

CE in the Biotechnology & Pharmaceutical Industries 2024: Symposium on the Practical Applications for the Analysis of Proteins, Nucleotides & Small Molecules

Schedule

Sunday, 15 September, 2024

08:00-09:00 Catalina Foyer

[Registration for Short Course Only](#)

Registration is open for short course attendees only until 5:00 PM.

08:00-09:00 Bristol 3

[Breakfast](#)

09:00-17:00 Bristol 3

[Short Course: Applications of Capillary Electrophoresis to the Analysis of Protein Therapeutics](#)

Tara Enda, Göran Hübner, Steffen Kiessig, Cari Sängner van de Griend

Short Course Facilitators: Cari Sängner van de Griend, *Kantisto BV*, Steffen Kiessig, *ten23 Health AG*, Göran Hübner, *Boehringer Ingelheim Pharma GmbH & Co. KG*, and Tara Enda, *Bristol-Myers Squibb Company*

Monday, 16 September, 2024

06:30-07:30

[WATCH NOW: Accelerating Biologics Analysis with the LabChip™ GXII Touch™ System](#)

This technical Seminar will be available to watch on demand 24/7 before and during the Symposium. Click on this session to access the presentation video.

NOTE: If prompted to login to view the video, enter your CASSS member credentials.

Presented by: Revvity

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07:30-08:30 Catalina Foyer

[Registration](#)

Registration will be open until 17:00

07:30-08:30 Fountain Terrace - Lobby Level

[New Member Breakfast](#)

07:30-08:30 Catalina 2

[Breakfast](#)

08:30-08:45 Catalina 1

[CASSS Welcome and Introductions](#)

08:45-10:00 Catalina 1

[Keynote I - Affinity Interactions by CE: The Western Blot and More](#)

Kristin Schultz-Kuszk

Session Chair: Kristin Schultz-Kuszk, *AstraZeneca*

Affinity interactions can be probed or utilized by separation techniques. The properties of CE such as high efficiency, fast separation, and small sample requirements enable new ways to study and use affinity in separations analysis. A classic example is western blotting. Western blotting is one of the most widely used protein assays and the lack of a miniaturized counterpart has likely held back the use of CE in routine biochemistry. We have interfaced chip separations to blotting membranes for rapid westerns. Potential for multi-protein analysis is greatly enhanced by this method. The high speed of electrophoresis allows intact non-covalent complexes to be separated and detected. This capability has been extensively used for immunoassay and aptamer assay. The former has been used to monitor living tissue samples. Protein-protein complexes involved in intracellular signaling can be analyzed to generate quantitative information on binding and selectivity. We have also demonstrated fast (< 1 s) separations of substrates and products from enzymes allowing rapid enzyme assays. The high speed of the assays suggests they could be used in HTS for drug discovery. To achieve this, we have developed a system that allows discrete samples to be rapidly loaded in sequence onto a chip for injection and separation. Using this method over 1000 injections have been achieved in 17 min. Preliminary results suggest the method is stable enough for HTS opening the door to robust HTS of protein-protein interactions and enzyme activity. While this talk will focus on reviewing these uses of CE, new directions in using fast LC for protein analysis will also be described.

Keynote Speaker:

Robert Kennedy, *University of Michigan*

[Meet CE Pharm's Keynote Speaker - Robert Kennedy](#)

10:00-10:15 Catalina 1

[CE Pharm Award](#)

10:15-11:15 Catalina 1

[Session I - Innovations in CE](#)

Mark Lies, David Michels

Session Chairs: Mark Lies, *Advanced Electrophoresis Solutions Ltd.* and David Michels, *Genentech, a Member of the Roche Group*

Session Speakers:

MS Online Coupling for Charge Heterogeneity Analysis of a Highly Glycosylated Recombinant Protein Vaccine

Xiaoxi Zhang, *Thermo Fisher Scientific Inc.*

Dual Hydrodynamic and Electrokinetic Actuation in a Capillary Assembly Enables DNA in Line Concentration and Separation

Frederic Ginot, *Adelis Tech*

11:15-11:30 Catalina 2

[Networking Break](#)

11:30-12:45 Catalina 1

Lunch and Learn Technical Seminar presented by SCIEX

Session Speakers:

Application of CGE for Purity Analysis in Cell and Gene Therapy

Ryan Hylands, *Pharmaron*

Utilizing High-Throughput Capillary Electrophoresis for Bioprocess Development Support

Brian Wei, *Sanofi*

12:45-14:15 Catalina 1

Session II - CGTP: Cell and Gene Therapy Products

Yan He, Cristina Montealegre

Session Chairs: Yan He, *Pfizer, Inc.* and Cristina Montealegre, *Solvias AG*

Session Speaker:

Comparison of CE-SDS Platforms to Quantitate Purity and Viral Protein Ratios of Adeno-associated Virus (AAV) Capsids

Kaixiang Huang, *Eli Lilly & Company*

Development and Troubleshooting of a CGE Method for Analysis of AAV Capsid Protein Purity

Gordon Freckleton, *Bristol Myers-Squibb Company*

Performance Assessment of an Improved CE Kit for Plasmid DNA Characterization in mRNA Therapeutic Development

Ryan Nai, *CSL*

14:15-14:25

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.

