

# CE in the Biotechnology & Pharmaceutical Industries 2023: Symposium on the Practical Applications for the Analysis of Proteins, Nucleotides & Small Molecules

Schedule

Sunday, 24 September, 2023

12:30-13:00

[Registration](#)

13:00-21:00 Room 310

[Short Course](#)

## **Applications of Capillary Electrophoresis to the Analysis of Protein Therapeutics**

This course will provide an overview of the fundamentals, modes, and selected applications of Capillary Electrophoresis (CE). The course concentrates on practical examples and case studies of the application of CE in the pharmaceutical and biotechnology industry. Although the focus is on (bio)pharmaceuticals, the principles apply for most quantitative CE methods.

The applications covered will feature current uses of CE in various areas of pharmaceutical development including process development and scale-up studies, product characterization, validated QC lot release, and QC stability testing. The main modes of CE that will be discussed include CZE, CE-SDS, CIEF, carbohydrate analysis, and CE-MS. Special attention will be paid to key operating parameters, good working practices, and daily maintenance.

After this course, you will have a good understanding on what happens inside a capillary during a CE separation. You will better appreciate what the critical method parameters are and have an increased knowledge of good working practices of CE.

Facilitator: Cari Sanger - van de Griend, *Kantisto B.V.*

Monday, 25 September, 2023

11:30-12:30 Liberty Foyer

[Registration](#)

*Registration will be open until 17:00*

11:30-12:30 Liberty Ballroom A

[Breakfast](#)

12:30-13:45 Liberty Ballroom B&C

[Keynote I](#)

Göran Hübner

## **A Journey Through Time and Electrical Field - 20 Years of Biopharmaceutical Analytics**

Maria Schwarz, *Solvias AG*

Discussion: 9:30 - 9:45

13:45-14:00 Liberty Ballroom B&C

CE Pharm Award

14:00-14:30 Liberty Ballroom A

Networking Break

14:30-16:00 Liberty Ballroom B&C

Session I: CE-MS and Product Characterization

Timothy Blanc, John Valliere-Douglass

CE-MS and Product Characterization

Session Speakers:

**Characterization of IgG1 Low Molecular Weight Variants by Correlating RPLC-MS with a CE-SDS Migration Time Shift Assay**

Nicole Langlois, *Northeastern University*

**Investigation of a Polypeptide-Cyclodextrin Interaction in Biologic Formulation Development and Assessment of its Binding Affinity Using Mobility Shift Affinity Capillary Electrophoresis**

Wenkui Lan, *Bristol Myers Squibb*

**We All Have Baggage: A Deep Dive into the Characterization of a Complex cIEF Electropherogram from an Antibody-drug Conjugate using a Novel Integrated icIEF-UV/MS System**

Kristin Schultz-Kuszek, *AstraZeneca*

Discussion 11:45 - 12:00

16:00-16:10 Liberty Ballroom B&C

Partner Showcase

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.

SCIEX: Greg Manley, *SCIEX*

Revvity: Menel Ben Frej, *Revvity*

16:10-17:45 Liberty Foyer

Lunch and Learn

Technical Seminar Presented by SCIEX: 12:25 - 13:25

**An Intact Protein MAM Workflow for Comprehensive Characterization of Charge Variants using the Intabio ZT System**

Scott Mack, *SCIEX*

**Comprehensive Characterization of the mRNA-lipid Nanoparticle by LC-MS and Multi-capillary Electrophoresis**

Jane Luo, *SCIEX*

Networking Break 13:25 - 13:45

17:45-19:15 Liberty Ballroom B&C

Session II: Gene Therapies and New Modalities Part I

Nathan Lacher, Kristin Schultz-Kuszek

**Session Speakers:**

**Development of an icIEF Assay for Monitoring AAV Capsid Proteins and Application to Gene Therapy Products**

Xiaoping He, *Pfizer, Inc.*

**Quantitation of Coxsackievirus A21 Viral Proteins in Mixtures of Empty and Full Capsids using Capillary Western**

Richard Rustandi, *Merck & Co., Inc.*

**Using Peptide Nucleic Acid Hybridization Probes for Qualitative and Quantitative Analysis of Nucleic Acid Therapeutics by Capillary Electrophoresis**

Andrei Hutanu, *Ten23*

Discussion: 15:00 - 15:15

19:15-19:25 Liberty Ballroom B&C

Partner Showcase

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.

Bio-Techne: Ed Chase, Bio-Techne

AES: Tony Chen, Advanced Electrophoresis Solutions Ltd.

19:25-20:00 Liberty Ballroom A

Networking Break

20:00-21:00 Rooms 306-308

Roundtable Session I

Table 1 - Peak Characterization - CGE , Peak Characterization CZE, Peak Characterization - CIEF

Table 2 - iCIEF - Becoming the CE Expert in Your Organization – Best Practices Exchange

Table 3 - Cell Therapy CE Applications

Table 4 - How Can We Ensure Our CE Methods Are QC Ready?

