CE in the Biotechnology & Pharmaceutical Industries 2025: Symposium on the Practical Applications for the Analysis of Proteins, Nucleotides & Small Molecules

Schedule

Sunday, 7 September, 2025

08:00-09:00 Foyer A-C

Registration for Short Course Only

Presentation type: IP - In Person

Registration is open for short course attendees only until 17:00.

08:00-09:00 Great Falls

Breakfast

Presentation type: IP - In Person

Breakfast is available for short course attendees only.

09:00-12:00 Glen Echo

Short Course Part I - Capillary Electrophoresis Fundamentals and Protein Therapeutic Applications

Presentation type: IP - In Person

This course offers a comprehensive overview of capillary electrophoresis (CE) fundamentals, modes, and applications, with a focus on practical examples, including tips and tricks and case studies in the pharmaceutical and biotechnology industries. Although the focus is on (bio)pharmaceuticals, the principles discussed are applicable to most quantitative CE methods.

Key topics covered in the course include:

- Applications in Pharmaceutical Development: Current uses of CE in various stages of pharmaceutical development, including process development, scale-up studies, product characterization, validated quality control (QC) lot release, and QC stability testing.

- Fundamentals of CE: Understanding the basic principles and mechanisms of CE separations.

- Good Working Practices: Best practices for daily maintenance and operation of CE systems to ensure reliable and reproducible results.

- Key Operating Parameters: Identification and optimization of critical method parameters for successful CE separations.

- Main Modes of CE: Detailed discussions on Capillary Zone Electrophoresis (CZE), Capillary Gel Electrophoresis (CE-SDS), Capillary Isoelectric Focusing (CIEF), and Capillary Electrophoresis-Mass Spectrometry (CE-MS).

By the end of the course, participants will have a solid understanding of the processes occurring inside a capillary during a CE separation. They will also gain an appreciation for the critical method parameters and acquire increased knowledge of good working practices of CE. In addition to the opportunity to learn new things or to consolidate existing knowledge, this course also offers a great opportunity to network and exchange ideas with experienced colleagues and, for first-time attendees, a warm welcome into the CASSS community.

Short Course Instructors:
Tara Enda, *Bristol-Myers Squibb Company*

Göran Hübner, *Boehringer Ingelheim Pharma GmbH & Co. KG*

Andrei Hutanu, *ten23 Health AG*

12:00-13:00 Great Falls

Lunch

Lunch is available for short course attendees only.

13:00-17:00 Glen Echo

Short Course Part II - Capillary Electrophoresis Fundamentals and Protein Therapeutic Applications

Presentation type: IP - In Person

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Monday, 8 September, 2025

07:30-08:30 Foyer A-C

Registration

Presentation type: IP - In Person

Registration will be open until 17:00

07:30-08:30 Foyer A-C

Breakfast

Presentation type: IP - In Person

07:30-08:30 White Oak A

New Member Breakfast

Presentation type: IP - In Person

08:30-08:45 Salon A-C

CASSS Welcome and Introductions

Mohamed Dawod
Presentation type: LS - Livestreamed

08:45-09:45 Salon A-C

Keynote I - Microtechnologies for Acquiring Biological Information

Mohamed Dawod, Kathir Muthusamy
Presentation type: LS - Livestreamed

The first report of micromachined devices that performed chemical separations, the silicon gas chromatograph (GC), occurred nearly five decades ago, but with reduced performance compared to conventional GCs. A couple of decades later, microfabricated fluidic devices that accomplished capillary electrophoresis (CE) separation strategies were first reported in the early 1990s with performance gains over conventional approaches. The field of microfluidics to address biochemical measurement problems has grown immensely across the world over the last four decades. Our laboratory experimentally entered the field of microfluidics in the early 1990s with the goal of implementing capillary electrophoresis (CE) on a microfabricated fluidic structure. These devices ultimately demonstrated excellent separative performance with 10-100 times faster results than capillary versions using sub-microliter injection volumes and laser-induced fluorescence detection. A commercial version of microchip CE was launched by Agilent in 1999 through a joint development agreement with Caliper Technologies. Fluorescence detection can be very sensitive, down to the single molecule level, and is generally applicable to biological molecules but provides little to no chemical information. Coupling chemical separations to mass spectrometry (MS) greatly enhances the chemical information that can be extracted from an experiment. The value of implementing electrospray ionization (ESI) in CE experiments was first been demonstrated in 1987. We first reported the monolithic integration of electrospray ionization on a microchip CE device in 1997, following with a refined nano-ESI version in 2008 with performance characteristics as good or better than pulled capillary ESI emitters. This design was commercially implemented in the ZipChip product launched by 908 Devices Inc. in 2016.

