CE in the Biotechnology & Pharmaceutical Industries: 
19th Symposium on the Practical Applications for the Analysis of Proteins, Nucleotides and Small Molecules 
(CE Pharm 2017)

Symposium Co-Chairs:

Steffen Kiessig, F. Hoffmann – La Roche Ltd.
David Michels, Genentech, a Member of the Roche Group

September 17-20, 2017
Boston Park Plaza Hotel
Boston, MA

Organized by
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Welcome to CE Pharm 2017: CE in the Biotechnology and Pharmaceutical Industries: 19th Symposium on the Practical Applications for the Analysis of Proteins, Nucleotides and Small Molecules

We are pleased to welcome you to CE Pharm 2017, a symposium devoted to the practical concerns that will strengthen the use of CE within the biotechnology and pharmaceutical industries. The goal of this symposium is to provide a forum for the discussion of recent developments in the analysis and characterization of protein therapeutics, nucleotides and small molecules by CE and related techniques. The symposium will feature presentations from leading experts within industry and regulatory agencies from around the world. Applications will highlight the use of CE in various areas of product development including high-throughput screening, process development, product characterization, formulation studies, validated lot release and stability testing. Attendees will have the opportunity to discuss the use of CE with regulatory agencies. In addition, CE troubleshooting approaches will be presented and instrumentation companies will show advances in CE instruments, sensitivity and reagents. The symposium will allow for open discussions aimed at improving and increasing the use of CE for analysis of proteins, small molecules, carbohydrates, metabolites, and other molecules, with a focus on validation and qualification, new technology and QbD.

The success of this symposium will depend not only on the outstanding cast of experienced and knowledgeable speakers and workshop leaders, but also on the interactions and open discussions that take place among the attendees. We encourage you to participate wholeheartedly in the discussion sections that have been designed to stimulate the exchange of ideas and information.

We would like to thank the speakers who are generously giving their time and resources and also you for your attendance, which will make this endeavor a success.


We are thankful for the expert assistance of CASSS and the audiovisual expertise of Michael Johnstone from MJ Audio-Visual Productions. Their experience and guidance in the preparation of this symposium have been invaluable.

THE SCIENTIFIC ORGANIZING COMMITTEE

Tim Blanc, Eli Lilly and Company
François de l'Escaillé, ANALIS s.a./n.v.
Mei Han, Amgen Inc.
Göran Hübner, Boehringer Ingelheim Pharma GmbH & Co. KG
Steffen Kiessig, F. Hoffmann-La Roche Ltd. (Co-chair)
Nathan Lacher, Pfizer, Inc.
C. Mark Lies, SCIEX
Henry Luo, Regeneron Pharmaceuticals
David A. Michels, Genentech, a Member of the Roche Group (Co-chair)

SungAe Suhr Park, Samsung Bioepis
Richard Rustandi, Merck & Co., Inc.
Oscar Salas-Solano, Seattle Genetics, Inc.
Maria Schwartz, Solvias AG
Zoran Sosić, Biogen
Ewoud van Tricht, Janssen Infectious Diseases and Vaccines
Hermann Wätzig, Technical University Braunschweig
Joel Welch, CDER, FDA
**CE Pharm Award History and Qualifications**

**Objective:**
Recognize and award an individual for **sustained** and **significant** contribution to the practical application of CE to the analysis of biotechnology and pharmaceutical products.

**Qualification for Award:**

a. **Advocate for CE from biotechnology and pharmaceutical industry**

b. Technical advancement or considered as a leader in developing or implementing various CE applications, such as:
   - New CE Application for R&D
   - CE Method Qualification
   - CE Method Validation
   - CE Method Transfer

c. Technical reputation, in terms of number of presentations, publications, and patents

d. Dedication to CE Pharm meeting as speaker, tutor, poster presenter or committee member

e. Mentor, advisor and advocate of industrial-based CE practitioners in other industrial applications such as food chemistry, forensics and clinical.

