Mark your calendars…
The AES Satellite Symposium on Advanced Electrophoresis Tools will be held October 2, 2006 in conjunction with the CEPharm International Symposium at the Hyatt Regency, Jersey City, NJ

The American Electrophoresis Society (AES) and California Separation Science Society (CaSSS) are pleased to announce the first in a series of jointly-sponsored satellite symposia with CEPharm on electrophoresis in the pharmaceutical and biotechnology industries. While CEPharm will continue to offer state-of-the-art programming and short-courses in practical capillary electrophoresis, the AES will feature speakers as well as hands-on training in areas that are complimentary to Capillary Electrophoresis. Attendees at CEPharm 2006 will not only hear about the latest work in capillary electrophoresis but will also learn about new developments in the broader field of electrophoresis.

This year, the AES sessions will focus on applied microchip and preparative electrophoresis and cross-platform reproducibility. The opening session will begin with a Plenary lecture on the foundations and future of lab-on-a-chip analysis followed by papers on commercial microchip platforms. The late-morning session will highlight commercial preparative platforms, including contributions from Agilent, Becton-Dickenson, and BioRad. The final session will feature a trio of papers on multidimension proteomics platforms and finish with a panel discussion on platform reproducibility led by several speakers from the AES and CEPharm oral sessions.

Following the panel discussion, Caliper Life Sciences will host a hands-on training session for their LabChip®90 microchip analyzer. Don’t miss this chance to get your hands on this state-of-the-art, lab-on-a-chip platform!

Featured Speakers Include:

**Lab-on-a-Chip**
- Prof. J. M. Ramsey, UNC Chapel Hill
- Dr. S. Jovanovich, Microchip Biotechnologies
- Dr. A. Chow, Caliper Life Sciences

**Preparative Electrophoresis**
- Dr. T. Preckel, Agilent
- Dr. P. O’Mullan, Becton-Dickenson
- Dr. A. Paulus, Bio-Rad Laboratories

**Mult-Dimensional Separations Platforms**
- Dr. A. Paulovich, Fred-Hutchinson Cancer Center
- Dr. N. Kendrick, Kendrick Labs Inc
- Dr. D. Speicher, Wistar Institute

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**Biomicrofluidics**
An AIP Access X-Press Publication

Submit an article from work presented at the annual meeting to a special edition of the new journal Biomicrofluidics. Contact our meeting organizers (see front page) for a full-page flier and more information. See also: [http://bmf.aip.org](http://bmf.aip.org)
All talks, workshops, posters and exhibitions will be held at the Hyatt Regency Jersey City. The Hyatt Regency is beautifully situated on the Hudson River, just across from Wall Street and offers stunning vistas of the Manhattan skyline and New York Harbor. The hotel is located adjacent to the PATH train station with direct access to both lower and midtown Manhattan. The handsomely appointed guest rooms offer spectacular views. In-room amenities include coffee makers, cable TV, in-room movies, hair dryers, irons and ironing boards. Business travelers will appreciate the two-line telephones with dataport connectivity and voice mail and T-Mobile® wireless Internet access. The fitness center offers views of lower Manhattan and features state-of-the-art equipment and an indoor swimming pool.

A room block is reserved for Symposium delegates at the special group rate of $249 USD for a single or double room plus 13% occupancy tax. The room reservation deadline is September 8, 2006. After September 8, 2006 reservations will be accepted on a space-available basis and at the prevailing room rate. The Hyatt Regency does require a deposit of one night’s rate plus tax via credit card to guarantee your reservation. Reservations made for the hotel need to be cancelled 48 hours before your arrival for a full refund. To make reservations, please contact the Hyatt Regency by telephone: 201-469-1234 or FAX: 201-432-4991. Please identify your self as an attendee of the “CE PHARM 2006 Symposium” to secure the above rates. 