Greg Manley, *SCIEX*

Matthew Courtney, *Advanced Electrophoresis Solutions Ltd.*

14:25-15:00 Catalina 2

Networking Break

15:00-16:05 Catalina 1

Session III - Regulatory

Jacek Cieslak, Tara Enda

Session Chairs: Jacek Cieslak, *CDER, FDA* and Tara Enda, *Bristol-Myers Squibb Company*

Session Speakers:

Emerging Technologies – FDA Process for Collaborating with Industry Partners to Introduce New Technologies

Anjali Shukla, *CDER, FDA*

Regulatory Considerations for Early-Stage Cell and Gene Therapies

Elvira Argus, *CBER, FDA*

16:05-16:15

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Ed Chase, *Bio-Techne*

Supporting Biomolecule Analysis

Steve Siembieda, *Agilent Technologies, Inc.*

16:15-16:25 Fountain Terrace - Lobby Level

Transition Time to Roundtables

16:25-17:25 Fountain Terrace - Lobby Level

Roundtable Session I

Table 1 - Technology and application advancements in CE

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

Table 3 - iCIEF - Becoming the CE Expert in Your Organization – Best Practices Exchange

Table 4 - CE Methods and Method Robustness - DOE Designing

Table 5 - Characterization of single Peaks from CE separations

Table 6 - CE/MS: Method Development, Application and Implementation in Biopharmaceutical Development

Table 7 - Is High Throughput Always Better?

Table 8 - Role of CE for Therapeutic Nucleic Acids: Gene Therapy and Vaccines

Table 9 - Life Cycle Management of CE Technology

Table 10 - Acknowledging and Discussing Addressing Imposter Syndrome in the Biopharmaceutical Industry

17:25-18:30 Catalina 2

Exhibitor Reception

Tuesday, 17 September, 2024

06:30-07:30

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07:30-08:30 Catalina Foyer

[Registration](#)

Registration will be open until 17:00

07:30-08:30 Catalina 2

[Breakfast](#)

07:45-08:15 Catalina 1

[Breakfast Technical Seminar presented by Agilent Technologies, Inc.](#)

Grab some breakfast and join us for a technical seminar presented by Agilent Technologies, Inc.

Breakfast will be served until 8:30am

mRNA Integrity by Agilent 5300 Fragment Analyzer
Shauna Salem, *Pfizer, Inc.*

08:30-10:00 Catalina 1

[Session IV - New Modalities](#)

Steffen Kiessig, Kathir Muthusamy

Session Chairs: Steffen Kiessig, *ten23 Health AG* and Kathir Muthusamy *Regeneron Pharmaceuticals Inc.*

Session Speakers:

Establishment of Single Streamlined Automated Workflow Enabling Concurrent Execution of Fragment Analysis and Ribogreen for Assessment of Quality and Quantity of mRNA in a Single Seamless Run
Kanwal Gill, *Pfizer, Inc.*

High-Throughput Capillary Electrophoresis of Several Biopharmaceutical Modalities Using the SCIEX Biophase 8800
John Orlet, *Pfizer, Inc.*

Too Much Sugar! A Case Study for CE Development of a Complex Fusion Protein
Mark Haverick, *Merck and Co.*

10:00-10:10

Partner Showcase

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Bob Swart, *Revvity*

Maksim Sliadnev, *Lumex Instruments Canada*

10:10-10:45 Catalina 2

Networking Break

10:45-11:45 Fountain Terrace - Lobby Level

Roundtable Session II

- Table 1 - Technology and application advancements in CE
- Table 2 - CGE - Becoming the CGE Expert in Your Organization - Best Practices Exchange
- Table 3 - iCIEF - Becoming the CE Expert in Your Organization - Best Practices Exchange
- Table 4 - CE Methods and Method Robustness - DOE Designing
- Table 5 - Characterization of Single Peaks from CE Separations
- Table 6 - ICHQ14 and What it Means to CE Method Development
- Table 7 - Analytical Platform Transfer: When and How Should it Be Done?
- Table 8 - Peak Integration in CE
- Table 9 - CE-MS in Regulatory Filings
- Table 10 - Building an Inclusive Knowledge Sharing Environment

11:45-12:45 Catalina 2

Poster Session

12:45-13:00 Catalina 1

Lunch

13:00-14:00 Catalina 1

Lunch and Learn Technical Seminar presented by Advanced Electrophoresis Solutions Ltd.

