales projection of US $ > 20 billion by 2010. Currently, over 100 antibodies are in various stages of development for several indications. And according to some estimates this class of therapeutics represents the fastest growing segment within the pharmaceutical/biotech industry. Almost all major pharmaceutical/Biotech companies have active programs in generating and developing antibody-based therapeutics.

Monoclonal antibodies represent a class of highly targeted, safe, and efficacious immuno-therapeutics. Marketed monoclonal antibodies come in various “flavors”: fully murine, chimeric, humanized, and fully human. Antibody generation technologies include in vivo methods such as the classical hybridoma approach; in vitro methods such as phage display and; a combination of both in vivo and in vitro approaches resulting in chimeric and/or
humanized antibodies. With a better understanding of antibody functions and advancements in genetic engineering technologies, new forms of highly specific, safe and efficacious antibody-based therapeutics are being developed.

Abbott Laboratories has emerged as one of the pioneers in antibody-based therapeutics, with HUMIRA, the first marketed fully human anti-TNF mAb, and several other antibodies in various stages of development. Abbott Bioresearch Center (ABC), Abbott Laboratories’ Center for Immunoscience and Biologics in Worcester, is a highly integrated Immunoscience/Biologics Research and Biologics manufacturing organization. We have established collaborations with key antibody generation technology providers as well as are developing proprietary technologies for making and/or enhancing functions of therapeutic antibodies. In this presentation I will discuss some critical aspects of antibody-based therapeutics and the science and rationale behind the discovery of HUMIRA®.

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Edmund (Ted) Sybertz, Ph.D
Senior Vice President, Scientific Affairs, Genzyme Corporation

Dr. Sybertz received his PhD in pharmacology from the University of Minnesota and did postdoctoral training at the University of Virginia. He spent 18 years at the Schering Plough Research Institute and was Senior Director and Presidential fellow CV/CNS research. Ted joined GelTex Pharmaceuticals, Inc. in 1998 as Senior Vice President of R&D and became General Manager of GelTex Pharmaceuticals shortly after the company merged with Genzyme Corporation. Dr. Sybertz also held the position of Senior Vice President Drug Discovery and Development at Genzyme until the beginning of 2006. He is now Senior Vice President Scientific Affairs at Genzyme and is heading up the company’s drug discovery and development initiatives in neglected diseases R&D. Ted is author or coauthor of about 100 scientific publications involving the discovery and development of new agents for treating cardiovascular, CNS, and metabolic diseases. He has served on numerous advisory boards, editorial boards and is currently a member of the SAB of Sirtris Pharmaceuticals

“Genzyme Corporation’s initiatives in neglected diseases drug discovery and development”

There is a great need for new medicines to treat the millions of people who suffer from the “neglected diseases” of the world. The pharmaceutical and biotechnology industry possesses a unique skills set that is urgently needed to advance medicines through the pipeline and to the patients. However, commercial challenges have limited the ability of companies to effectively apply their resources to this area. Genzyme has recently initiated the Humanitarian Assistance for Neglected Diseases (HAND) program to contribute to advancement of therapies for treating neglected diseases. The initiative is the vehicle through which Genzyme will identify, manage, and execute programs in this area. Through this program we intend to commit part of our drug development capabilities to neglected
diseases. We will seek no profit for these efforts and will out license relevant intellectual property through third parties. Our intent is to focus our efforts on those areas in which we have a specific expertise and to work with partners in industry, academics and public-private partnerships to develop drugs. We have formed early collaborations with the Broad Institute of Harvard and MIT and with the Medicines for Malaria Venture for discovering new drugs for treating malaria. In addition we have initiated a collaboration with the Drugs for Neglected Diseases Institute for discovering new therapies for treating Human African Trypanosomiasis.

Genzyme has developed an expertise and compounds that target key metabolic pathways in parasites and our initial efforts will involve exploiting those pathways to identify new therapies. These pathways include iron metabolism, polyamine metabolism, and glycolipid metabolism. The presentation will describe the HAND program and provide a background and rationale for our approaches.