Past Recipients of the "CE Pharm Award" include:

2006 - Norberto Guzman – *Johnson & Johnson*
2007 - Kevin Altria – *GlaxoSmithKline*
2008 - Anthony Chen and Wassim Nashabeh – *Genentech, Inc.*
2009 - Stacey Ma – *Genentech, Inc.*
2010 - SungAe Suhr Park – *Amgen Inc.*
2011 - Oscar Salas-Solano – *Seattle Genetics, Inc.*
2012 - Franka Kálmán – *University of Applied Sciences Western Switzerland*
2013 - András Guttman – *Northeastern University*
2014 - Michel Girard – *Health Canada*
2015 - Cari Sänger - van de Griend – *Kantisto BV*
2016 - Sarah Kennett - *CDER, FDA*
2017 - Winner will be announced Wednesday at 10:00 AM.

Do you think we are missing someone influential? Add your suggestion to the list.

**Suggestions for next year’s award can be submitted with your post-meeting evaluation.**
CASSS CE Pharm Student Travel Grants

CASSS is pleased to provide a limited number of student travel grants for students who present applicable posters at CE Pharm 2017. PhD students or post-doctoral fellows conducting research in academia or industry throughout the world are eligible.

Why you should apply:
This symposium gives insight into the current topics and issues under discussion within the pharmaceutical and biotech industry and, as such, gives attendees the opportunity to bridge between industry, academia and regulatory agencies. The presentations and workshops will be devoted to practical concerns that 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. As a participant, you will have an excellent opportunity to meet, network and participate in exchanging knowledge for mutual education with other CE practitioners.

Requirements are:
- Present a poster on a CE topic
- Proof of studentship/post-doc status
- Recommendation from the supervisor/advisor

CASSS has awarded student travel grants to the following individuals:

**Isomeric Separation of Positively Labeled N-glycans by CE-ESI-MS**
Guinevere S.M. Kammeijer, *Leiden University Medical Center, Leiden, Netherlands*

**Enhancing Microchip Electrophoresis with Embedded Fused Silica Capillary for Cellular Analysis**
Benjamin T. Mehl, *St. Louis University, St. Louis, MO USA*

**Capillary Electrophoresis of Antiperspirant Ingredients: Characterization and Quantification of Aluminum Chlorohydrates Oligomer**
Nesrine Ouadah, *IBMM, Montpellier, France*
The Scientific Organizing Committee gratefully acknowledges the following strategic partners for their generous support of this Symposium:

### Strategic Program Partners

**Platinum**
- Biogen

**Gold**
- Eli Lilly and Company
- Pfizer, Inc.

### Diamond Program Partners

- ProteinSimple, a Bio-Techne brand
- PerkinElmer

### Platinum Program Partner

- SCIEX

### Gold Program Partner

- Agilent Technologies

### Silver Program Partner

- Amgen Inc.

### Bronze Program Partner

- Sanofi
Exhibitors

908 Devices Inc.
Agilent Technologies
CMP Scientific, Corp.
PerkinElmer
ProteinSimple, a Bio-Techne brand
ProZyme
SCIEX
Thermo Fisher Scientific
The Scientific Organizing Committee gratefully acknowledges the following media for their promotional consideration of CE Pharm 2017:

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<thead>
<tr>
<th>Media Program Partners</th>
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<tbody>
<tr>
<td>American Laboratory/labcompare</td>
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<tr>
<td>American Pharmaceutical Review</td>
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<tr>
<td>The Analytical Scientist</td>
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<tr>
<td>BioProcess International</td>
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<tr>
<td>Genetic Engineering &amp; Biotechnology News</td>
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<td>International Pharmaceutical Quality</td>
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<td>separationsNOW.com</td>
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<td>Technology Networks</td>
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CE Pharm 2017
Scientific Final Program Summary