The Ramsey laboratory began exploring the miniaturization of MS in 1996 with a focus on ion trap mass analyzers. We realized a path to handheld MS by discovering that 1-mm scale ion traps could operate at pressures exceeding 1 Torr, or a thousand to a million times high pressure than conventional MS. High Pressure Mass Spectrometry (HPMS) greatly reduces the size, weight, and power of the vacuum system and enabled 908 Devices to launch the first commercially available handheld MS in 2014 for safety and security applications. Compact MS analyzers have also been implemented in life sciences instrumentation, e.g., the Rebel product launched by 908 Devices, which couples microchip CE to and HPMS analyzer.

This presentation will discuss the development of these technologies and their application to biological measurement problems relevant to researchers and the pharmaceutical industry.

Keynote Speaker:
J. Michael Ramsey, *University of North Carolina, Chapel Hill*

09:45-10:00 Salon A-C

CE Pharm Award

Mohamed Dawod
Presentation type: LS - Livestreamed

10:00-11:15 Salon A-C

Session I - Application and Advancements in CE Innovations

Esme Candish, Mark Lies, David Michels
Presentation type: LS - Livestreamed

Session Speakers:

Capillary Gel Electrophoresis for Gardasil and Gardasil®9 Purity Determination
Ashley Prout, *Merck & Co., Inc.*

Advancement of Capillary Gel Electrophoresis Through the Use of Native Fluorescence Detection
Jessica Taylor, *Teva Pharmaceutical Industries Ltd.*

Charge Heterogeneity Analysis of Antibody Drug Conjugates: Capillary Zone Electrophoresis
Rick Linkous, AstraZeneca

11:15-11:30 Salon A-C

Session I - Panel Discussion

Esme Candish, Mark Lies, David Michels
Presentation type: LS - Livestreamed

11:30-12:45 Foyer A-C

Lunch

Presentation type: IP - In Person

11:45-12:45 Foyer A-C

Lunch and Learn Technical Seminar Presented by SCIEX

Presentation type: LS - Livestreamed

Session Speakers:

BioPhase 8800 System: Advancing Capillary Electrophoresis With Native Fluorescence Detection
Fang Wang, *SCIEX*

Label-Free Native Fluorescence for High-Sensitivity Protein Analysis using a Multi-Capillary Electrophoresis System
Brian Wei, Sanofi

12:45-14:00 Salon A-C

Session II - CGTP – Cell and Gene Therapy

Mohamed Dawod, Tara Enda
Presentation type: LS - Livestreamed

Session Speakers:

A Tale of Tails: Using the Power of Capillary Electrophoresis for the Analytical Characterization of mRNA
Deanna Di Grandi, *Regeneron Pharmaceuticals Inc.*

Development and Optimization of a CGE-LIF Method for RNA Integrity Characterization using SCIEX 9000 RNA Kit
Yuqing Cozzens, *Pfizer, Inc.*

High-Throughput Plasmid DNA Isoform Analysis Using Capillary Gel Electrophoresis
Lisa De Martini, *Novartis Pharmaceutical Manufacturing GmbH*

14:00-14:15 Salon A-C

Session II - Panel Discussion

Mohamed Dawod, Tara Enda
Presentation type: LS - Livestreamed

14:15-14:25 Salon A-C

Partner Showcase

Presentation type: LS - Livestreamed

The following vendor partners will each present a 5-minute presentation on their company's products and services. Join to learn more about our exhibitors and how they can help better serve you and your customers.

