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

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Abstract:

Capillary Gel Electrophoresis (CGE) is an analytical technique widely used in the biopharmaceutical industry for the separation and analysis of biomolecules. Join us for an interactive exchange of best practices aimed at highlighting the knowledge and skills needed to excel in CGE, overcome challenges, and drive innovation in biopharma workflows.

Attendees will discuss the most effective strategies for CGE onboarding and continuous education, ensuring that new analysts can quickly and confidently perform CGE assays. Perspectives on troubleshooting common issues such as capillary blockages, poor resolution, and unexpected results will be shared, along with practical solutions to ensure robust and reproducible assays. Participants will share examples of troubleshooting strategies for unexpected results or anomalies in CGE data, offering insights into systematic approaches to problem-solving.

The session will touch upon the latest technological advancements in CGE and the future innovations needed to further enhance its capabilities. Attendees will explore emerging biopharma trends and technologies that hold promise for the future of CGE, encouraging participants to stay ahead of the curve in this evolving field.

This roundtable aims to provide a comprehensive overview of CGE, focusing on effective training strategies, troubleshooting common issues, and exploring future innovations in CGE technology.

Questions for discussion:

Training

1. What are the most effective strategies to train and mentor new team members to become proficient in CGE?

2. Can you share some best practices for maintaining and cleaning CGE equipment to ensure consistent performance?

3. How do you ensure the robustness and reproducibility of CGE methods in routine analysis?

Troubleshooting

1. What are the most common technical issues encountered during CGE analysis, and practical solutions to resolve?

2. What steps can be taken to troubleshoot and correct poor resolution or peak shape in CGE?

3. Can you share examples of troubleshooting strategies for unexpected results or anomalies in CGE data?

Data Interpretation

1. What are the critical aspects to consider when interpreting CGE data?

2. How do you differentiate between true peaks and artifacts in CGE electropherograms?

Advanced Applications and Innovations:

1. What are the latest technological advancements in CGE you have applied?

2. What future CGE innovations are needed?

Notes:

1. Training and Mentorship
   - Implement a buddy system for more focused training (smaller groups)
   - Conduct lunch and learn seminars to increase awareness
   - Utilize application notes from vendor sites as training resources

2. Best Practices
   a. Equipment Handling
      - Proper training on cutting capillaries
      - Option to use pre-cut capillaries (more robust but expensive)
      - Assign a dedicated group for capillary cutting

   b. Maintenance and Cleaning
      - Emphasize the importance of equipment cleaning and maintenance
      - Focus on injector cleaning, especially for PA800 systems due to scalloping issues
      - Utilize SCIEX videos for cleaning instructions
      - Implement and document cleaning schedules in Test Methods.

3. Method Optimization and Challenges

- Address the difficulty of CGE method optimization compared to HPLC

- Sensitivity issues especially with regards to Clips. Limited scope to improve sensitivity by increasing concentration due to capillary space constraints.

- Need for a wider range of gels to accommodate various sizing needs

- Call for vendors to develop gels with different percentages for broader applications

4. Data Analysis and Integration & Cross-industrial Standardization

- Address the industry-wide issue of peak integrations

- Proposal for cross industrial collaboration to share databases of reference materials with integrations

- Work towards establishing a unified approach for peak integration

- Address issues with training personnel on Empower software, particularly for integrations

-- Expert Intelligence Company (https://www.expertintelligence.ai) is calling for industry collaborators to assess the automated processing methods

-References:

-Session V - From Peak to Shining Peak: Traversing the CE-SDS Landscape- Integration of Electropherograms in GMP Labs Under Increasing Scrutiny Due to Data Integrity Intensive Inspections by Hermann Watzig, Braunschweig Technical University

-Troubleshooting Workshop hosted by Timothy Blanc (Eli Lilly and Company) & Dr. Cari Sänger – van de Griend, Kantisto

5. Specific Technical Considerations

- Chromeo Dye: Signal variation upon reinjection

- Consider quenching effects of different dyes

- Emphasize the importance of adequate aperture selection

6. Automation and Technological Advancements

- Automation in sample preparation can greatly enhance reproducibility and efficiency in CGE analyses

- Consider the impact of automation on training requirements and workflow efficiency,

- Reference: Session IV - New Modalities

- 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