Keynote Presentations

Robert S. Langer, Sc.D.
MIT

Homer L. Pearce, Ph.D.
Eli Lilly

Saghir Akhtar, Ph.D.
Cardiff University

Errol De Souza, Ph.D.
Archemix

Barry Eisenstein, M.D.
Cubist

Larry Gold, Ph.D.
SomaLogic

Steven C. Quay, M.D., Ph.D.
Nastech

The Only Industry Event for Manufacturing and Development of Oligonucleotide and Peptide Products

May 1-5, 2005 • Boston Convention & Exhibition Center • Boston, MA

Big Pharma's Perspective on the Future of Oligo-Based Therapeutics

Novel Technologies and Commercialization Strategies for Therapeutics, Diagnostics, and Research

Supply Chain: Minimizing Risk and Improving Economics

Updates on Leading Clinical and Preclinical Candidates from Eyetech, Cubist, Human Genome Sciences, Coley Pharmaceuticals and Corgentech – and more

Featured Presentation:

Products, Sources, and Sites: An FDA Perspective

Blair A. Fraser, Ph.D., Deputy Director, Division of New Drug Chemistry 2, Office of New Drug Chemistry, Office of Pharmaceutical Sciences, CDER, US FDA

TEAM DISCOUNT

Attend for FREE when 2 of your colleagues register
See p. 15 for details
This year more than ever, if you work in oligonucleotide- or peptide-based therapeutics, you need to get the behind-the-scenes scoop on what’s happening right now in the industry – and what will happen next.

TIDES® 2005 showcases the enormous pipeline potential of both categories, as well as recent successes, current challenges and potential solutions. It also provides proven tactics on how to serve the needs of the multi-billion dollar diagnostics industry.

You will gain critical insights through:

- An update from the FDA on raw materials, development, scale-up, and technology transfer
- A CMC tutorial session on how to avoid pitfalls
- Best practices for Process and analytical methods validation
- The latest technology breakthroughs in solid supports for synthesis of therapeutics, synthesis optimization of spiegelmers, and manufacturing oligos for DNA probe-based diagnostics
- A small interactive group discussion on how to define starting materials

Merck and Nastech Pharmaceuticals just signed a deal worth over $300 million for the rights to a nasal spray peptide drug for obesity. Hear the success story from the CEO of Nastech. Peptide drugs of the future may be enhanced by the technology that led Human Genome Sciences to a nearly $200 million-dollar deal with GSK. Learn about the albumin fusion protein technology that made the deal possible from an HGS scientist.

Discover the latest in formulation and delivery advances in an expanded, full-day session with world-renowned keynote speaker and winner of the Lemelson-MIT prize for being “one of the most prolific inventors in medicine,” Professor Robert S. Langer of MIT. In addition, get an enlightened look at the delivery challenges for most classes of nucleic acid-based therapeutics from Professor Saghir Akhtar of Cardiff University, and learn substantial new information on solving the challenge of siRNA delivery from Dr. Nassim Usman of Sirna Therapeutics.

### Network with Your Colleagues!

At TIDES® 2005 we’ve organized a number of unique interactive experiences to help you connect with the presenters and attendees!

- **NEW structured matchmaking event** – prior to the conference, identify other attendees you’d like to meet and we’ll arrange meetings for you! See page 8.
- Join colleagues and industry experts for intimate roundtable luncheon discussions on critical industry topics. See page 9.
- Speak with leading industry experts during our “Ask the Experts” luncheon. Ask your specific technical questions. See page 10.
- Relax between sessions and share your thoughts with colleagues during the numerous refreshment breaks and luncheons.
- Enjoy wine, beer and hors d’oeuvres during our evening receptions on Monday and Tuesday.
- Visit your business associates and connect with new ones in the Exhibit Hall. See page 15 for a complete list of exhibitors.
- Get your ticket to the Wine Festival networking event on Wednesday night. See page 11 for registration details.

TIDES® 2005 is a “can’t miss” program – register today to ensure your space!
## Conference-at-a-Glance

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<th>Registration Hours:</th>
<th>Sunday, May 1</th>
<th>Monday, May 2</th>
<th>Tuesday, May 3</th>
<th>Wednesday, May 4</th>
<th>Thursday, May 5</th>
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<td>1:00 pm to 5:00 pm</td>
<td>7:30 am to 7:00 pm</td>
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<td>7:30 am to 5:45 pm</td>
<td>8:00 am to 12:15 pm</td>
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### Sunday, May 1, 2005

**Afternoon Concurrent Symposia**
- Chemistry, Manufacturing, and Controls (CMC) Tutorial
- Production and Analysis of Oligos for Diagnostics, Chips and Arrays

### Monday, May 2, 2005

**Morning**
- Technologies for Preclinical Development of Oligonucleotides
- Technologies for Preclinical Development of Peptides

**Afternoon**
- Updates on Oligonucleotide-Based Products in Development
- Updates on Peptide-Based Products in Development

Opening Reception in Exhibit Hall sponsored by NeoMPS

### Tuesday, May 3, 2005

**Morning**
- Networking Match-Making Session
- Emerging Technologies with Technology Workshops
- Overcoming Supply Chain Challenges
- Starting Materials

**Afternoon**
- Economics and Critical Challenges of TIDES Manufacturing
- Lunch, Roundtable Discussions and Poster/Exhibit Viewing

### Wednesday, May 4, 2005

**Full Day on Formulation & Delivery**
- Strategies to Improve Delivery of Existing Drugs
  - Lunch: Ask the Experts and Final Poster and Exhibit Viewing
- Strategies to Modify Drugs for Improved Delivery via PEGylation and Conjugates
  - Optional Special Event: Wine Tasting at Vinalia

### Thursday, May 5, 2005

**Morning**
- Process and Analytical Methods Validation

## Media Partners

Visit www.IBCLifeSciences.com/TIDES for up-to-date information on this event & to register online.
Distinguished Faculty

Adam C. Bell, Ph.D., Senior Scientist II, Lead Product Development, Human Genome Sciences

Michael D. Bentley, Ph.D., Vice President, Research, Nektar Therapeutics

J. D. Bernardy, J.D., Vice President, Regulatory Affairs, Quality Assurance & Clinical Operations, Aeris Therapeutics, Inc.