Sunday, September 17, 2017

08:30 – 09:00  Breakfast (for course attendees ONLY) in Berkeley/Clarendon

08:30 – 13:00  Registration (for course attendees ONLY) in the Ballroom Foyer

09:00 – 17:00

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>12:30 – 13:30</td>
<td>Hosted Lunch (for course attendees ONLY) in Berkeley/Clarendon</td>
</tr>
<tr>
<td>16:30 – 18:00</td>
<td>Registration CE Pharm 2017 in the Ballroom Foyer</td>
</tr>
<tr>
<td>17:00 – 19:00</td>
<td>Welcome Reception in the Statler Ballroom</td>
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</table>

Short Course in the Arlington Room
Applications of Capillary Electrophoresis to the Analysis of Protein Therapeutics
Short Course Facilitators:
David A. Michels, Genentech, a Member of the Roche Group, South San Francisco, CA USA
and Cari Sänger - van de Griend, Kantisto BV, Baarn, The Netherlands
Monday, September 18, 2017

07:30 – 18:15  **Registration** in the Ballroom Foyer

07:30 – 08:30  **Breakfast** in the Terrace Room

08:30 – 08:45  **Welcome and Introductory Comments** in the Georgian Room
   Steffen Kiessig, *F. Hoffmann-La Roche Ltd., Basel, Switzerland*

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### **Keynote I Session** in the Georgian Room

**Session Chair: David Michels, Genentech, a Member of the Roche Group, South San Francisco, CA USA**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>08:45 – 09:30</td>
<td><strong>Global Biologics Regulatory Trends: Opportunities and Challenges</strong> Wassim Nashabeh, <em>F. Hoffmann-La Roche Ltd., Basel, Switzerland</em></td>
</tr>
<tr>
<td>09:30 – 09:45</td>
<td><strong>Discussion</strong></td>
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<tr>
<td>09:45 – 10:15</td>
<td><strong>Break</strong> – Visit the Exhibits and Posters in the Terrace Room</td>
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### **Analysis of Product and Process Related Impurities Using CE Session** in the Georgian Room

**Session Chairs: Tim Blanc, Eli Lilly and Company, Branchburg, NJ USA and C. Mark Lies, SCIEX, Brea, CA USA**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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</thead>
<tbody>
<tr>
<td>10:15 – 10:40</td>
<td><strong>Characterization of Highly Basic Species of High Concentration mAb by CE and HPLC</strong> Yan He, <em>Pfizer, Inc., Chesterfield, MO USA</em></td>
</tr>
<tr>
<td>10:40 – 11:05</td>
<td><strong>Analytical Challenges Faced During the Development of a Capillary Gel Electrophoresis Method for Nanobody® Molecules</strong> Mark Anthony Haverick, <em>Merck &amp; Co., Inc., Kenilworth, NJ USA</em></td>
</tr>
<tr>
<td>11:05 – 11:30</td>
<td><strong>Chiral Purity of Amino Acids Originated from Oligopeptides</strong> Claudia Michael, <em>Solvias AG, Basel, Switzerland</em></td>
</tr>
<tr>
<td>11:30 – 11:45</td>
<td><strong>Discussion</strong></td>
</tr>
<tr>
<td>11:45 – 12:00</td>
<td><strong>Lunch for Technical Seminar Attendees</strong> – Please take lunch and return to the Georgian Room for the “Lunch and Learn”</td>
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<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>12:00 – 13:00</td>
<td><strong>Technical Seminar/Lunch and Learn</strong></td>
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**TBD**

**TBD**

*Sponsored by SCIEX*  **Georgian Room**

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Monday, September 18, 2017 continued

13:00 – 13:15  **Mini Break** – Visit the Exhibits and Posters in the Terrace Room