En Li, Ph.D
Vice President and Global Head of Models of Disease Center, Novartis Institutes for BioMedical research

Dr. Li is Vice President and Global Head of Models of Disease Center at the Novartis Institutes for BioMedical Research. He also serves as Head of the Epigenetics Program. Prior to joining Novartis in 2003, he was an Associate Professor of Medicine of Harvard Medical School and Massachusetts General Hospital. He received his Bachelor of Science degree in biochemistry from Beijing University in 1984 and his Ph.D. degree in biology from MIT in 1992. Dr. Li is a well established biologist in the field of epigenetics and developmental biology. His laboratory discovered a family of DNA cytosine methyltransferases that establish DNA methylation patterns in the mammalian genome. His main research interests include chromatin regulation, stem cell biology, and TGF-/BMP signaling in mammalian development and disease.

“Innovative Drug Discovery in China: Mission possible?”

Many multinational pharmaceutical companies are setting up R&D centers in China to take advantage of the local talent pool, vast patient population, and significantly lower costs for R&D, and they appreciate the difficulty and risk of doing innovative drug discovery in China. What has not been extensively explored is how MNCs can work with Chinese government, academic institutions, and biotech companies to create a unique environment for innovation and collaboration on drug discovery and development, and how Chinese scientists trained in US may benefit from the opportunities and contribute to the growth and development of the drug industry in China.
**Mark T. Goulet, Ph.D**  
*Executive Director, Drug Design and Optimization, Merck Research Laboratories-Boston*

Dr. Goulet, Executive Director of Chemistry at Merck Research Laboratories in Boston, Massachusetts, received a B.S. degree in Chemistry from the University of Michigan and a Ph.D. in Chemistry from Yale University. He joined Merck at the Rahway, New Jersey, site in 1987 and in 2004 moved to Boston to become Head of Chemistry at the opening of this new research facility. During his career, Dr. Goulet has headed medicinal chemistry teams working to develop new therapies for organ transplant rejection, endometriosis, obesity and atherosclerosis. Current interests include the discovery of breakthrough medicines for the treatment of cancer and Alzheimer’s disease.

“**Building a 21st Century Research Laboratory**”

In August 2004 Merck Research Laboratories opened its newest research facility in Boston, Massachusetts. Research at MRL-Boston is directed toward the discovery of new therapies for Cancer and Alzheimer’s disease. This drug discovery laboratory was designed to incorporate processes for increased efficiency and sited to take advantage of proximity for forging strong relations with academic and biotech collaborators. Aspects of drug discovery within the new MRL-Boston laboratory will be discussed.

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**Bing Yu, Ph.D**  
*COO, AstaTech, Inc.*

Dr. Yu received a MS (1985) and a Ph.D (1987) in Chemical Engineering from East China University of Science and Technology (ECUST). He attended MBA training from 1995 to 1997 at Wharton Business School, University of Pennsylvania.

His work experience includes:

- Post-doc, Chemistry Dept., Clarkson University, 1987 to 1991, New York;
- 1991 to 2002, Rohm and Haas Company, the increasing responsibility from Sr. scientist, R&D group leader, product manager, quality manager for Asia Pacific region, Six Sigma project leader;
- 2004 to March, 2006, a NJ based pharmaceutical technology company, Director of Global Operations;
- 4/2006 to now, AstaTech, Inc., COO

“**A Case Study about Doing Business in China**”
Dr. Bing Yu had been the Director of Global Operations at Chiral Quest, Inc. since 2004 and has become the COO at AstaTech, Inc. since April 2006. Both companies have major business operations in China and marketing in the USA and over the world. He shares his experiences of doing business in China.

Ajaz Hussain, Ph.D  
*Vice President & Global Head of Biopharmaceutical Development, Sandoz*

Dr. Ajaz S. Hussain currently serves as a Vice President and Global Head for Biopharmaceuticals Development at Sandoz, a Novartis Company. Prior to this appointment he served as the Deputy Director, Office of Pharmaceutical Science, CDER, FDA. He championed FDA’s PAT, CGMP’s for the 21st Century and the Critical Path Initiatives. In 2005 the FDA’s PAT Team he led received the Pharmaceutical Manufacturing Magazine’s - 2005 Pharmaceutical Manufacturing Team of the Year Award, the FDA and the CDER Scientific Achievement Award for the year 2005. He currently serves as Adjunct Professor at the Universities of Purdue (Pharmacy) and Michigan (Pharmaceutical Engineering) and is a Visiting Professor at the University of Basel. He is a Fellow of the American Association of Pharmaceutical Scientists and the Swiss Society for Pharmaceutical Sciences. He is also the recipient of the Robert D'Solvo Distinguished Alumni Award from the University of Cincinnati and numerous FDA awards including Outstanding Service and Excellence in Review Sciences.