NOTE: Check-in time is 3:00 pm and check-out time is 12:00 pm.
The goal of this Symposium is to provide a forum for the discussion of recent developments in CE analysis of protein, nucleotide and small molecule pharmaceuticals. The presentations and workshops will be devoted completely to practical concerns to strengthen the use of CE within the biotechnology and pharmaceutical industries. Applications will highlight uses of CE in various areas of product development including high throughput screening, formulation studies, process development, product characterization and validated lot release and stability testing. The Symposium will feature presentations from leading experts within the industries and the regulatory agencies (FDA, Health Canada, European Pharmacopeia). The workshops will allow for open discussions of specific techniques and/or applications including protein analysis, carbohydrate analysis, CE/MS, oligonucleotide and chiral separations as well as validation of CE assays for product release. Specifically, two workshops will focus on the implementation of assays, including assay troubleshooting, assay transfer, and instrument qualification (IQ/OQ/PQ).

The Symposium will begin on Monday, October 2nd with two full-day optional practical Courses. Kevin Altria from GlaxoSmithKline will teach “Overview of the Application of CE to the Analysis of Small Molecule Pharmaceuticals” and Chantal Felten and Oscar Solano, both from Genentech, Inc. will teach “Applications of CE to the Analysis of Protein Therapeutics”. BRAND NEW this year, also being held on Monday, October 2nd, will be the AES Satellite Symposium on “Fundamental and Advanced Electrophoresis”. Attendees of the AES Satellite Symposium will not only hear about the latest work in capillary electrophoresis but will also learn about new developments in the broader field of electrophoresis. Following the optional Courses, the Symposium will continue with three full days of seminars, practical workshops, technical seminars on different CE applications, networking lunches and reception and poster sessions. The Symposium will end on Friday, October 6th with a full day optional advanced Course. Kevin Altria from GlaxoSmithKline will teach “Method Optimization and Troubleshooting in Capillary Electrophoresis”.

As in past years, the California Separation Science Society (CaSSS), a not-for-profit professional association designed to organize symposia and provide other educational and networking opportunities for separation, pharmaceutical and bioanalytical scientists throughout the world, will generously sponsor the Symposium.

Symposium Organizing Committee

Kevin Altria, GlaxoSmithKline
William Ciccone, MicroSolv Technology Corporation
Michelle Frazier-Jessen, CDER, FDA
Oliver Grosche, Novartis Pharma K.K., Tsukuba Research Institute (co-chair)
Cornelius Ivory, Washington State University
Ilias Jimidar, Johnson & Johnson Pharmaceutical R & D
Franka Kálmán, Solvias AG
Mark Lies, Beckman Coulter, Inc.
Stacey Ma, Genentech, Inc.
Wassim Nashabeh, Genentech, Inc.
Brian K. Nunnally, Wyeth
SungAe Park, Amgen Inc. (co-chair)

Call For Abstracts

Abstract Submission:

Please choose the following procedure for submitting an abstract. The Organizing Committee invites pharmaceutical scientists from industry, government regulatory agencies and academia to submit abstracts on their current work. **August 31, 2006** is the deadline for poster abstract submission. Abstracts can be submitted through the Symposium Web site at [www.casss.org](http://www.casss.org). Please indicate whether the submitted abstract is for an oral presentation, a poster presentation or an invited talk.
Preliminary List of Confirmed Speakers & Topics

An Alternative Way to Qualify Cell Culture Media (Raw Material for Production) by CE (MEKC)
K.C. Cheng, Medarex, Inc., Bloomsbury, NJ USA

Capillary Electrophoresis Methods for Therapeutic Biologics: Regulatory Considerations from the European Perspective
Stephan Christians, Paul Ehrlich Institute, Langen, Germany

The Analysis of Transferrin Isoforms with Capillary Electrophoresis in Biological Fluids
Francois de l’Escaille, ANALYS S.A., Sauerlee, Belgium

Application of CE and CE-MS in Quality Control of Small Molecules and Dendrimeric Active Substances
Cornelia Feisel, Schering AG, Berlin, Germany

Capillary Electrophoresis Methods for Therapeutic Biologics: Regulatory Considerations from the FDA Perspective
Michelle Frazier-Jessen, CDER, FDA, Bethesda, MD USA

Improved CE-MS Methods for Characterization of Biomolecules
Lynn Gennaro, Genentech, Inc., South San Francisco, CA USA

Characterization of Influenza Vaccine Constituents by Capillary Electrophoresis
Michel Girard, Health Canada / Centre for Biologics Research, Ottawa, Canada

Determination of Inflammatory Biomarkers by Immunoaffinity Capillary Electrophoresis
Norberto Guzman, Johnson & Johnson Pharmaceutical R & D, Raritan, NJ USA