14:25-15:00 Foyer A-C

Networking Break

Presentation type: IP - In Person

15:00-16:15 Salon A-C

Session III - Regulatory

Timothy Blanc, Jacek Cieslak, Cristina Montealegre
Presentation type: LS - Livestreamed

Session Speakers:

Reference Data for Peak Integration in Capillary Electrophoresis: Another Successful CASSS Project
Hermann Wätzig, *Technical University of Braunschweig*

Leveraging Prior Knowledge in Analytical Method Development and Validation: Regulatory Considerations for Protein Products
Bazarra Damdinsuren, CDER, FDA

Evaluating the Impact of Analytical Method Parameters on Therapeutic mRNA Integrity by Capillary Gel Electrophoresis
Huixin Lu, *Health Canada*

16:15-16:30 Salon A-C

Session III - Panel Discussion

Timothy Blanc, Jacek Cieslak, Cristina Montealegre
Presentation type: LS - Livestreamed

16:30-17:30 White Oak A

Roundtable Session I

Presentation type: IP - In Person

Table 1 - Strategies and Challenges with Peak Integration in CE

Table 2 - Communicating Issues with Capillary Electrophoresis Methods to Managment, QA, and Regulatory

Table 3 - CE/MS: Currents Trends and Applications in Biopharmaceutical Development

Table 4 - Technology Advancements in CE

Table 5 - mRNA Vaccine CE Applications

Table 6 - Forgotten CE Technologies: CGE, ITP, Affinity CE, Taylor Dispersion

Table 7 - Strategies and Qualification of Critical Reagents

Table 8 - ICH Q2(R2) and CE

Table 9 - Managing Critical Reagents for Capillary Electrophoresis Methods

Table 10 - What is the Future of Belonging in the Workplace?

17:30-18:30 Foyer A-C

Exhibitor Reception

Presentation type: IP - In Person

Tuesday, 9 September, 2025

07:30-08:20 Foyer A-C

Registration

Presentation type: IP - In Person

Registration will be open until 17:00

07:30-08:20 Foyer A-C

Breakfast

Presentation type: IP - In Person

07:45-08:15 Salon A-C

Plasmid Topology Analysis with the Agilent Fragment Analyzer System | Presented by Agilent Technologies, Inc.

Presentation type: LS - Livestreamed

Session Speaker:

Plasmid Topology Analysis with the Agilent Fragment Analyzer System
Johannes Schlecht, *Agilent Technologies Germany GmbH & Co. KG, Germany*

08:20-09:35 Salon A-C

Session IV - New Modalities

Yan He, Mark Lies
Presentation type: LS - Livestreamed

Session Speakers:

Chemotype Agnostic DAR with CE-SDS
Natalie Jones, *Pfizer, Inc.*

Separation of Virus Like Particles and Nano-Emulsions for Vaccine Development by Capillary Zone Electrophoresis
Adam Sutton, *Merck & Co., Inc.*

A Novel Derivatization-Based CGE Assay for Quantifying Free Proteins in Conjugate Vaccines
Haofu Huang, *Merck & Co., Inc.*

09:35-09:50 Salon A-C

Session IV - Panel Discusion

Yan He, Mark Lies
Presentation type: LS - Livestreamed

09:50-10:00 Salon A-C

Partner Showcase: Bio-Techne and AES

Presentation type: LS - Livestreamed
The following vendor partners will each present a 5-minute presentation on their company's products and services. Join to learn more about our exhibitors and how they can help better serve you and your customers.

10:00-10:30 Foyer A-C

Networking Break

Presentation type: IP - In Person

10:30-11:30 White Oak A

Roundtable Session II

Presentation type: IP - In Person
Table 1 - Strategies and Challenges with Peak Integration in CE

Table 2 - Communicating Issues with Capillary Electrophoresis Methods to Management, QA, and Regulatory

Table 3 - CE/MS: Currents Trends and Applications in Biopharmaceutical Development

Table 4 - Technology Advancements in CE

Table 5 - mRNA Vaccine CE Applications

Table 6 - iCIEF Peak Characterization

Table 7 - How Fast Can We Go Without Sacrificing Quality?

Table 8 - SDS-CGE and CGE Method Development and Application

Table 9 - iCIEF - Becoming the CE Expert in Your Organization – Best Practices Exchange

Table 10 - Empowering a Speak-up Culture in the Biopharmaceutical Industry: Promoting Psychological Safety

11:30-12:15 Foyer A-C

Poster Session

Presentation type: IP - In Person

12:15-13:30 Foyer A-C

Lunch

Presentation type: IP - In Person

12:30-13:30 Salon A-C

Advances in Capillary Electrophoresis for Biotherapeutic Development | Presented by Bio-techne

Presentation type: LS - Livestreamed
Advances in Capillary Electrophoresis for Biotherapeutic Development
John Orlet, *Pfizer, Inc.*
Nelly Luong, *Technical University of Braunschweig*

