Table 8: CE Data Processing - Success Stories and Needed Improvements

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Scope:

Capillary electrophoresis ("CE") is a powerful analytical and investigatory tool commonly found in both academic and industrial biochemical facilities. By separating material based on charge, size or both, CE provides analysts with succinct and actionable information about numerous aspects of the molecule in question. Just as the hardware behind CE assays are under constant development, the software tools and analyst proficiency must follow suit. This is no easy task; from new software packages to preferential data handling techniques, staying current with CE instrumentation and methods is a daunting challenge. However, although the assay relies on separation, there is no reason we must remain separated ourselves. Whether you specialize in evaluating charge variants or subunits, or you work with intact biotherapeutic proteins or small molecules, come join the conversation as we discuss CE hardware and software tips, tricks, and welcomed improvements.

Discussion Notes:

1. What data processing challenges are you currently facing?

    a. Technical difficulties – "glitches and hiccups"

    b. Manual integration of low-level species – fragments, etc

        i. Software ability and analyst proficiency/consistency between sites

        ii. "Analysts do not always understand the full capabilities of Empower"

2. Do you like using CE manufacturer's software or third-party like Empower, Chromeleon, etc?

    a. Empower is the favorite

    b. 32karat and Chromeleon used for some molecules, but transitioning to Empower

3. Training new software users in a "virtual environment"

    a. Pre-COVID, all training was hands-on. Now, lots of teams meetings

    b. Strategies that work for virtual software training:

        i. Multiple meetings/reviews

        ii. Formal documentation for reference

        iii. Ensuring that the person being trained is the one "making the clicks"

       iv.   Lots of practice!

       v.   Incorporate a post-training follow up

4. What brought you to this table? Was there something specific you wanted to discuss?

    a. Data integration: "How do we remain consistent with our integration across systems?"

       i.   Wavy baselines, analyst proficiency, differing software packages, etc

       ii.   Transitioning to Empower

5. If you had one wish for your software, what would it be?

    a. More accessible/digestible training and reference materials

    b. Being able to make more visually-appealing data reports in Empower to pass along to QC labs

6. Challenges of integrating orthogonal data with CE

    a. Differing sites may not have equivalent software programs

       i.   Potential concerns from a regulatory perspective

    b. Analyst-to-analyst consistency

       i.   Ensuring data processing methods are robust is essential

    c. Automation of data-processing workflows

7. What can vendors do to assist with automation workflows?

    a. Comparisons of autointegrations between data-processing software packages (Empower vs 32karat, etc)