Capillary Electrophoresis for Biologics From the Standpoint of the Japanese Pharmacopeia
Kazuzuki Kakehi, Kinki University, Osaka, Japan

Peak Splitting / Artificial Impurity Effects in Chiral Capillary Electrophoresis with Sulfated Cyclodextrins
Franka Kalmán, Solvias AG, Basel, Switzerland

Opening the IEF Blackbox Part 1: Effects of Anolyte and Catholyte on Determination of pI Values
Sanjiv Lalwani, Texas A & M University, College Station, TX USA

Integrated Microdevices for Genetic Analysis with ‘Smart’ Valving Fluidic Control
James Landers, University of Virginia, Charlottesville, VA USA

cIEF Method Application in Pharmaceutical Development and Its Challenges for Quality Control
Connie Lu, Tanox, Inc., Houston, TX USA

Development of Methods for Forensic Drug Screening Using CE, CE/MS and Microfluidic Approaches
Bruce McCord, Florida International University, Miami, FL USA

Clinical Diagnosis and Therapy Evaluation Based on Proteome Analysis Utilizing Capillary Electrophoresis Coupled Mass Spectrometry
Harald Mischak, Mosaques Diagnostics & Therapeutics, Hanover, Germany

CE-SDS-NGS: A Powerful Tool for the Purity Evaluation of Biopharmaceuticals
Bernd Moritz, F Hoffmann-La Roche Ltd., Basel, Switzerland

Investigation of Vesicle Electrokinetic Chromatography as an In Vitro Assay for the Estimation of Intestinal Permeability of Pharmaceutical Drug Candidates
Robert Pascoe, Merck & Co., Inc., West Point, PA USA

Use of Capillary Electrophoresis to Reduce Development Cycle Timelines
Larry Rose, SOMA (US), LLC, Berkeley, CA USA

Implementation of SDS-CGE and cIEF Methods for GMP Testing of Monoclonal Antibodies: Method Development, Validation and Transfer Experience
Margaret Ruesch, Pfizer, Chesterfield, MO USA

Ann Van Schepdael, Catholic University, Louvain, Belgium (invited)

When Capillary Electrophoresis-Mass Spectrometry is the Most Effective Technique in Problem Solving
Dora Visky, Johnson & Johnson Pharmaceutical R & D, LLC, Raritan, NJ USA

CE - A Useful Tool in Pharmaceutical Development
Markus Zeitz, Novartis Pharma AG, Basel, Switzerland

Introduction of an Imaged cIEF Method into a QC Lab for MAb Analysis
Jifeng Zhang, Amgen, Inc., Thousand Oaks, CA USA

CE Registration

You may register for the CE in the Biotechnology & Pharmaceutical Industries Symposium at the early discounted registration rate if your completed registration form, with payment, is received on or before September 15, 2006. Higher fees will apply to registrations received after this date.

Members in good standing of the California Separation Science Society (CaSSS) may register for the 8th CE Symposium at a lower rate than non-members. If you are not currently a member of CaSSS, it is not too late to join to take advantage of the lower meeting registration rate.

- Register Online: www.casss.org (online membership enrollment/renewal and application also available)
- Register by Mail: (check payment only) Download and print the registration form from the web site, complete and mail to the California Separation Science Society, 156 South Spruce Avenue #214, South San Francisco, CA 94080-4556. Make checks payable to California Separation Science Society.

Fees are in US$ and must be paid in US$.