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>13:15</td>
<td><strong>Late Breaking Session</strong> in the Georgian Room</td>
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<tr>
<td></td>
<td>Session Chairs: Gröan Hübner, <em>Boehringer Ingelheim Pharma GmbH &amp; Co. KG, Biberach, Germany</em> and Henry Luo, <em>Regeneron Pharmaceuticals, Tarrytown, NY USA</em></td>
</tr>
<tr>
<td>13:15</td>
<td><strong>Isomeric Separation of Positively Labeled N-glycans by CE-ESI-MS</strong></td>
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<td>Guinevere Kammeijer, <em>Leiden University Medical Center, Leiden, Netherlands</em></td>
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<tr>
<td>13:40</td>
<td><strong>Novel Approaches for CE-SDS Peak Characterization – Comparison to Current Approaches and Combination with Orthogonal Methods</strong></td>
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<td>Bernd Moritz, <em>F. Hoffmann-La Roche Ltd.</em>, <em>Basel, Switzerland</em></td>
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<tr>
<td>14:05</td>
<td><strong>TBD</strong></td>
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<tr>
<td>14:30</td>
<td><strong>Discussion</strong></td>
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<tr>
<td>14:45</td>
<td><strong>Poster Session</strong> – Visit the Exhibits and Posters in the Terrace Room</td>
</tr>
<tr>
<td>16:15</td>
<td><strong>CE Pharm Partner Showcase</strong> in the Georgian Room</td>
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<tr>
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<td>Facilitator: Mei Han, <em>Amgen, Inc. South San Francisco, CA USA</em></td>
</tr>
<tr>
<td>17:05</td>
<td><strong>Workshop I: Troubleshooting</strong> in the Georgian Room</td>
</tr>
<tr>
<td></td>
<td>Workshop Facilitators: Tim Blanc, <em>Eli Lilly and Company, Branchburg, NJ USA</em> and Cari Sänger - van de Griend, <em>Kantisto BV, Baarn, Netherlands</em></td>
</tr>
<tr>
<td>18:05</td>
<td><strong>Exhibition Reception</strong> – Visit the Exhibitors in the Terrace Room</td>
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</tbody>
</table>
Tuesday, September 19, 2017

08:00 – 17:30  **Registration** in the Ballroom Foyer

07:30 – 08:30  **Breakfast** in the Terrace Room

07:30 – 08:30  **1st Time Attendee Breakfast** in Arlington

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**Keynote II Session** in the Georgian Room

Session Chair: Hermann Wätzig, *Technical University Braunschweig, Braunschweig, Germany*

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Content</th>
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</table>
| 08:30 – 09:15 | CE Enantioseparations and Application to the Determination of the Stereoisomeric Purity of Drugs  
               Gerhard Scriba, *University of Jena, Jena, Germany* |
| 09:15 – 09:30 | Discussion                                                                      |
| 09:30 – 10:00 | **Break** – Visit the Exhibits and Posters in the Terrace Room                   |

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**Deep Dive into CE Session** in the Georgian Room

Session Chairs: Maria Schwarz, *Solvias AG, Kaiseraugst, Switzerland*  
and Zoran Sosic, *Biogen, Cambridge, MA USA*

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Content</th>
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| 10:00 – 10:25 | Using SDS-Titrations Monitored by Differential Scanning Calorimetry (DSC) to Develop a Robust Non-Reduced Capillary Electrophoresis Sodium Dodecyl Sulfate (NR-CE-SDS) Method for an Atypical IgG1 MAb  
               Patricia Molina, *Genentech, a Member of the Roche Group, South San Francisco, CA USA* |
               Frederike Winkhaus, *Roche Diagnostics GmbH, Penzberg, Germany* |
| 10:50 – 11:15 | Capillary Electrophoresis of Small Molecules – Challenges and Applications  
               Roman Szucs, *Pfizer, Inc., Sandwich, United Kingdom* |
| 11:15 – 11:30 | Discussion                                                                      |
| 11:30 – 11:45 | **Lunch for Technical Seminar Attendees** – Please take lunch and return to the Georgian Room for the “Lunch and Learn” |

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Tuesday, September 19, 2017 continued

