Becoming the CE Expert in Your Organization – Best Practices Exchange

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Abstract

Imaged capillary isoelectric focusing, or iCIEF, is a commonly used method across the biopharmaceutical industry for charge variant analysis as it separates proteins by their isoelectric point (pI). Poorly resolved shoulders, spike peaks, peak splitting, and repeatability are all issues that analysts face when running iCIEF. When these issues arise, are you the individual that everyone approaches? If so, think about when this began occurring and what led to this. If not, think about what would be required to become a iCIEF superstar. While iCIEF is commonly used in development and quality control laboratories world-wide by analysts with varying levels of experience, true expertise in this area is not as common as you might think. This roundtable will focus on the means to become a iCIEF expert by sharing best practices, methods of learning and training, and common experiences.

Discussion Questions

1. How would one go about mentoring someone in becoming an iCIEF expert?
2. What are some of the best tools/trainings available to learn iCIEF (online, books, vendors, etc.)?
3. What are some of the most beneficial ways of learning iCIEF best practices, pitfalls, etc.?
4. What is most difficult in becoming an expert in iCIEF?

Notes:

If I were to ask you to rank your expert level from 0-10, where would you place yourself?

- Largely binary grouping of 0 or 5, with a few experts indicating ~7.

1. How would one go about mentoring someone in becoming an iCIEF expert?

- Get a new analyst in lab with the expectation that they perform the assay several times to get comfortable with methods, data processing. After that, introduce the analyst to development work, bring them in on project-related SME duties with gradual exposure.
- You may find that some analysts want to learn to perform the assay first, then ask questions later, while some will delve into theory with many questions before running.
- Some trainers will instruct new analysts to read through theory or other documentation, then then go through the technique.
- Some users suggest keeping instrument information/how-to guides near the instrument so that easily accessible.
- Agreed that is instrument maintenance is critical to technical expertise. Along with that, introducing new inexperienced users (i.e. contractors) may lead to observed wear-and-tear.
- Consensus that learning takes years, so an analyst should give themself time to grow.

2. What are some of the best tools/trainings available to learn iCIEF (online, books, vendors, etc.)?

- Internal slide decks and presentations addressing how/why use of this technique.
- Vendor notes for straightforward guides
- Vendor training “academies”, i.e. SCIEX Now Learning Hub
- Vendor-provided training courses, often led by field applications scientists

2b. For those who are more experienced in their role, how long did it take you to become an “expert”?

- Answer 1: 2-2.5 years, self-taught for a majority things
- Answer 2: 1 year – many hours with service engineers due to being an early Maurice adopter. Development work can provide opportunities for deeper understanding.
- Answer 3: 2-3 years, but time was spent working on many different technologies beyond just icIEF.

3. What are some of the most beneficial ways of learning iCIEF best practices, pitfalls, etc.?

- Failed experiments are integral in asking why to build expertise.
- Suggestion to document challenges that come up thoroughly and format in a troubleshooting guide.
- Changing parameters one factor at a time can help to understand impact of method parameters, time permitting.
- Comment made that platform methods take away from knowledge-gaining opportunities for novice scientists.

4. What was the most difficult aspect in becoming an expert?

- Learning to troubleshoot an assay.
- Building confidence when not trained in an analytical field.
- Learning everything with one modality (e.g. mAbs), then being asked to quickly pivot to a new, unfamiliar application.

5. What are some of the challenges with communicating results or data to non-experts?

- Reporting relative standard deviation (RSD): acidic peaks can be small, variability is magnified for even low variability. This can seem concerning.
- Discussion surrounding electropherogram appearance using, e.g. Sciex PA800+ vs Maurice. Check for differences in smoothing algorithm usage, emphasize the LOQ, or consider not presenting electropherograms without a particular purpose in-mind.
- Capturing method variability – it can be challenging to communicate what is a real change vs. what is inherent to the method in use.
    - Suggestion to maintain longitudinal data sets showing trending for system suitability samples.

Additional tips about maintenance…

- Some instruments can require a lot of routine maintenance, so rinsing and cleaning are important for quality and longevity.
- If a clog is observed with Maurice, soaking the capillary inlet in warm water can loosen clogs.
- Question re: capillary and ampholyte lot-to-lot variability. It is not uncommon for different lots to perform with a degree of variability, but proper marker use mitigate many problems.
- Empower driver integration can introduce challenges when assigning marker peaks, versus using Compass to assign markers and exporting (where they can be simply edited in the software).