Registration Fees

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<tr>
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<th>On or Before Sept.15</th>
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<tbody>
<tr>
<td>Symposium /Industrial</td>
<td>$895</td>
<td>$995</td>
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<tr>
<td>Symposium / Academic or Government</td>
<td>$425</td>
<td>$525</td>
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<tr>
<td>Symposium / Students and Postdocs</td>
<td>$195</td>
<td>$295</td>
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<tr>
<td>Course: Analysis of Small Molecules</td>
<td>$425</td>
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<tr>
<td>Mon. Oct. 2nd 9:00 am – 3:00 pm</td>
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<tr>
<td>Course: Analysis of Protein Therapeutics</td>
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<td>Mon. Oct. 2nd 9:00 am – 3:00 pm</td>
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<tr>
<td>Satellite Symposium: Fundamental /Advanced Electrophoresis – Mon. Oct. 2nd 9:00 am – 3:00 pm</td>
<td>$425</td>
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<td>Hands-on Training</td>
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<td>Mon. Oct. 2nd 3:30 – 5:30 pm</td>
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<tr>
<td>Course: Method Optimization</td>
<td>$425</td>
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<tr>
<td>Fri. Oct. 6th 9:00 am – 3:00 pm</td>
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Full Symposium registration includes all meetings from Tuesday, October 3rd at 8:00 am through Thursday, October 5th at 5:00 pm, continental breakfast and refreshment breaks for three days, hosted networking lunches, Wednesday evening exhibitor and poster reception, as well as a copy of the final program/abstract book. Symposium registration does not include the optional Satellite Symposium and Hands-on Training on Monday the two full-day optional Courses on Monday or the full-day optional Course on Friday. Courses and Satellite Symposium registrations include handout materials, continental breakfast, refreshment breaks and lunch.

Cancellation Policy

A refund will be available if cancellation notice is received in the CaSSS office by September 18, 2006, less a $95 administrative fee. No refunds will be available after this date. Substitutions are accepted.
Course Options

Optional Full-Day Course
Monday, October 2, 2006 9:00 am – 3:00 pm
(An additional registration fee is required to attend Course)

Overview of the Application of CE to the Analysis of Small Molecule Pharmaceuticals
Kevin Altria, GlaxoSmithKline R & D, Essex, United Kingdom

The one day session will provide an introduction to CE and the routine applications for analysis of small molecule. Background theory and the fundamentals of CE will be covered. This will be followed by an overview of the instrumentation, application and aspects of method development. Specific topics will include micellar electrokinetic capillary chromatography (MECC), chiral separations, capillary ion analysis and use of indirect UV detection. The session will also provide details regarding the validation of CE methods, regulatory issues and descriptions of a variety of other applications for the small molecule CE. The session will be complemented by a comprehensive handout of all the slides used. The course will also include use of a simulator and video to aid understanding.

Optional Full-Day Course
Monday, October 2, 2006 9:00 am – 3:00 pm
(An additional registration fee is required to attend Course)

Applications of CE to the Analysis of Protein Therapeutics
Chantal Felten and Oscar Salas-Solano, Genentech, Inc., South San Francisco, CA USA

This course will provide an overview of the fundamentals, modes and selected applications of CE as it applies to protein analysis in the biotechnology industry. The course will have a significant focus on practical industrial concerns in the application of CE in the analysis of protein therapeutics. The applications covered will feature know-how of current uses of CE in various areas of protein pharmaceutical development including formulation studies, process development and scale-up studies, product characterization and validated lot release and stability QC testing. The specific modes of CE that will be discussed include carbohydrate analysis, CZE, c-IEF and CE-SDS. The latter part of the course will focus on the interpretation of ICH Analytical Validation Guidelines as they apply to validation of CE methods for protein analysis and the use of these methods in routine cGMP lot release testing of marketed biologics. Finally, the advantages and limitations of the various CE methodologies in assessing the identity, purity and stability of biotechnology products will be discussed.

Optional Full-Day Course
Friday, October 6, 2006 9:00 am – 3:00 pm
(An additional registration fee is required to attend Course)

Method Optimization and Troubleshooting in Capillary Electrophoresis
Kevin Altria, GlaxoSmithKline R & D, Essex, United Kingdom

The fundamentals of CE will be briefly reviewed. An in-depth description of the correct practical operating procedures and how to successfully run a separation will be covered. The approaches to method optimization during method development will then be described paying particular attention to the influence of key operating parameters. Factors affecting routine short and long term operation will be presented which include aspects such as buffer depletion, capillary conditioning and sample diluent effects. The approaches to the optimization of precision in quantitative analysis such as use of internal standards and optimal injection procedures will be detailed. The possible mechanisms to improve detector sensitivity such as capillary modifications and buffer selection will then be covered. Good working practices such as dedication and storage of capillaries, and avoidance of carryover effects will be described. Finally detailed focus will be paid to systematic troubleshooting approaches in CE and a listing of fixes to commonly encountered problems will be provided. This course will be interactive with the participants who can bring their non-confidential separation problems along for discussion.

