**Strategies-Instrument Bridging & Replacement Implementation**

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**Abstract:**

As technologies advance rapidly with innovations and scientific breakthroughs, lab instrumentation has expanded its scope and functionality tremendously, making new assays or sophisticated analyses that were once wishful thinking a reality. The world of CE is certainly among one of the most benefited. However, while we embrace a greater capacity and/or easiness of using these new lab instruments, we often encounter challenges in trying to bridge gaps between the established practices with current standard equipment and the next-gen of powerful new instruments.

Mentioned here are just a few examples from familiar lab practices. First, ProteinSimple's next-gen Maurice is being implemented to replace the current industrial goldstandard iCE (icIEF) instrument, the iCE3, in many universities and pharma companies. The new instruments provide quick, easy, intuitive operation, and a dual capability of doing charge and size analyses on one single instrument. However, seamlessly replacing benchmark instrumentation requires careful planning and experimental data-based documentation to bridge knowledge and quality gaps between iCE3 and Maurice before a full implementation can be reached, especially in a GMP environment.

Another example is SCIEX's icIEF instrument Intabio, which offers direct online coupling capability with mass spectrometry, allowing identity characterization of separated charge species. Also, from SCIEX, there is a new CE platform that is gaining momentum in the Biopharma industry, the BioPhase 8800 system. BioPhase is the next generation CE after PA 800 plus, a multicapillary instrument equipped with both UV and LIF detection and a complete suite of applications helping analysts tackle not only the everyday challenges of analytical development, but the throughput bottle necks form upstream bioprocessing.

The main focus of this round table is to discuss strategy for implementation of such new instrumentation from a more practical aspect, as well to serve as an experience sharing platform, so that we will all be better prepared to adapt to the new instrumentation and maximize its functionality.

**Discussion Questions and Notes:**

1. Take the ProteinSimple example of iCE3 transitioning to Maurice, share your experiences or expectations in bridging the two generations of iCE instruments and challenges in implementing the Maurice.

2. What are some benefits/challenges of coupling CE technology with mass spectrometry either directly online or through fractionation with subsequent CE-MS or LC-MS characterization for charge or size species?

3. What are some of the major challenges in implementing a new instrument or replacing an old, in general or from your own personal experiences?

4. What other technological frontiers in CE instrumentation evaluation, bridging and implementation have you explored?

Topic 1. On the transition from iCE3 to Maurice

Protein Simple conducted a round-robin with 23 companies worldwide, generating data on both platforms to show data comparability and ensure transition. Even though the study successfully demonstrated comparability between the two platforms, it serves as a base for a more in-depth internal study.

The company adopting the replacement still has substantial work, costing millions of dollars in reagent, time, samples and manpower. The process can take several years to complete. Especially because regulatory agencies will require new filings for commercial products.

Janssen has over 100 molecules in dozens of countries that show identical results in other platforms.

They must demonstrate comparable data on the same molecule on two different platforms. As regulatory agencies require, a stability study is part of the evidence package for equivalency results for 2 platforms or other technologies.

Pfizer picks early and late-stage samples and different modalities to test platform and molecule-specific methods. These molecules are typically representative of 80% of the molecules they have. The goal is to show no significant impact from the technology on overall data.

In some cases, it is possible to have both platforms in transition

What a vendor can do to simplify the transition

1. The new platform shall have the same reagents
2. The new platform shall have the same system suitability

Removing a reagent, modifying it or even obsoleting it, the vendor is forcing the end-user to re-evaluate and re-assess resolutions, migration time, methods, system suitability parameters

Topic 2. Benefits of coupling CE to MS

Today's technologies show a much-improved profile comparison to cIEF-UV than earlier technologies.

Adopting a dedicated MS for a CE like the Intabio system is challenging.

SW control is essential to be the same for all platforms. Intabio needs SCIEX-OS, which is challenging to adopt.

Are you bridging cIEF to CZE? What are the limitations to moving to CZE? CZE is generally challenging because of the basic and acidic variant resolution and pI values. Also, there is resistance to adoption if a platform brings little benefit to the end-user needs.

Vendor SW typically has shortcomings with regulatory tools. That's why we need Empower.

Quality/regulatory have requirements that sw vendors will hardly comply with: audit trails, redundancies, and central back-ups.

iCE has 21CFR part 11 tools for compliance. However, when using Compass on Maurice, the data is not on the central server, and that's a problem.

In GMP environment, SW is the major hurdle to overcome from the quality/regulatory standpoint.

In non-GMP environments, data-based evidence is required to adopt a new platform.