Daniel Bourgin, Ph.D., Associate Director, New Business Development, Lonza AG, Switzerland

Jean-Paul Castaigne, M.D., Chief Operating Officer and Chief Science Officer, Conjunchem Inc.

Wayman Wendell Cheatham, M.D., FACE, Corporate VP and Chief Medical Officer, MannKind Corporation

Seppe De Gelas, M.Sc., Regulatory Affairs and Quality Assurance Manager, UCB-Bioproducts, UCB S.A., Belgium

Karen Fleshman, Ph.D., Senior Director, Regulatory Affairs, CMC, EyeTech Pharmaceuticals, Inc.

Blair A. Fraser, Ph.D., Deputy Director, Division of New Drug Chemistry 2, Office of New Drug Chemistry, Office of Pharmaceutical Sciences, CDER, US FDA

Glen Paul Freiberg, Vice President, Regulatory, Quality and Government Affairs, Gen-Probe Incorporated

Angelika Fretzen, MBA, Ph.D., Director of Chemical Development, Microbia, Inc.

Patrick Giljum, Head of Operations, BioTechLogic, Inc.

Juan B. Gonzalez, Director of Validation, Aveca Biotechnology, Inc.

Lars Holmberg, Ph.D., Director, GE Healthcare, Sweden

Christopher P. Holmes, Ph.D., Senior Director, Chemistry, Affymax, Inc.

Gerd Hummel, Ph.D, Director, Medicinal Chemistry, Jerini AG, Germany

Professor Ian Jones, Professor of Virology, School of Animal and Microbial Sciences, University of Reading, United Kingdom

Krishna Kallury, Ph.D., Senior Research Scientist, Phenomex

Melissa A. Kelly, Vice President, Oncology, Geron Corporation

Kurt Kessler, Ph.D., Scientific Project Director, Sanofi-Aventis, Germany (invited)

Arthur M. Krieg, M.D., Chief Scientific Officer, Coley Pharmaceuticals

Michael Killeen, Regional Manager, Purification, Pall Life Sciences

Markus Kurz, Ph.D., Associate Director, Chemistry, Archemix Corp.

Marsha L. Langhorst, Senior Analytical Specialist, The Dow Chemical Co.

Thomas W. Leonard, Ph.D., R.Ph., Vice President and Chief Scientific Officer, Merrion Pharmaceuticals, Inc.

Joakim Lundeborg, Ph.D., Professor, Alba Nova University Center, Department of Biotechnology, Royal Institute of Technology, Sweden

James F. Majewski, Director of Quality Assurance, Praceis Pharmaceuticals Incorporated

Leslie M. McEvoy, Ph.D., Vice President, Research and Development, Corgentech, Inc.

Michael J. McLean, Ph.D., President, Aveca Biotechnology, Inc.

Rachel Meyers, Ph.D., Associate Director of Research, Alnylam Pharmaceuticals

Dov Michaeli, M.D., Ph.D., Senior Vice President, Chief Medical Officer, Apthon Corporation

Roger Micheli, Ph.D., Head, Analytical Research and Regulatory Affairs, Roche Colorado Corporation

Robert J. Miller, Ph.D., Senior Director, Biomaterials Science & Engineering, Genzyme Corporation

Brett P. Monia, Ph.D., Vice President, Antisense Drug Discovery, Isis Pharmaceuticals, Inc.

Paul Morley, Ph.D., Chief Scientific Officer, Zelos Therapeutics Inc.

Birgitta Mörnstam, M.Sc., Manager, Qualification & Validation Europe, PolyPeptide Laboratories AB, Sweden

Gary F. Musso, Ph.D., Vice President, Development, Praceis Pharmaceuticals Incorporated

Steven J. Prestrelski, Ph.D., Executive Director, Product Development, Amylin Pharmaceuticals, Inc.

Anthony N. Scozzari, Vice President, Drug Substance Manufacturing and Process Chemistry, Isis Pharmaceuticals, Inc.

David T. Shima, Ph.D., Vice President, Research & Strategic Development, Eyetech Pharmaceuticals, Inc.; Director, Eyetech Research Center

James R. Thayer Ph.D., Staff Research Biochemist, Dionex Corporation

Stephen F. Tuck, Ph.D., Vice President, Biopharmaceutical Development, Dynavax Technologies

Nassim Usman, Ph.D., Senior Vice President and Chief Operating Officer, Sirna Therapeutics, Inc.

Michael Verlander, D. Phil., Executive Vice President, PolyPeptide Laboratories, Inc.

Stefan Vonhoff, Ph.D., Production Manager, NOXXON Pharma AG, Germany

William G. Weisburg, Ph.D., Executive Director, Infectious Disease Diagnostics, Nanogen, Inc.

Fran Wincott, Ph.D., Vice President, Oligonucleotide Manufacturing and Development, Eyetech Pharmaceuticals, Inc.

Dr. Andreas Wolter, Managing Director, PolyLog Biochemie GmbH Hamburg, Germany

Sunday, May 1, 2005

1:00 Registration for TIDES® Begins

Choose from Two Concurrent Afternoon Symposia

### Symposium #1:

**Chemistry, Manufacturing, and Controls (CMC) Tutorial**

2:00  Chairperson’s Remarks  
Gary F. Musso, Ph.D., Vice President, Development, Praecis Pharmaceuticals Incorporated

2:15  Taking a Lead to an IND: Do’s and Don’ts  
The elements of the CMC dossier are addressed relative to the guidance documents promulgated by the FDA, with specific emphasis on the oligonucleotide- and peptide-based NCE’s. Aspects of both the drug substance (API) and drug product sections are discussed.  
Gary F. Musso, Ph.D., Vice President, Development, Praecis Pharmaceuticals Incorporated

2:45  Update on European Registration Procedures  
In Europe there are two types of marketing authorizations and several regulatory procedures to obtain these licenses: Centralized procedure, Decentralized procedure, Mutual recognition procedure and National procedure. The presentation illustrates the advantages and disadvantages of each system with examples.  
Seppe De Gelas, M. Sc., Regulatory Affairs and Quality Assurance Manager, UCB-Bioproducts, UCB S.A., Belgium

3:15  Networking Refreshment Break

3:45  From IND to NDA: The Challenges of Meeting CMC Requirements for Peptides  
The development of peptide APIs presents some unique challenges, not only because of the complexity of peptide molecules in general, but also because peptides are specifically excluded from virtually every guidance document. A “common sense” approach, based on interpretation of existing guidance documents and experience with US and European regulatory agencies, will be presented in a “what to do and when” format.  
Michael Verlander, D. Phil., Executive Vice President, PolyPeptide Laboratories, Inc.

