

Roundtable Session 1 – 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:

- **AI and Automation:** There was a strong emphasis on using AI and automation to drive digital transformation, particularly in automating data review. This could help reduce human errors and improve efficiency. AI is constantly learning and evolving.
- **Standardization and Method Development:** Participants discussed the possibility of standardizing platforms and using AI to generate design of experiments (DOE) based on previous data. This could streamline assay development and leverage AI for future method development. Method remediation was also discussed using AI to leverage historical data and recommend areas of improvement. Is it possible to correlate certain method parameters to get to a desired state?
- **Predictive and Troubleshooting Capabilities:** AI's ability to predict stability study outcomes and troubleshoot assay/sample failures was highlighted as a significant benefit. Real-time monitoring and trend analysis using AI were also considered valuable.
- **Risk Assessments and Regulatory Compliance:** The importance of conducting risk assessments and ensuring regulatory compliance was noted. Legal considerations were mentioned, emphasizing caution in AI applications.

- **Efficiency and Data Utilization:** The session explored ways to build efficiency throughout the product lifecycle using AI. Leveraging clinical data to inform future testing and method development was discussed.
- **Challenges and Caution:** Participants acknowledged challenges such as proprietary data and the need for careful use of AI. The balance between teaching AI and guiding its outputs was considered crucial. In addition, there are various systems that need to share information with one another.