Workshop Descriptions

Inter-Company Collaboration on Biomolecule CE Analysis: Part II Results of the First Protocol
Wednesday, October 4, 2006
A series of inter-company collaboration projects were conducted in the area of small molecule analysis by capillary electrophoresis in the 1990’s. The positive results from these studies have been heavily cited as supporting data that well developed and controlled CE methods can be applied routinely in an industrial environment. A project team was formed from a number of interested Biopharmaceutical companies to conduct a cross-company collaboration exercise. This exercise was designed to generate data from different companies to compare methodologies and demonstrate the robustness of biomolecule CE. The data on migration times, purities, and resolution for a representative biomolecule run on a single type of instrument was reported in Chromatographia. The second part of the protocol, comparing several different instruments, will be discussed. This exercise will facilitate both increased regulatory and industrial opinion of CE for Biopharmaceutical analysis.

Instrument Qualification (IQ/OQ/PQ)
Tuesday, October 3, 2006
Instrument qualification is a critical aspect of compliance in the laboratory. While the requirements are straight forward, the execution can be challenging. The workshop is designed to discuss the current and future strategies of customers, vendors, and regulatory authorities on CE-instrument qualification (IQ/OQ/PQ), testing procedures, software-related issues, testing-kits, standards and reagents. The workshop will begin with several short presentations and then follow with an open forum to discuss the new pragmatic approaches to the qualification of analytical instrumentation. Active participation of the vendors is anticipated. The vendors will provide updates on the availability of qualification tools as well as discuss future challenges based on new instrumentation. Customers will be able to discuss their needs and ask questions of the experts and vendors. Regulatory representatives will be present to express their expectations of CE equipment qualification. Examples of case studies are welcome.

Method Validation, Method Transfer and Troubleshooting
Wednesday, October 4, 2006
This session will compromise of a series of short presentations on experiences encountered during the routine application, validation and transfer of CE methods. This will cover both analysis of small molecule pharmaceuticals and biopharmaceuticals. Details of the typical validation protocol content that are employed will be detailed. The figures of merit for validation criteria routinely obtained will be discussed and illustrated - including precision, accuracy, linearity. Experiences of method transfer, between analysts, laboratories and sites will be presented and described. In particular operational difficulties and problem solutions will be highlighted. The remainder of the session will be open for all attendees to raise questions for the expert panel. In addition attendees will be encouraged to share learning’s for their experiences in routine method operation, and method validation and transfer.
Satellite Symposium and Hands-on Training Session

Monday, October 2, 2006  9:00 am – 3:00 pm
(Hands-on Training Session 3:30 – 5:30 pm)

(An additional registration fee is required to attend this American Electrophoresis Society (AES) and CaSSS jointly-sponsored session)

AES Satellite Symposium on Fundamental and Advanced Electrophoresis
Co-Chairs: Bahram Fathollahi, Caliper Life Sciences
Cornelius Ivory, Washington State University

The American Electrophoresis Society (AES) and CaSSS are pleased to announce the first in a series of jointly-sponsored satellite symposia with CE Pharm on electrophoresis in the pharmaceutical and biotechnology industries. While CE Pharm will continue to offer state-of-the-art programming and short-courses in applied and practical capillary electrophoresis, the AES will feature speakers as well as hands-on training in areas that are complimentary to CE. Attendees at CE Pharm 2006 will not only hear about the latest work in capillary electrophoresis but will also learn about new developments in the broader field of electrophoresis.

This year, the AES sessions will focus on applied microchip and preparative electrophoresis, theory and simulations, and cross-platform reproducibility. The opening session will begin with a plenary lecture on the foundations and future of lab-on-a-chip analysis followed by papers on commercial microchip platforms. The second session will feature preparative platforms and computer simulations used in the design and optimization of microchip and CE protocols. The final session will begin with a paper on cross-platform reproducibility and finish with a panel discussion on the same topic featuring several speakers from the AES oral sessions. Following the panel discussion, Caliper Life Sciences will host a hands-on training session for their LabChip®90 microchip analyzer.
Sponsored and organized by the California Separation Science Society (CaSSS)

8th Symposium on the Practical Applications for the Analysis of Proteins, Nucleotides and Small Molecules

CE in the Biotechnology & Pharmaceutical Industries