4:15  How to Use the Common Technical Document (CTD) Format for Regulatory Submissions  
Requests to conduct clinical trials (IND’s & CTA’s) and market products (NDA’s/BLA’s & MAA’s) all require CMC/quality information. The ICH process has largely harmonized the information required for marketing applications. Independent FDA and European (Clinical Trial Directive) initiatives permit building marketing authorizations from similarly structured clinical trial applications, permitting efficiencies throughout the development process.  
J. D. Bernardy, J.D., Vice President, Regulatory Affairs, Quality Assurance & Clinical Operations, Aeris Therapeutics, Inc.

4:45  Pre-Approval Inspections (PAI’s)  
This tutorial addresses the PAI process covering United States and European Union Pre-Approval and Post-Approval Regulatory Inspections. Reference CMC Source Documents (NDA/CTD), cGMP’s, guidelines, compliance programs and associated regulations are addressed and related to the PAI process. Mock audits, their relevance when conducted by Independent Experts, are discussed and suggested as the “Evaluation Model.”  
James F. Majewski, Director of Quality Assurance, Praecis Pharmaceuticals Incorporated

5:15  Close of Symposium

### Symposium #2:

**Production and Analysis of Oligos for Diagnostics, Chips and Arrays**

2:00  Chairperson’s Remarks  
James Russell, Ph.D., Senior Manager of Process and Analytical Chemistry Research, Gen-Probe Incorporated

2:15  Novel Strategies for the High-Throughput Purification of Synthetic Oligonucleotides  
A new technology addresses the need for an alternative to the HPLC-based purification of synthetic oligonucleotides. The cartridge-based protocol, applicable to one micromole or higher level of synthesis, caters to a high-throughput environment without sacrificing yield and purity. This novel methodology consists of a unique sorbent that would retain 5’-tritylated oligonucleotides strongly, while enabling the removal of untritylated failure sequences.  
Krishna Kallury, Ph.D., Senior Research Scientist, Phenomenex

2:45  Improving Options for Chromatographic Oligonucleotide Purity Analysis  
Multiple approaches are used to determine API yields and identify contaminants during therapeutic oligonucleotide (ON) development. Chromatography with the DNA Pac PA100 satisfied these requirements for over a decade and is now enhanced with the new DNA Pac PA200. These columns support tailored ON resolution with enhanced peak shape, selectivity, and sample throughput in research, development, and quality assessment environments.  
James R. Thayer Ph.D., Staff Research Biochemist, Dionex Corporation

3:15  Networking Refreshment Break

Today’s DNA probes, with far from 100% full length content, compromise the reliability of microarray data quality, adversely affecting the performance of synthetic DNA microarrays. Methods to achieve higher signal intensity and linearity for synthetic targets, using purified probes produced with novel techniques for spotted and in situ synthesized DNA microarrays, are presented.  
Joakim Lundeberg, Ph.D., Professor, Alba Nova University Center, Department of Biotechnology, Royal Institute of Technology, Sweden

4:15  Advantages and Challenges of Outsourcing Case Study Diagnostic Oligos from Vendors  
Oligonucleotide quality is fundamental in DNA probe-based diagnostics. Outsourcing is a business, technical, and regulatory strategy. Shared expectations on yield, analytical methods, specifications, logistics, and communication are crucial. Harmonization of purity methods is usually the source of greatest controversy. Experiences gained through several projects with various anonymous vendors will be examined.  
William G. Weisburg, Ph.D., Executive Director, Infectious Disease Diagnostics, Nanogen, Inc.

4:45  Close of Symposium

Visit www.IBCLifeSciences.com/TIDES for up-to-date information on this event & to register online
# Monday, May 2, 2005 • Main Conference