“The Evolving Omnitrope Story and Adam Smith’s ‘Invisible Hand’ Concept”

Using the Omnitrope story as background for the discussion of FOPP, which is a new chapter for the Biotech industry that increase competition. Companies will need to be prepared to work competitively and productively for individual (company) gain and cooperatively for the overall good of society.

SAPA-NE 2005 Outstanding Contribution Award

Bingli Ma  
Junjun Wu  
Weijun Ma

Qing Huang  
Liqiang Tou  
Bin Zhang

Ming Dong  
Jun Han
The Novartis Institutes for BioMedical Research (NIBR) is Novartis’ global research organization. Headquartered in Cambridge, Massachusetts, USA, and with research facilities around the world, its mission is to develop innovative medicines for patients worldwide. Scientists at Novartis Institutes are blazing a new path in drug discovery by integrating various scientific disciplines, fostering interaction among scientists from within and outside of Novartis, and developing partnerships with academic research institutions and biotechnology companies to move beyond the traditional boundaries of translational research. Research at Novartis Institutes begins and ends with the patient. Recent scientific advances, such as the sequencing of the human and other genomes, have catalyzed a unique opportunity for discovering drugs that can address the underlying causes of disease. Novartis Institutes is capitalizing on such advances by positioning itself at the intersection of genomics and medicine. Novartis’ key attributes include scientifically focusing on medicines to address the basic molecular mechanisms underlying disease, organizationally pursuing a comprehensive, multi-disciplinary structure built around human genetics, model systems, imaging technologies, and chemical diversity, and culturally building activities on extensive and deep collaborations with scientific innovators in academic organizations and biotechnology companies. Novartis Institutes currently has areas of concentration in; cardiovascular disease; dermatology/immunopathology; diabetes and metabolism; genetic therapy; infectious diseases; nervous system disorders; oncology; musculoskeletal; respiratory diseases; and transplantation. Research at Novartis Institutes is truly a worldwide endeavor, with research facilities located in the following locations: Basel, Switzerland; Horsham and London, UK; Vienna, Austria; Tsukuba, Japan; East Hanover, NJ; Novartis Institutes Headquarters, Cambridge, MA, USA.
Platinum Sponsor: Eisai Research Institute, Inc.

Eisai Research Institute, Inc. (http://www.eisai.com) is a global human health care corporation striving for innovative solutions in the prevention, cure, and care for the health and well-being of people worldwide. In the past few years, Eisai has supported SAPA-NE activities both financially and through its employees. This year, Eisai is the lead corporate sponsor for the last two SAPA-NE annual conferences. Eisai’s support has made SAPA-NE to be a strong organization in promoting pharmaceutical science and technology, and has built an excellent example for Eisai to be a leading global company to improve human healthcare.

Gold Sponsor: ArQule, Inc.

ArQule, Inc. is a biotechnology company engaged in research and development of next-generation small-molecule cancer therapeutics based on its innovative Activated Checkpoint TherapySM (ACTSM) platform. ACTSM compounds are intended to improve the way cancer patients are treated because they selectively kill cancer cells and spare normal cells by restoring and activating cellular checkpoints that are defective in cancer. In addition to advancing its own programs, ArQule continues to advance the drug discovery efforts of pharmaceutical collaborators by providing high-quality library design and high throughput synthesis to enhance and accelerate lead generation and optimization using its proprietary Automated Molecular Assembly Plant (AMAP™) technology platform. ArQule has active collaborations with Pfizer, Novartis, and Sankyo.

Gold Sponsor: Wyeth Biotech

Wyeth Biotech is dedicated to the successful development and manufacturing of recombinant protein biopharmaceuticals. Biopharmaceutical drugs are a rapidly growing segment of Wyeth's business. As a result of the success of several innovative products such as Enbrel® (etanercept), RefActo® Antihemophilic Factor (Recombinant) and BeneFix® Coagulation Factor IX (Recombinant), Wyeth is positioned at the forefront of the biopharmaceutical revolution that is transforming disease treatment around the world.

