Table 4: iCIEF - Becoming the CE Expert in Your Organization – Best Practices Exchange

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Scope:

iCIEF has become a stable in any analytical and process development laboratory to characterize complex biopharmaceutical products. However, there is a wealth of knowledge that may go unwritten in an SOP that makes this assay successful across users, instruments, and geographies. This roundtable aims to discuss what is this knowledge and the best practices to exchange this knowledge. Best practices may require internal user meetings, internal symposia, vendor sponsored user events. In the spirit of collaboration and cooperation, how to enable one to become a CE Expert in the organization?

Questions for Discussion:

1. What challenges currently exist for a successful iCIEF assay?
2. What challenges currently exist for a new user to become an expert in iCIEF?
3. Are there any gaps around training and troubleshooting?
4. What challenges currently exist to keep one from becoming an expert in iCIEF?
5. Are there sufficient literature or descriptive user manuals available to guide the new users? Are there guides comprehensive enough?
6. Are there tools/online assistance available to help interpret the data and refine the assays?
7. Are there sufficient information sessions available to share novel improvements to the systems?

Discussion Notes:

There are several difficulties faced by a new iciEF user. This is mainly due to gaps in knowledge between the experts and the new users. Following as the key takeaways from our discussion to overcome this knowledge gap.

- After developing an assay, if it's not properly documented by the former members, new staff members must start over. So, good documentation would save time and help new users to handle the work.
- Updating the established protocols timely helps to keep all the protocols UpToDate.
- New users have difficulties when the existing SOPs doesn't document when an experiment is acceptable and when it's not, and missing information in SOPs such as

level of impurities, reliable concentration ranges etc. Therefore, including detailed information is helpful.

- The protocols that are in use need to be optimized for currently available reagents and instruments .
- New users have technical and hardware selection difficulties when following a protocol. It's good to document best practices knowledge together with the protocol.
    - Sample vial selection
    - Temperature control during an experiment
    - Quality issues with the reagents and cartridges
    - Instrument maintenance
- Initiate a forum within the group or the company of IEF users to start troubleshooting and the share knowledge.