## 7:30 Registration, Coffee, Tea, and Pastries

<table>
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<tr>
<th>Track One</th>
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<tr>
<td><strong>Technologies for Preclinical Development of Oligonucleotides</strong></td>
<td><strong>Technologies for Preclinical Development of Peptides</strong></td>
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<td><strong>8:30 Chairperson’s Remarks</strong></td>
<td><strong>8:30 Chairperson’s Remarks</strong></td>
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<td>David Epstein, Ph.D., Vice President, Biology, Archemix Corp.</td>
<td>Christopher P. Holmes, Ph.D., Senior Director, Chemistry, Affymax, Inc.</td>
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<td><strong>8:45 Oligonucleotide Therapeutics and Diagnostics: Into the Home Stretch</strong></td>
<td><strong>8:45 Oligonucleotide Therapeutics and Diagnostics: Into the Home Stretch</strong></td>
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<td>Biotech and pharmaceutical companies have solved many of the problems associated with oligonucleotides as drugs, in vivo imaging agents, and in vitro diagnostics. Specific oligonucleotide therapeutics (approved or abandoned) will be used as &quot;case studies&quot; to see if the next decade can be even more successful. Oligonucleotide drugs, with great target specificities, affinities, and low toxicities, can be favorably compared with orally active drugs.</td>
<td>Larry Gold, Ph.D., CEO and Chairman of the Board, SomaLogic, Inc.</td>
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<td><strong>9:15 Advances in Preclinical Development of siRNA Therapeutics</strong></td>
<td><strong>9:15 Advances in Preclinical Development of siRNA Therapeutics</strong></td>
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<td>RNA interference (RNAi) holds significant promise as a therapeutic approach to silence disease-causing genes, particularly those that encode &quot;non-druggable&quot; targets. The key hurdle for RNAi therapeutics is in vivo delivery. A critical requirement for achieving systemic RNAi in vivo is the introduction of &quot;drug-like&quot; properties, such as stability, cellular delivery and tissue bioavailability, into synthetic siRNAs. Our progress in achieving in vivo silencing of endogenous genes with modified siRNAs will be discussed.</td>
<td>Rachel Meyers, Ph.D., Associate Director of Research, Alnylam Pharmaceuticals</td>
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<td><strong>10:00 Networking Refreshment Break</strong></td>
<td><strong>10:00 Networking Refreshment Break</strong></td>
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<td><strong>10:30 Therapeutic Application of RnaseH-Based Antisense Technology for the Treatment of Chronic Diseases</strong></td>
<td><strong>10:30 Advancing the Promise of Peptide Therapeutics through Stable Fusion with Human Serum Albumin</strong></td>
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<td>RNaseH-based antisense drugs have recently entered clinical trials for the treatment of diabetes and hypercholesterolemia. Preclinical and clinical results are presented that demonstrate the utility and efficiency of this technology for novel drug discovery for the treatment of type 2 diabetes and dyslipidemia.</td>
<td>The effective use of peptides and proteins as therapeutics is limited by their relatively short half-lives. Genetic fusion with human serum albumin enables large-scale manufacture of fully active fusion proteins from yeast and mammalian cells. The long half-lives of these proteins allows for enhanced therapeutic potential with less frequent administration.</td>
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<tr>
<td>Brett P. Monia, Ph.D., Vice President, Antisense Drug Discovery, Isis Pharmaceuticals, Inc.</td>
<td>Adam C. Bell, Ph.D., Senior Scientist II, Lead Product Development, Human Genome Sciences</td>
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<td><strong>11:00 ISS-Based Products for Treatment and Prevention of Allergies and Infectious Disease</strong></td>
<td><strong>11:00 Update on AVE0010 / ZP10: A Glucagon-Like Peptide 1 Analog for Type 2 Diabetes</strong></td>
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<td>Dynavax’s Synthetic Immunostimulatory DNA Sequences (ISS) enhance the ability of the immune system to fight disease and prevent inflammation. This presentation provides a clinical and manufacturing update. The phase II/III products are an ISS-linked ragweed allergen (AIC) which has provided positive results in clinical trials for the treatment of ragweed allergy, and a next-generation ISS-based hepatitis B vaccine which has recently shown positive interim results.</td>
<td>Please visit <a href="http://www.IBCLifeSciences.com/TIDES">www.IBCLifeSciences.com/TIDES</a> for program updates.</td>
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<tr>
<td>Stephen F. Tuck, Ph.D., Vice President, Biopharmaceutical Development, Dynavax Technologies</td>
<td>Kurt Kesseler, Ph.D., Scientific Project Direction, Sanofi-Aventis, Germany (invited)</td>
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<tr>
<td><strong>11:30 Regulatory Planning for Oligo Scientists</strong></td>
<td><strong>11:30 Ostabolin-C: A Novel PTH Analogue for the Treatment of Postmenopausal Osteoporosis and Psoriasis</strong></td>
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<td>To accelerate products to clinical evaluations and approvals, scientists in oligo development should consider how to align their developments with the transfer process. Topics to be considered include the regulators’ approaches to stability and purity and how industry may or may not set specifications. Approaching FDA guidance from the perspective of the Regulatory Affairs department will also be discussed.</td>
<td>Zelos’s modifications to PTH based on an understanding of PTH signaling led to the cyclized 31-amino acid peptide called Ostabolin-C™. Ostabolin-C™ is a potent stimulator of bone formation, but unlike other PTHs does not stimulate bone resorption and hypercalcemia. Zelos will initiate a phase II trial in osteoporosis (SC injection) and a phase I trial for the topical treatment of psoriasis in early 2005.</td>
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<td>Glen Paul Freiberg, Vice President, Regulatory, Quality and Government Affairs, Gen-Probe Incorporated</td>
<td>Paul Morley, Ph.D., Chief Technical Officer, Zelos Therapeutics Inc.</td>
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<td><strong>12:00 Lunch on your own</strong></td>
<td><strong>12:00 Lunch on your own</strong></td>
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To Register, Tel: (508) 616-5550 • Fax: (508) 616-5522 • E-mail: reg@ibcusa.com
Monday, May 2, 2005

**Track One**

**Updates on Oligonucleotide-Based Products in Development**

1:45 Chairperson’s Remarks  
Eugen Uhlmann, Ph.D., Vice President, Chemical Development, Coley Pharmaceutical GmbH, Germany

2:00 Macugen™ and the Treatment of Ocular Neovascular Disease  
Neovascular diseases collectively represent the major causes of blindness in the developed world. Age-related macular degeneration and diabetic retinopathy are both characterized by periods of abnormal, destructive vessel growth and vessel leakage that impair the normal visual process, and if untreated can lead to blindness. Eyetech’s current development strategy, focusing on a highly specific aptamer-based blockade of VEGF signaling, will be discussed.

David T. Shima, Ph.D., Vice President, Research & Strategic Development, Eyetech Pharmaceuticals, Inc.; Director, Eyetech Research Center

2:30 Therapeutic Activities of CpG ODN in Metastatic Cancer  
CpG dinucleotides in phosphorothioate ODN can engage the Toll-like receptor (TLR)9, thereby stimulating innate and adaptive immunity. More than 700 human subjects have been injected with CpG 7909 in various clinical trials, including a randomized controlled phase II clinical trial for lung cancer where the CpG treatment has improved response rates when combined with standard chemotherapy.

Arthur M. Krieg, M.D., Chief Scientific Officer, Coley Pharmaceuticals

3:00 NF-kappaB Oligonucleotide Decoy for Treatment of Eczema: Preclinical Efficacy and Clinical Trial Overview  
Corgentech’s NF-kappaB Transcription Factor Decoy, a highly selective and potent oligonucleotide-based inhibitor of immune and inflammatory responses, has shown efficacy in models of eczema, IBD, arthritis, and cancer. Preclinical, pharmacology and toxicology data, as well as an overview of the phase I/I clinical trial in eczema, will be presented.

Leslie M. McEvoy, Ph.D., Vice President, Research and Development, Corgentech, Inc.

3:30 Networking Refreshment Break

**Track Two**

**Updates on Peptide-Based Products in Development**

1:45 Chairperson’s Remarks  
Alain Scaro, Ph.D., Director, UCB-Bioproducts Division, UCB S.A., Belgium

2:00 Chemical Synthesis and Characterization of MD-1100: A Novel Oral Peptide Therapeutic for the Treatment of Gastrointestinal Disorders  
We are developing MD-1100 as a therapeutic agent for the treatment of constipation-predominant irritable bowel syndrome (c-IBS) and additional gastrointestinal (GI) disorders. MD-1100 is a 14 amino acid peptide with 3-disulfide bonds that acts on the lumen of the intestine to stimulate intestinal fluid secretion and transit and lowers the perception of intestinal pain. Analytical characterization of MD-1100 was accomplished utilizing LC/MS/MS and NMR.