Integration of CEInfinite icIEF for the Expansion of Subsequent Analysis Strategies
Gianna Pescatore, *Eli Lilly and Company* and Xiaoxi Zhang, *Thermo Fisher Scientific*

14:00-15:30

Session V - From Peak to Shining Peak: Traversing the CE-SDS Landscape

Timothy Blanc, Bernd Moritz

Session Chairs: Timothy Blanc, *Eli Lilly and Company* and Bernd Moritz, *F. Hoffmann-La Roche Ltd.*

Session Speaker:

Integration of Electropherograms in GMP Labs Under Increasing Scrutiny Due to Data Integrity Intensive Inspections

Hermann Watzig, *Braunschweig Technical University*

Optimizing a Chip-Based Capillary Electrophoresis Method for Rapid Protein Characterization

Gregory Schlobohm, *Amgen Inc.*

Sodium Dodecyl Sulfate - Capillary Agarose Gel Electrophoresis of Therapeutic Proteins: Ultrafast Separations With No Baseline Humps

Dániel Sárközy, *Applied Bioanalytics Ltd.*

15:30-15:35

Partner Showcase

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Analysis at the Speed of Life

Hampus Engstroem, *908 Devices*

15:35-16:15 Catalina 2

Networking Break

16:15-17:00 Catalina 1

Emerging Professionals

Timothy Blanc, Esme Candish

Session Chairs: Tim Blanc, *Eli Lilly and Company* and Esme Candish, *Amgen Inc.*

Session Speakers:

Universal Study Design for Instrument Updates in Pharmaceutical Release Analytics

Anne Ries, *Boehringer Ingelheim Pharma GmbH & Co. KG*

Capillary Isoelectric Focusing of Simple Liposomal Models

Pavína Dadajová, *Institute of Analytical Chemistry, Brno, Czech Republic*

Wednesday, 18 September, 2024

06:30-07:30

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07:30-09:00 Catalina Foyer

Registration

Registration will be open until 15:30

08:00-09:00 Catalina 2

Breakfast

09:00-10:15 Catalina 1

Keynote II - Proteoform-Enabled Workflows Maturing for Robust Characterization of Biopharmaceuticals and Endogenous Antibodies

Neil L. Kelleher, PhD is the Walter and Mary Glass Professor of Molecular Biosciences and professor of chemistry in the Weinberg College of Arts and Sciences at Northwestern University

[Meet the Keynote Speaker: Neil Kelleher](#)

10:15-11:15 Catalina 2

Poster Session

11:15-12:45 Catalina 1

Troubleshooting Workshop

Timothy Blanc, Cari Sanger van de Griend, Kristin Schultz-Kuszk

Hosted by:

Dr. Cari Sanger - van de Griend, *Kantisto*

Tim Blanc, *Eli Lilly and Company*

Kristin Schultz-Kuszk, *AstraZeneca*

12:45-14:00 Catalina 1

Lunch and Learn Technical Seminar presented by Bio-Techne

Latest Advances in Biotherapeutic Characterization Using Maurice and MauriceFlex icIEF Systems

Chris Heger, *Bio-Techne*, Amreen Jonas, *Mersana Therapeutics*, and Christopher Cammarata, *Janssen Research & Development*

14:00-15:30 Catalina 1

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

Esme Candish, Göran Hübner

Session Chairs: Esme Candish, *Amgen, Inc.* and Göran Hübner, *Boehringer Ingelheim Pharma GmbH & Co. KG*

Session Speakers:

Charge Variant Microheterogeneity Explored via icIEF for the Analysis of Complex Biopharmaceuticals and Biosimilarity Assessment

Sara Carillo, *NIBRT*

Reduced CE-SDS Atypical Impurity Peaks (note- investigated and Identify Common Lab Contaminants that can Manifest as Peaks in the Electropherograms

Hinnerk Saathoff, *Formycon AG. Munich, Germany*

icIEF-MS Characterization of Charge Isoforms for Biotherapeutic Products

Xiaoping He, *Pfizer, Inc.*

15:30-16:00 Catalina 1

Closing Remarks and Invitation to CE Pharm 2025