Table 5: Collaborations and Instrumentation Development

Facilitator: Thomas Niedringhaus, *Genentech, a Member of the Roche Group, South San Francisco, CA United States*

Scribe: Nathan Lacher, *Pfizer, Inc. Chesterfield, MO United States*

Scope:
Capillary electrophoresis (CE) methods have become an increasingly essential part of the analytical control strategy throughout the biopharmaceutical industry. Over time, the CE instrumentation that is used in these methods have evolved to incorporate automation, improved separation efficiency, low sample requirements, fast analysis times, and the ability to identify peaks with the coupling of CE to mass spectrometry (MS). The improvements to CE instrumentation over the years have been the direct result of ongoing dialog and collaborations between instrument vendors and the end users, analytical groups within the biopharmaceutical industry.

The goal of this roundtable discussion is to connect vendors of CE instrumentation with the end users in Biopharma analytical groups in an effort to devise improved collaboration practices. There will be a focus on discussing the types of collaborations and the corresponding objectives and value. In addition, participants will examine avenues for securing resources as well as key information and materials needed to attain a successful collaboration that results in highly-impactful next-generation CE instrumentation.

Questions for Discussion:

1. What types of collaborations are you interested in, and what are the objectives of these collaborations? Cost reduction, quality improvement (e.g. vendor product optimization), new methodology, new product offerings, etc.
2. How do we overcome barriers to achieving successful collaborations? Resource deployment such as vendor access to new therapeutics, internal focus, project priorities, etc.
3. What mechanisms should be in place to safeguard critical information but not restrict innovation? Who owns the IP? Individual party or shared?
4. What mutual values between two parties can be achieved from these collaborations?
5. Should the new product from a collaboration be developed as a custom solution for a single company or be made available to other companies within the industry?

Discussion Notes:

What Types of collaborations?

- Vendors focus on collaborations with academia and Biopharm to continue to keep their products current. Vendors try to develop solutions for pain points that exist within pharma. If the solution proposed by vendors is not quite there, they would like help from pharma to make sure the developments solve the problem. The size of the pharm company does not impact the willingness of the vendor to collaborate with a pharm company. Vendors take customer feedback to determine what products they will focus their efforts on.

- Pharma - there is an interest to collaborate with vendors to develop instrumentation, kits, columns, etc to solve new issues that are encountered when companies move away from standard mAbs (ADCs, vaccines, gene therapy, cell therapy, etc). There is continued interest to characterize charge-based separations with more of a focus on direct analysis.

- Collaborations can really be in two forms:
    - Custom – whereby pharma pays for development and technology will specifically only go to that company. Have sole access or exclusivity for a given period of time can be advantageous allow pharm to block others from getting regulatory product approval
    - General developments – vendors/pharma collaborate at no cost to advance technology for the greater good of industry

Barriers?

- Legal – legal can be a challenge to ensure wording is right. Legal within Pharm generally want to use their template for agreements. Important to make sure the scope is adequately defined. In general

- Pandemic- Resources are definitely constrained as a result of the pandemic. Many companies are only operating at 50% occupancy within their labs. This makes it challenging to get all the work done to advance the portfolio. In this situation there will generally not be resources available for technology evaluation/development.

- Resources- instrument vendors generally don't reach out for collaborations if they don't have the resources internally to do the heavy lifting for the collaboration.

- Sample- sample availability can be a problem. Pharma legal may not allow real-world samples to be supplied to vendors. Alternatively, new modalities such as Gene Therapy have low process yields which makes it difficult to even do technology development within Pharma. In these situations, Pharma will not have any material to supply to vendors. Some newer modalities such as Gene Therapy can be obtained from CMOs that sell different serotypes of AAV that could be used for development purposes.