Angelika Fretzen, MBA, Ph.D., Director of Chemical Development, Microbiia, Inc.

2:30 Development of an Immunogen for a Therapeutic Vaccine (INSEGIA™) to Treat Gastrointestinal Cancers  
INSEGIA is designed to elicit antibodies against the amino-terminal end of gastrin-17 (G17) and glycine-extended gastrin-17 (Gly-G17). It has been formulated in an emulsion suitable for intramuscular injection. Results from phase II clinical trials in colorectal, gastric, and pancreatic cancers, as well as phase III trials in pancreatic cancer are addressed in this presentation.

Dov Michaeli, M.D., Ph.D., Senior Vice President, Chief Medical Officer, Aphton Corporation

3:00 Icatibant An Old Story? Results about the Development of the Bradykinin Receptor Antagonist Icatibant  
This presentation provides additional details and updates on Icatibant, a known compound with a new story. Results on recent developments of Icatibant will be presented.

Gerd Hummel, Ph.D, Director, Medicinal Chemistry, Jerini AG, Germany

3:30 Networking Refreshment Break

**Keynote Presentations**

- **Attendees from both tracks participate in this session**

4:00 Cubist’s Development of CUBICIN® (Development of Daptomycin IV)  
– First in Class  
This talk will describe the development of Cubicin, a first-in-class antibiotic now approved for use in seriously ill, hospitalized patients with complicated skin and skin structure infections. Also known generically as daptomycin, it is also being studied in potentially fatal bloodstream infections and bacterial endocarditis due to highly resistant strains of Staphylococcus aureus.

Barry Eisenstein, M.D., Senior Vice President, Scientific Affairs, Cubist Pharmaceuticals, Inc.

4:45 Aptamers: The Next Generation of Therapeutics  
Aptamers are nucleic acid derived macromolecules that bind with high affinity and specificity to proteins in a fashion similar to antibodies and, thereby, elicit a pharmacological effect. Archemix is developing aptamer therapeutics to treat a range of human diseases. Current clinical and preclinical data on therapeutic agents in the Archemix discovery and development pipeline will be presented.

Errol De Souza, Ph.D., President and CEO, Archemix Corp.

5:30 Opening Reception in Exhibit Hall  
Learn about new technologies and services from over 65 supplier companies! Meet with more than 20 poster presenters and make new contacts while enjoying wine, beer, and appetizers.

Visit www.IBCLifeSciences.com/TIDES for up-to-date information on this event & to register online
8:00 Networking Match-Making Session
Meeting the right people and making a connection are key ingredients to succeeding in business. Participate in this conference feature and we’ll organize one-on-one meetings based on your personal profile.
Once you have registered, getting involved is easy!
FIRST: Register for TIDES® at www.IBCLifeSciences.com/TIDES
SECOND: Sign up at http://networkingmatch.com/ibcusa/ and create your online profile to provide other TIDES® networking participants with details about you and your organization.
THIRD: Review the profiles of other TIDES® networking participants and submit meeting requests to identify whom you want to meet.
Plus, if there is anyone you don’t want to meet, you can specify that too.
FOURTH: The NetworkingMatch computer calculates a targeted meeting list based on your profile and requests, and provides it to you prior to the conference.
FIFTH: Attend the TIDES® Networking Match-Making session and meet the people on your list!
This special event feature is the fastest and easiest way to connect with the people you want one-on-one with! The sooner you register, the more likely you’ll be able to meet the people you identify! Your meetings will take place Tuesday, May 3 from 8:00 - 9:15 a.m. Seating is limited and Networking Match Making registrants will be accepted on a first-come, first-served basis.
Sign up now at http://networkingmatch.com/ibcusa/
You must be a registered TIDES® delegate to sign up for the Networking Match-Making Session.

Emerging Technologies

9:15 Chairperson’s Remarks
Anthony N. Scozzari, Vice President, Drug Substance Manufacturing and Process Chemistry, Isis Pharmaceuticals, Inc.

9:20 A New Solid Support and Universal Linker Technology for Oligonucleotide Manufacturing
Isis has redefined its approach to synthesis of oligonucleotides to reduce cost and increase scalability. The revised synthesis procedure involves three new components: 1) A new hydroxyl-functionalized high performance solid support; 2) A universal molecule to replace various nucleosides attached to support; and 3) 4,5-Dicyanoimidazole as an efficient replacement for 1H-tetrazole.
Anthony N. Scozzari, Vice President, Drug Substance Manufacturing and Process Chemistry, Isis Pharmaceuticals, Inc.

9:45 Technology Workshop
New Developments in the Synthesis of Clinical-Grade Oligonucleotides
GE Healthcare, formerly Amersham Biosciences, has developed OligoPilot™ 400, a new instrument specifically for the synthesis of clinical-grade oligonucleotides. This presentation demonstrates how the OligoPilot 400 design allows for quick installation within a laboratory environment – minimizing facility and infrastructure expenditure. Examples of the full scale range, 4 to 30mmol are shown for both DNA & RNA synthesis, highlighting further cost savings through the use of optimized flow paths requiring minimum reagent consumptions per cycle.
Lars Holmberg, Ph.D., Director, GE Healthcare, Sweden

10:15 Synthesis Optimization of a Ghrelin-binding RNA-Spiegelmer (44nt) on OligoPrep™ Support
An optimized method for synthesis of long RNA (>40nt) using OligoPrep™ support was developed, scaled up and used for the production of a 44nt RNA-Spiegelmer binding octanoylated ghrelin, a peptide involved in the regulation of food uptake and metabolism. Results from in vitro and in vivo studies are presented as a potential application of the Spiegelmer for the treatment of obesity and related disorders.
Stefan Vonhoff, Ph.D., Production Manager, NOXXON Pharma AG, Germany

10:40 Networking Refreshment Break and Exhibit/Poster Viewing

Sponsored by:

11:25 Technology Workshop
A Membrane-Based Approach for Oligonucleotide Purification
Anion exchange membrane chromatography, then tangential flow filtration of the purified oligonucleotide, provide pre-packed, scalable and high-throughput downstream processing methods. Review the data on the capture of phosphorothioated oligonucleotide from a crude mixture on ion-exchange membrane chromatography. The talk highlights the elimination of column packing, packing validation, and reduction of buffer usage, providing high flow rates without affecting dynamic binding capacity.
Michael Killeen, Regional Manager, Purification, Pall Life Sciences

Overcoming Supply Chain Challenges

11:55 What to do about Biological Risks such as BSE?
The outbreak of bovine spongiform encephalitis in cattle in the UK in 1986 and its passage to humans raised concerns that animal derived materials used in manufacturing could be the source of adventitious agents. Professor Jones answers the questions: What is BSE? How is it detected? What should be done to minimise the risk and ensure a safe product?
Professor Ian Jones, Professor of Virology, School of Animal and Microbial Sciences, University of Reading, United Kingdom

12:20 Improved Starting Materials for RNA Active Substances
High overall purity and consistency are essential requirements for starting materials that are employed in the manufacture of RNA active substances. The presentation highlights impurity profiles of the most critical materials, RNA phosphoramidites, and the impact of found impurities on API quality. A new activator molecule designed for RNA oligonucleotide synthesis is introduced and applied in the synthesis of siRNA.
Dr. Andreas Wolter, Managing Director, Proligo Biochemie GmbH Hamburg, Germany

“Focused, practical, and unique forum for the exchange of up-to-date research and technological ideas between protein, peptide, and nucleotide scientists.”
Tuesday, May 3, 2005 (continued)

12:45 Lunch in Exhibit Hall with Continued Discussions at Roundtables
Have lunch, interact with technology and service providers, chat with poster presenters, or take part in the roundtable discussions in small groups on critical industry topics.

Roundtable Discussion Topics
Starting Materials for Oligonucleotide-Based Therapeutics
Moderator: Karen Fleshman, Ph.D., Senior Director, Regulatory Affairs, CMC, EyeTech Pharmaceuticals, Inc.
Starting Materials for Peptide-Based Therapeutics
Moderator: TBA
Economics of Peptide-Based Therapeutics
Moderators:
Jose de Chastonay, Ph.D., President, Bachem Americas
Alain Scarso, Ph.D., Director, UCB-Bioproducts Division, UCB S.A., Belgium
Economics of Oligo-Based Therapeutics
Moderator: Michael J. McLean, Ph.D., President, Avecia Biotechnology, Inc.

Critical Challenges in TIDES
Manufacturing: Economics of Commercialization

2:00 Chairperson's Remarks
Jose de Chastonay, Ph.D., President, Bachem Americas

2:15 Solid Phase versus Recombinant Synthesis of Peptides – An Integrative Comparison
Production of peptides requires different strategies depending on the size, complexity, and quantity. Subsequent to the IND filing, companies are faced with the selection of a suitable and economical viable route for clinical trials and commercial production of their peptide candidate. Based on examples of long- and medium-sized peptides, the presentation will make the comparison between industrial solid phase synthesis and recombinant technology, considering all aspects.

Daniel Bourgin, Ph.D., Associate Director, New Business Development, Lonza AG, Switzerland

2:45 Factors Influencing Cost of Oligonucleotide API’s
There is a common perception that the biggest cost drivers in the manufacture of oligonucleotide drugs are the unit costs of the most expensive raw materials — amidites and solid supports. While this may be true for high volume manufacture, it masks the contribution from fixed costs required to operate a compliant facility and to manufacture to cGMP. These inescapable cost elements become far more dominant contributors at the smaller volumes required for the current drug candidates. This presentation tries to answer the question “why can’t I get 500g for the same unit cost as 100kg?”

Michael J. McLean, Ph.D., President, Avecia Biotechnology, Inc.

3:15 Networking Refreshment Break and Exhibit/Poster Viewing
Sponsored by:

Keynote Presentations

4:00 Future Prospects for Oligonucleotide-Based Therapeutics
As with the introduction of all new technologies destined to change medicine, the history of oligonucleotide-based therapeutics is marked with occasions of great promise and momentary disappointment. Signal events in the past have provided a foundation on which to refine these technologies and suggest a future that continues to be filled with challenge and opportunity.

Homer L. Pearce, Ph.D., Distinguished Research Fellow, Lilly Research Laboratories, Eli Lilly and Co.

4:40 Partnerships in Therapeutic Peptide Products: Nastech Pharmaceutical and Merck & Co., Inc. on Intranasal Peptide YY3-36 Alliance
The partnership between Nastech and Merck provides an example of the growing interest in peptide therapeutics in combination with technology that can deliver these molecules safely and effectively. This presentation will examine the critical elements in developing an intranasal Peptide YY3-36 formulation and securing a co-development and co-promotion alliance with a major global pharmaceutical company.

Steven C. Quay, M.D., Ph.D., Chairman of the Board, President and CEO, Nastech Pharmaceutical Company Inc.

5:15 Products, Sources, and Sites: An FDA Perspective
Oligonucleotide and Peptide drug products are subject to a variety of regulatory considerations. Raw materials, development, scale-up, and technology transfer can be affected. Various guidelines and guidelines published by the FDA and by international organizations influence regulatory considerations. Raw materials, development, scale-up, and technology transfer can be affected. Various guidelines and guidelines published by the FDA and by international organizations influence regulatory decisions in product development. These concepts, comparing and contrasting the various requirements, and providing the current FDA perspective applicable to oligonucleotide and peptide drug products are revisited.

Blair A. Fraser, Ph.D., Deputy Director, Division of New Drug Chemistry 2, Office of New Drug Chemistry, Office of Pharmaceutical Sciences, CDER, US FDA

5:45 Networking Reception in Exhibit Hall
6:00-7:00 Dedicated Poster Viewing

“Comprehensive, controversial, compelling – come back!”
Hans Schuhbauer, Commercial Project Manager, Raylo Chemicals–Degussa

Visit www.IBCLifeSciences.com/TIDES for up-to-date information on this event & to register online
7:30 Registration, Coffee, Tea, and Pastries

Strategies to Improve Delivery of Existing Drugs

8:00 Co-Chairpersons' Opening Remarks
Ze’ev Shaked, Ph.D., President and CEO, Spherics, Inc.
Perry Calias, Ph.D., Senior Director, Chemistry and Drug Delivery, Eyetech Pharmaceuticals, Inc.