For the past six years, Wyeth has been supporting SAPA-NE activities both financially and through its employees. Wyeth executives, scientists and attorneys have addressed several SAPA-NE symposia and conferences. This year, Wyeth is the silver corporate sponsor. All of these actions demonstrate the company’s leadership, quality, integrity, respect for people, and spirit of collaboration. In summary, Wyeth’s support to SAPA-NE is an excellent example of its contribution to our community and society.
Gold Sponsor: Blue Sky Biotech Inc.

Blue Sky Biotech Inc. is a Contract Research Organization (CRO) located in Worcester, MA. The Company offers large pharma/biotech research services in the “Gene to Protein” space. Three laboratories are linked in Blue Sky’s service pipeline: Molecular Biology, Tissue Culture/Fermentation, and Protein Sciences. Blue Sky’s Management Team has over 50 yrs of experience in the industry, and delivers true pharma-grade expertise and assistance. Some popular services we provide are: Gene Synthesis, *In Vitro* Transcription, Vector Construction, Bacterial Fermentation, Baculoviral _Expression, Mammalian _Expression, Yeast _Expression, and Protein Purification. Blue Sky has developed a novel baculoviral system (IKM™) that allows for fast turnaround of “high-titer” viral amplification and remarkably consistent protein _expression_. Blue Sky scientists have purified over 600 proteins, and frequently engage in research-scale method (process) development projects. Blue Sky is New England’s Drug Discovery “Lab Down the Hall”

Merck & Co., Inc. is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck discovers, develops, manufactures and markets vaccines and medicines in over 20 therapeutic categories. The company also devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them. Merck also publishes unbiased health information as a not-for-profit service. For more information, visit [www.merck.com](http://www.merck.com).
Silver Sponsor: Abbott Bioresearch Center (ABC)

Abbott Bioresearch Center (ABC) is the Worcester-based biotechnology drug discovery and biologics manufacturing unit of Abbott Laboratories, one of the world's leading health care companies. The 440,000-sq. ft. facility is located 35 miles west of Boston on a 30-acre landscaped site, and houses 685 employees. ABC is part of Abbott Laboratories Global Pharmaceutical Research and Development (GPRD).

ABC combines the innovation spirit of biotechnology with the stability of a big pharmaceutical company. Between ABS and Abbott park we have some of the best scientists in the country who are working with cutting-edge technologies. Specific to ABC there is a focus on monoclonal antibodies and small molecules, both of which promise to deliver high quality compounds for critical therapeutic areas.

Silver Sponsor: Ariad Pharmaceuticals, Inc.

ARIAD is engaged in the discovery and development of breakthrough medicines to treat cancer by regulating cell signaling with small molecules. The Company is developing a comprehensive approach to patients with cancer that addresses the greatest medical need – aggressive and advanced-stage cancers for which current treatments are inadequate. ARIAD also has an exclusive license to pioneering technology and patents related to certain NF-κB treatment methods, and the discovery and development of drugs to regulate NF-κB cell-signaling activity, which may be useful in treating certain diseases. Additional information about ARIAD can be found on the web at http://www.ariad.com.
Silver Sponsor: Pfizer

Pfizer Inc discovers, develops, manufactures, and markets leading prescription medicines for humans and animals and many of the world's best-known consumer brands. Our innovative, value-added products improve the quality of life of people around the world and help them enjoy longer, healthier, and more productive lives. The company has three business segments: health care, animal health and consumer health care. Our products are available in more than 150 countries.

Silver Sponsor: WuXi PharmaTech

WuXi PharmaTech Shanghai-based WuXi PharmaTech Co., Ltd. offers global pharmaceutical/bio-pharmaceutical companies diverse outsourcing services in combinatorial, medicinal, synthetic chemistry and manufacturing. Importantly, it also allows them to take full advantage of the lower research costs in China. WuXi PharmaTech's rapidly expanding line of services ranges from early stage discovery chemistry through lead optimization chemistry, all the way to process research & development and bulk manufacture of active pharmaceutical ingredients. With the addition of a new GMP plant at Jinshan in Shanghai, WuXi PharmaTech has further increased its bulk production capacity to meet rapidly growing customer demand. WuXi PharmaTech's strong capabilities and impressive track record enable the company to provide a broad spectrum of integrated development services from milligram to metric ton scaled active pharmaceutical ingredients, intermediates and raw materials. Currently, WuXi PharmaTech's client list includes over 60 leading drug discovery companies covering a majority of the world's largest pharmaceutical companies.
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Sino-American Pharmaceutical Professionals Association - New England (SAPA-NE)