Table 5 - CE/MS: Method Development, Application and Implementation in Biopharmaceutical Development

Table 6 - Beyond the mAb – Fusion Proteins, Bispecifics, and Peptides Applications

Table 7 - Gene Therapies, Vaccine and AAV CE Applications

Table 8 - Strategies for Instrument Bridging and Instrument Replacement Implementation

Table 9 - Unaddressed Challenges & Technical Innovations

Table 10 - DEI: Unconscious Bias in the Workplace

21:00-22:00

Exhibitor Reception

Tuesday, 26 September, 2023

11:30-12:30 Liberty Foyer

Registration

*Registration will be open until 17:00*

11:30-12:30 Independence Ballroom

New Member Breakfast

11:30-12:30 Liberty Ballroom A

Breakfast

12:30-14:00 Liberty Ballroom B&C

Session III: Gene Therapies and New Modalities Part II

David Michels, Kathir Muthusamy  
Gene Therapies and New Modalities Part II

Session Speakers:

**High Throughput LabChip Purity Assessment Method for Gene Delivery Vehicles**

Anubhav Tripathi, *Brown University*

**Nucleic Acid Analysis by Capillary Gel Electrophoresis (CGE): Developing and Implementing a Multivalent Analytical Assay to Characterize and Control In-Process Mixtures of Cell Therapy Products**

Brian Roper, *Genentech*

**Development, Qualification and Understanding Spike Protein in COVID-19 Vaccine using Capillary Western Technology**

Paul Gillespie, *Merck & Co., Inc.*

Discussion: 9:45 - 10:00

14:00-14:10 Liberty Ballroom B&C

Partner Showcase

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.

CMP Scientific: James Xia, CMP Scientific  
Genovis: Laurent Rieux, Genovis, Inc.

14:10-14:45 Liberty Ballroom A

Networking Break

14:45-15:45 Rooms 306-308

Roundtable Session II

- Table 1 - What to do With Unexpected Shoulder Peaks in cIEF and CE-SDS
- Table 2 - CGE - Becoming the CE Expert in Your Organization - Best Practices Exchange
- Table 3 - Cell Therapy CE Applications
- Table 4 - How Can We Ensure Our CE Methods Are QC Ready?
- Table 5 - CE/MS: Method Development, Application and Implementation in Biopharmaceutical Development
- Table 6 - Beyond the mAb - Fusion Proteins, Bispecifics, and Peptides Applications
- Table 7 - Gene Therapies, Vaccine and AAV CE Applications
- Table 8 - Strategies for Instrument Bridging and Instrument Replacement Implementation
- Table 9 - Unaddressed Challenges & Technical Innovations
- Table 10 - DEI: Unconscious Bias in the Workplace

15:45-16:45 Independence Ballroom

Poster Session

16:45-18:30 Liberty Ballroom B&C

Lunch and Learn

Technical Seminar Presented by Bio-Techne: 13:00-14:00

Networking Break 14:00 - 14:30

18:30-20:00 Liberty Ballroom B&C

Session IV: Life Cycle Management

Tara Enda, Göran Hübner

Session Speakers:

**Case Studies in cIEF and CE-SDS Analytical Transfers in a GMP Environment**

Derek Schildt, *AstraZeneca*

**Multi-Capillary Gel Electrophoresis to Increase Throughput for the Purity Analysis of Biotherapeutic Proteins**

Theresa Merlino, *Janssen*

**ICHQ14, AQBd, Method Life Cycle Management - What Does This All Mean for My CE Method Development?**

Cari Sängler, *van de Griend*

Discussion 15:55 - 16:00

20:00-20:30 Liberty Ballroom A

Networking Break

20:30-21:30 Liberty Ballroom B&C

Emerging Professionals

Esme Candish, Mohamed Dawod

Session Speakers:

**An Assessment of a Prototype Buffer Matrix on the PA 800 Plus System for Purity and Fragment Analysis**

Vaidehi Bhagat, *AstraZeneca*

**Dual Dynamic Staining Electrophoretic Detection and Characterization of dsRNA Contaminants in mRNA Vaccines**

Adriana Coll de Peña, *Brown University*

**Development of Capillary Electrophoresis Methods for the Analysis of Cellular Metabolites for Life Detection on Ocean Worlds**

Emily Kurfman, *University of Kansas*

**Robots in Pharmaceutical Quality Control: A Comparative Study of Automated Liquid Handlers in Terms of Precision, and Usability**

Rebecca Wiesner, *Technische Universität Braunschweig*

Discussion: 17:10 - 17:30

Wednesday, 27 September, 2023

11:30-13:00 Liberty Foyer

Registration

*Registration will be open until 15:30*

11:30-13:00 Liberty Ballroom A

Breakfast

13:00-13:30 Liberty Ballroom B&C

Spotlight Talk

Nathan Lacher

**Single-Run Separation and Quantification of 14 Cannabinoids Using Capillary Electrophoresis**

Emil Zaripov, *University of Ottawa*

13:30-14:30 Independence Ballroom

Poster Session

14:30-16:00 Liberty Ballroom B&C

Troubleshooting Workshop

Timothy Blanc

Session Speaker:

Doug Johnson, *AstraZeneca*

16:00-17:00 Liberty Foyer

Hosted Lunch

17:00-18:30 Liberty Ballroom B&C

Session VI: Innovations in CE

Esme Candish, Mark Lies

Session Speakers:

**Using Digestion by IdeS Protease to Improve Quantification of Degradants in Monoclonal Antibodies by Non-Reducing Capillary Gel Electrophoresis**

Andrew McClain, *BMS*

**Characterization of Proteins Using Native and SDS Capillary Gel Electrophoresis Online Coupled to Electrospray Ionization Mass Spectrometry**

Gábor Járvas, *University of Pannonia*

**Rapid and High Throughput CE Assays of Enzyme Activity**

Lisa Holland, *West Virginia University*

Discussion: 15:30 - 15:45

18:30-18:45 Liberty Ballroom B&C

Closing Comments