Keynote Presentations

8:15 Advances in Drug Delivery
Dr. Langer analyzes novel approaches for drug delivery, including injectable microspheres, novel polymers, controlled release microchips, new aerosols, and ultrasound assisted transdermal delivery.
Robert S. Langer, Sc.D., Kenneth J. Germeshausen Professor of Chemical and Biomedical Engineering, Massachusetts Institute of Technology

9:00 Gene Silencing Nucleic Acids: Pharmaceutical Challenges to Delivery
Gene silencing nucleic acids such as siRNA, antisense oligonucleotides, DNAzymes and ribozymes have great therapeutic potential in sequence-specifically inhibiting disease-causing genes. However, their large molecular weight and charged nature pose great pharmaceutical challenges to their clinical development. This presentation provides an overview of the challenges faced in the efficient delivery of these macromolecules in vitro and in vivo and suggests possible solutions to these hurdles in the clinical development of gene silencing nucleic acids.
Professor Saghir Akhtar, Ph.D., Chair of Drug Delivery and Director, Centre for Genome-Based Therapeutics, Welsh School of Pharmacy, Cardiff University, United Kingdom

9:45 Announcement of Poster Award Winner
Sponsored by: BioProcess International

9:50 Networking Refreshment Break and Exhibit/Poster Viewing
Sponsored by: ChemGenes Corporation

10:30 Alternative Drug Delivery for Metabolic Peptide Hormones
Amylin Pharmaceuticals is developing peptide hormones for treatment of diabetes and obesity. Being peptides, these compounds are typically delivered as subcutaneous injections. In addition, Amylin is investigating alternative drug delivery systems for the administration of these hormones. This presentation focuses on Amylin’s approach to alternate delivery systems and representative data from ongoing programs.
Steven J. Prestrelski, Ph.D., Executive Director, Product Development, Amylin Pharmaceuticals, Inc.

11:00 The Technosphere® Matrix – Achieving Significant Organic Molecule Stabilization and Increased Bioavailability
Technosphere® particles represent an excellent resource for the loading of materials for therapeutic intervention including peptides, proteins, oligonucleotides, and small molecules. Currently in clinical development for pulmonary delivery of drugs, including insulin, the platform has also demonstrated significant utility for delivery of otherwise unstable proteins and hormones intravenously and orally with excellent bioavailability.
Wayman Wendell Cheatham, M.D., FACE, Corporate VP and Chief Medical Officer, MannKind Corporation

11:30 Oral Delivery Techniques for Poorly Permeable Compounds
Oral delivery of poorly permeable drugs, especially peptides and oligonucleotides, remains a major therapeutic challenge. GIPET, a GRAS-based oral permeation enhancer technology has been developed to meet this need. A broad range of compounds from biphosphonates to peptides and polysaccharides has been successfully delivered orally with the technology.
Thomas W. Leonard, Ph.D., R.Ph., Vice President and Chief Scientific Officer, Merrion Pharmaceuticals, Inc.

12:00 in vivo Delivery and Efficacy of siRNA
The successful delivery of siRNA-based therapeutics will require chemical modification of the siRNA to enhance stability and specificity and will be further enhanced by formulation using lipidic carriers.
Nassim Usman, Ph.D., Senior Vice President and Chief Operating Officer, Sirna Therapeutics, Inc.

12:30 Lunch in Exhibit Hall and “Ask the Experts” Session
Final Opportunity for Exhibit and Poster Viewing

“Ask the Experts” Session
Don’t miss this opportunity to ask your specific technical questions to leading experts in oligonucleotide and peptide drug manufacturing and development. The sessions take place at roundtables in the exhibit hall during lunch. Ask your questions to the following experts:
Barry Eisenstein, M.D., Senior Vice President, Scientific Affairs, Cubist Pharmaceuticals, Inc.
Leslie M. McEvoy, Ph.D., Vice President, Research and Development, Cargile Technology, Inc.
Michael Verlander, D. Phil., Executive Vice President, PolyPeptide Laboratories, Inc.
Fran Wincott, Ph.D., Vice President, Oligonucleotide Manufacturing and Development, Eyetech Pharmaceuticals, Inc.

“TIDES is a ‘must attend’ event. Looking forward to meeting you in Boston.”
– Dr. Jörn Hoffmeyer, International Product Manager, Merck KGaA, Darmstadt, Germany

Wednesday, May 4, 2005 • Formulation & Delivery Day
Strategies to Modify Drugs for Improved Delivery via PEGylation and Conjugates

2:00 Chairpersons’ Remarks
Gary F. Musso, Ph.D., Vice President, Development, Praecis Pharmaceuticals, Inc.
Fran Wincott, Ph.D., Vice President, Oligonucleotide Manufacturing and Development, Eyetech Pharmaceuticals, Inc.

2:15 Strategies for Reversible Peptide Pegylation
Protein PEGylation is a clinically proven platform for enhancing the properties of therapeutic proteins and is of rapidly increasing interest for peptides. For peptides, however, significant loss of bioactivity upon PEGylation can be an impediment to product development. Here we discuss PEGylation strategies leading to peptide prodrugs which liberate active peptides upon hydrolysis.

Michael D. Bentley, Ph.D., Vice President, Research, Nektar Therapeutics

2:45 Recent Advances in Development of Therapeutic Aptamers – Post-SELEX Optimization and Pegylation
Aptamers leads are discovered through in vitro selection from pools of random sequence oligonucleotides. Structural stability, nuclease resistance and target binding affinity can be drastically improved by introducing nucleotide base and backbone modifications. Furthermore, PK and distribution parameters can be fine-tuned by attaching a PEG group chosen from a variety of available sizes, geometries and attachment chemistries. Optimization data with an emphasis on aptamer performance, manufacturing, formulation, and cost considerations are presented.

Markus Kurz, Ph.D., Associate Director, Chemistry, Archemix Corp.

3:15 Hematide™, a Synthetic PEGylated Peptide for the Treatment of Anemia
Affymax has discovered a synthetic PEGylated peptide that acts as a potent erythropoiesis stimulating agent (ESA) that is currently in clinical trials. Issues regarding the characterization of this PEG-Peptide conjugate will be described, in addition to a summary of the preclinical and clinical results obtained thus far.