13:30-14:45 Salon A-C

Session V - From Peak to Shining Peak: Traversing the cIEF Landscape

Tara Enda, Kristin Schultz-Kuszak
Presentation type: LS - Livestreamed

Session Speaker:

Efficient Charge Variant Analysis of Therapeutic Antibodies Using Direct ICIEF Fractionation Combined With NanoLC-MS/MS Peptide Mapping
Yiran Liang, *Genentech, a Member of the Roche Group*

Improving ADC Sample Stability in icIEF by Altering Separation Matrix pH a Case Study
Huiyuan Li, *Bristol-Myers Squibb Company*

Protein Charge Identification Using the MauriceFlex
Aakash Patel, *AstraZeneca*

14:45-15:00 Salon A-C

Session V - Panel Discussion

Tara Enda, Kristin Schultz-Kuszak
Presentation type: LS - Livestreamed

15:00-15:30 Foyer A-C

Networking Break

Presentation type: IP - In Person

15:30-16:00 Salon A-C

Session VI - Next Generation Investigators

Timothy Blanc, Esme Candish, David Michels
Presentation type: LS - Livestreamed

Session Speakers:

Capillary Electrophoresis to Quantify Drug Inhibition of H1N1 and H5N1 Neuraminidases
Laura Taylor, *West Virginia University*

Design of a Capillary Isoelectric Focusing Electrospray Ionization-Mass Spectrometry Interface for High Resolution Proteoform Analysis
Caitlin Kerr, *Bristol-Myers Squibb Company*

Utilizing Fluorescence Detection to Improve icIEF Analysis
Gianna Pescatore, *Eli Lilly and Company*

16:00-16:15 Salon A-C

Session VI - Panel Discussion

Timothy Blanc, Esme Candish, David Michels
Presentation type: LS - Livestreamed

16:15-17:00 Salon A-C

Spotlight Talk and Q&A

Mohamed Dawod, Kathir Muthusamy
Presentation type: LS - Livestreamed

Session Speaker:

Big Data for a Deep Problem: Understanding and Predicting the Formation of DES
Carlos Garcia, *Clemson University*

Wednesday, 10 September, 2025

07:30-09:00 Foyer A-C

Registration

Presentation type: IP - In Person

Registration will be open until 14:00

08:00-09:00 Foyer A-C

Breakfast

Presentation type: IP - In Person

09:00-10:00 Salon A-C

Keynote II - CE'ing Into the Future: The Role of Capillary Electrophoresis in Innovation for Biological Products

Mohamed Dawod, Kathir Muthusamy
Presentation type: LS - Livestreamed

Keynote Speaker:

Joel Welch, *FDA, CDER*

10:00-11:00 Foyer A-C

Poster Session

Presentation type: IP - In Person

11:00-12:45 Salon A-C

Troubleshooting Workshop

Timothy Blanc, Cari Sänger van de Griend
Presentation type: LS - Livestreamed

12:45-14:00 Foyer A-C

Lunch

Presentation type: IP - In Person

13:00-14:00 Salon A-C

Unraveling Biopharmaceutical Heterogeneity with Advanced Imaged Capillary Isoelectric Focusing Methodologies | Presented by Advanced Electrophoresis Solutions Ltd.

Presentation type: LS - Livestreamed

Unraveling Biopharmaceutical Heterogeneity with Advanced Imaged Capillary Isoelectric Focusing Methodologies
Mark Lies, Advanced Electrophoresis Solutions Ltd.

14:00-14:50 Salon A-C

Session VII - CE-MS and Peak ID, Product Characterization

Göran Hübner, Bernd Moritz
Presentation type: LS - Livestreamed

Session Speakers:

High-Performance Native Separation of mAb Proteoforms by CZE-MS Under Native and Denaturing nanoESI Conditions for Ultrasensitive Charge Variant Characterization
Ann-Katrin Schwenzer, *Aalen University*

Advanced Charge Heterogeneity Profiling of Antibody Drug Conjugates via icIEF Fractionation and Mass Spectrometry
Xiaochan Zhang, *MilliporeSigma*

14:50-15:05 Salon A-C

Session VII - Panel Discussion

Göran Hübner, Bernd Moritz
Presentation type: LS - Livestreamed

15:05-15:30 Salon A-C

Closing Remarks and Invitation to CE Pharm 2026

Presentation type: LS - Livestreamed