

Roundtable Session 2 – Table 1 – Applications of AI for Bioassays

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Abstract:

Artificial Intelligence (AI) is a rapidly growing field with innumerable applications in biopharmaceutical development. One key area within biopharmaceutical development that has the potential to benefit from AI is the establishment of the assay used for assessing product potency. During assay development, whether it be a cell-based or non cell-based assay, numerous parameters are assessed with the ultimate outcome being the establishment of the potency assay.

Below are a few questions to stimulate our conversation when thinking about the potential power of AI applications for bioassays. Bring your questions to further help fuel this roundtable discussion!

Discussion Questions:

1. What applications of AI and Generative AI could benefit the process for developing the potency assay for product lot release and stability testing?
2. How much will prior knowledge regarding the assays developed at your company play a role?

Notes:

- **Method Development:** AI can assist in method development by providing options and ideas based on specific parameters. AI can also be used for statistical analysis, although human validation is still necessary. It can help identify and support time-consuming tasks like data mining for troubleshooting purposes.
- **Streamlining Potency Assays:** The possibility of streamlining potency assays using AI was discussed through shared media formulations, consumables, cell lines (when applicable), equipment, and assay format. AI could be used for scientific/SOP writing, language checks, although it is not always dependable. AI may be able to analyze data from a proceduralized, searchable data lake with real-time trending, but often times there are numerous data sources from which these data need to be accessed.
- **Automation vs AI:** It is important to differentiate between automation and AI. AI is constantly learning and evolving and is only as strong as the data provided to it. It is important to be specific when asking AI questions. There are compliance issues with proprietary information and security around shared data.
- **Real-Time Monitoring:** AI could perform real-time monitoring to keep an eye on trends and changes in critical reagent lots, equipment, analyst performance, etc. It could also

be used for monitoring cell maintenance parameters such as passaging, viability, and doubling time to ensure sufficient cell performance when used in an assay. AI can assist in method development by providing options and ideas based on specific parameters.