Christopher P. Holmes, Ph.D., Senior Director, Chemistry, Affymax, Inc.

3:45 Networking Refreshment Break
Sponsored by:

4:15 GRN163L: A Potent and Specific Telomerase Inhibitor for Cancer Therapy
Geron is pursuing development of GRN163L, a lipid modified N3’-P3’ thio-phosphoramidate oligonucleotide that inhibits intracellular telomerase more efficiently than its parent non-lipidated thio-phosphoramidate compound, GRN163. The increased potency and improved pharmacokinetic and pharmacodynamic properties of lipid-conjugated GRN163L are discussed.

Melissa A. Kelly, Vice President, Oncology, Geron Corporation

4:45 The Bioconjugation of DAC-GRF and DAC-GLP 1 to Albumin Increases their Half Life and Decreases their Immunogenicity Potential
DAC peptides covalently bind to albumin, increasing half-life and duration of activity from minutes to days. Pre-clinical and clinical studies (>700 people with 250 for 3 months) have shown no immunogenic reactions, good tolerability with no technology-related side effects, as well as a half life and a duration of efficacy of about 10 days.

Jean-Paul Castaigne, M.D., Chief Operating Officer and Chief Science Officer, Conjuchem Inc.

5:15 Drug Delivery and Targeting Using Chemically Modified Hyaluronan
Hyaluronan is a component of a variety of tissues (e.g., cartilage) and body fluids (e.g., synovial fluid, vitreous). HA binds to receptors (CD44, CD168) that transports HA into cells. Recently we have focused on using chemically modified HA to target and transport therapeutics into cells using these HA receptors.

Robert J. Miller, Ph.D., Senior Director, Biomaterials Science & Engineering, Genzyme Corporation

5:45 Close of Wednesday Sessions

Call for Poster Submissions
The organizers of TIDES® recognize the significant educational value in the poster presentations. Any registered conference attendee may sign up to present a poster.

Cash Poster Award Sponsored by:

Posters will be reviewed by the TIDES® and BioProcess International™ SAB’s and one winner will receive a cash prize of $250. Criteria include novelty, applicability, and clarity of data presented.

The poster abstract, along with full payment of conference registration and poster fees must be received by April 14, 2005 for the abstract to be included in the conference CD-Rom and poster board assignment to be made. (See page 15 for fees.) Abstracts received late or without fees paid may not be included in CD-Rom, receive board assignments or be eligible for the award.

The size of the conference poster board is 4’h x 8’w. Please note: Poster presentations may not be used as exhibit displays or for marketing purposes. All posters are subject to approval by conference organizers.

Poster abstracts must be submitted online by April 14, 2005 at www.IBCLifeSciences.com/TIDES.

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11
### Process and Analytical Methods Validation: Strategies for Analytical, API, and Drug Product Validation

**8:30 Co-Chairpersons’ Remarks**

Michael J. McLean, Ph.D., President, Avecia Biotechnology, Inc.

Michael Verlander, D. Phil., Executive Vice President, PolyPeptide Laboratories, Inc.

**8:45 Process Validation of Macugen API: An Exercise in Submission Preparation and Inspection Readiness**

Examine the stages of process validation (pre-qualification, manufacturing qualification, and life cycle qualification), and the relationship of each of these to the submission preparation and Pre-Approval Inspection readiness. The study is co-presented by scientists from Eyetech Pharmaceuticals (the sponsor) and BioTechLogic, Inc. (a manufacturing management firm).

Patrick Giljum, Head of Operations, BioTechLogic, Inc.

**9:15 An Approach for Successful Process Validation**

“Validation is a team effort” is not an empty mantra in validation. Involving process development in validation planning and in pre-validation work minimizes time and cost. Process validation based on early identification of critical process steps and critical process parameters minimizes the validation effort and enhances the chances for a successful validated and robust process. Examples from experience with the validation of manufacturing processes for peptide API’s are reported.

Birgitta Mörnstam, M.Sc., Manager, Qualification & Validation Europe, PolyPeptide Laboratories AB, Sweden

**9:45 Column Lifetime**

This presentation outlines how, as part of a process validation study, the chromatography column performance was evaluated to allow the resin life (or rather end of life) to be predicted. It also illustrates how key quality and yield attributes can be trended to help predict expected results from crude to pool.

Juan B. Gonzalez, Director of Validation, Avecia Biotechnology, Inc.

**10:15 Networking Refreshment Break**

**10:45 Insights into Critical Aspects of Analytical Procedures for Nucleic Acid Medicines**

This presentation discusses analytical method improvements to enable validation, allow precise quantitation of impurities, and reduce analysis time. Critical parameters are described for accurate determination of sodium content, residual solvents, and metals. HPLC suitability criteria have been refined to quantitate impurities at levels approaching the detection limit.

Marsha L. Langhorst, Senior Analytical Specialist, The Dow Chemical Co.

**11:15 Analytical Validation of Peptide Water Content – Challenges and Lessons from a Seemingly Innocuous Test**

Water determination is a fundamental and seemingly straightforward compendial test. The measurement of water in peptide materials is an essential test used to calculate the drug charge during drug product manufacture. Our experience with this test led to a very complicated investigation of discrepant variance and to a very unusual validation process. Along the way, we learned valuable lessons about the peculiar nature of peptides.

Roger Micheli, Ph.D., Head, Analytical Research and Regulatory Affairs, Roche Colorado Corporation

**11:45 Analytical Considerations in the Development of RNAi Based Biopharmaceuticals**

Therapeutics based on siRNA technology make treatment of molecular disease targets possible. Nevertheless, accurate sequencing and determination of critical modifications for the assurance of potency, purity, identity, safety during development, and commercialization remain essential. This discussion will review various experimental variables that contribute to the ruggedness and precision of analytical methodology, as well as the confidence level in sequence coverage, in applications with siRNA biopharmaceuticals.


**12:15 Close of TIDES® 2005**

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5:30 p.m. - 7:00 p.m.

Tuesday, May 3
10:30 a.m. - 7:15 p.m.

Wednesday, May 4
9:45 a.m. - 2:00 p.m.
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