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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<tbody>
<tr>
<td>11:45 – 12:45</td>
<td>Technical Seminar/Lunch and Learn</td>
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<td>TBD</td>
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<td>Sponsored by ProteinSimple, a Bio-Techne brand</td>
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<td></td>
<td><strong>Georgian Room</strong></td>
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<tr>
<td>12:45 – 14:15</td>
<td>Poster Session - Visit the Exhibits and Posters in the Terrace Room</td>
</tr>
<tr>
<td>14:15 – 15:00</td>
<td>A QbD and CE – Speeding up or Slowing Down?</td>
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<td></td>
<td>Cari Sänger - van de Griend, Kantisto BV, Baarn, Netherlands</td>
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<tr>
<td>15:00 – 15:15</td>
<td>Discussion</td>
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<tr>
<td>15:15 – 16:15</td>
<td>Technical Seminar</td>
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<td>TBD</td>
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<td>Sponsored by PerkinElmer</td>
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<td></td>
<td><strong>Georgian Room</strong></td>
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<tr>
<td>16:15 – 16:30</td>
<td>Mini Break</td>
</tr>
<tr>
<td>16:30 – 16:55</td>
<td>Novel CZE Method for the Quantifications of Intact Adenovirus Particles – AQBd Implementation and Application</td>
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<td>Ewoud van Tricht, Janssen Infectious Diseases and Vaccines, Leiden, Netherlands</td>
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<tr>
<td>16:55 – 17:20</td>
<td>Charge-based Separation of Lipid Nanoparticles for mRNA Vaccine by Imaged Capillary Isoelectric Focusing</td>
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<td>John Loughney, Merck &amp; Co., Inc., West Point, PA USA</td>
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<tr>
<td>17:20 – 17:45</td>
<td>Identification and Quantitation of Intact Virus-like Particles of Human Papillomavirus (HPV-VLP) using Capillary Electrophoresis</td>
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<td>Virginie Bettonville, University of Liège, Liège, Belgium</td>
</tr>
</tbody>
</table>
Tuesday, September 19, 2017 continued

17:45 – 18:00  Discussion

18:00 – 19:00

**Roundtable Discussions** in Arlington/Berkeley
Wednesday, September 20, 2017

08:00 – 12:00  Registration in the Ballroom Foyer

07:30 – 08:30  Breakfast in the Terrace Room

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Regulatory Session in the Georgian Room
Session Chairs: Francois de L’Escaille, Analis R&D, Suralee, Belgium
and Oscar Salas-Solano, Seattle Genetics, Inc., Bothell, WA USA

08:30 – 08:55  TBD
TBD

08:55 – 09:20  Evaluation of New Technology for the Quality Control Laboratories
Jeffrey M. Schneiderheinze, Regeneron Pharmaceuticals, Inc.,
Rensselaer, NY USA

09:20 – 09:45  Development of Complementary Approaches Using Capillary Electrophoresis for the Evaluation and Regulation of Vaccine Product and Biologics
Simon Sauve, Health Canada, Ottawa, ON Canada

09:45 – 10:00  Discussion

10:00 – 10:15  Presentation of the CE Pharm Award

10:15 – 10:45  Break in the Terrace Room

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Hyphenated Techniques Session in the Georgian Room
Session Chairs: Gröan Hübner, Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany and Mei Han, Amgen, Inc., South San Francisco, CA USA

10:45 – 11:10  Capillary Electrophoresis-Mass Spectrometry Method Development for Biomarkers of Indoleamine 2,3-Dioxygenase
Yunan Wang, Amgen Inc., South San Francisco, CA USA

11:10 – 11:35  Microchip Electrophoresis Coupled to MS for Process Monitoring and Rapid Product Quality Determination for mAbs
Seth Marden, Biogen, Cambridge, MA USA

11:35 – 12:00  High Resolution CZE-MS Peptide Mapping with Improved Separation, Peptide Recovery, and PTM Analysis for mAbs and ADCs
Oluwatosin Dada, Seattle Genetics, Inc., Bothell, WA USA
12:00-12:15  Discussion

12:15-12:20  Closing Comments in the Georgian Room
            David A. Michels, Genentech, a Member of the Roche Group, South San Francisco, CA USA