Roundtable Session 1 – Table 14 – Applications of Artificial Intelligence / Machine Learning and Automation

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Abstract:

The integration of Artificial Intelligence (AI), Machine Learning (ML), and automation into biopharmaceutical development and manufacturing presents a transformative opportunity to enhance product quality, improve efficiency, and drive innovation. By leveraging these technologies, companies can better harness data, gain deeper insights, and automate complex tasks across the product lifecycle—from early development to commercial production. The potential applications range from optimizing process controls, predictive maintenance, and real-time monitoring, to refining quality by design (QbD) initiatives and supporting decision-making in regulatory submissions.

However, significant challenges remain. Successfully deploying AI/ML and automation involves overcoming barriers related to model validation, data integrity, regulatory expectations, and cross-functional alignment. Regulatory guidance on the use of AI/ML in a GMP setting is still emerging, raising questions about compliance, traceability, and long-term viability of these models. As the biopharmaceutical industry embraces these advancements, there is a need for shared knowledge on best practices, addressing both technical and regulatory hurdles, and understanding how to integrate AI/ML and automation as part of an overarching control strategy.

This roundtable will focus on exploring practical experiences, successes, and challenges in applying AI/ML and automation to biopharmaceutical manufacturing. Participants will engage in discussions on implementation strategies, model validation, regulatory considerations, and lessons learned in order to collaboratively shape the future of these technologies in our industry.

Discussion Questions:

How is your organization currently leveraging AI/ML? What have been the primary drivers and barriers to implementation?

In what ways has automation impacted quality and process control in your organization? How have you measured improvements or outcomes?

How does your organization validate/plan to validate AI/ML models for use in a GMP environment? What are the key considerations for ensuring model reliability and regulatory compliance?

What are the most significant data integrity and security challenges associated with implementing AI/ML and automation, and how have you addressed them?

How do you foresee AI/ML and automation evolving in the biopharmaceutical space, and what emerging trends or technologies are you most interested in exploring?

Notes:

Attendees represented a wide-range from software providers/vendors of various sorts, media, and individuals in biotech/pharma with applications from connectivity of analytical instruments to LIMS and document generation.

Often the question is how can we use AI to do something “better” and the answer really depends on the use case / application (eg. is it greater insight or is it greater efficiency?)

Wide ranging applications – eg. using OpenAI to do authoring of regulatory content to using ML for interpretation of data (eg. NGS data) for cell line selection

Workforce development – most folks are not trained, eg. are not expert at prompt engineering

LLMs are non-deterministic – the output of different LLMs are always different, and dealing with reproducibility depending on prompts is still a learning exercise.

Quality experimenting with graphs to connect and to visualize trends and events, not currently for GMP but eventually maybe (eg. connect an event to an SOP to a deviation). Namely a QA application of AI/ML to look for signals that might not otherwise be detected. Eg. can use semantic similarity using an LLM to pull out those connections.

Issue potentially of patentability of manufacturing processes that use AI/ML as part of the control. (because of the ownership of the AI that was used)

Putting IR (RFI, query, RTQ) responses into a data lake (historical information) and then using that to train (refine) the LLM for automated authoring. The labor-intensive part was tagging the initial “dataset” of the data lake to give context (metadata). You have to classify the data into relevant buckets to make it meaningful. And that takes data scientists who understand the data in order to label it first. Versus taking an existing LLM that was trained already but the training set may not have been relevant, so this is more like a targeted refinement.

Can also use AI for prompt engineering, more like using prior knowledge to “train” for prompt engineering.

Issue of informational retrieval using, for example, a basic “RAG” (retrieval augmented generation) system to then feed into the AI, is part of the challenge. So improving how the AI retrieves the information from which it will build the output can improve output.

Adding “guiderails” that use the right metadata augments and ensures that the AI is retrieving the right starting information.

Another application is using an LLM to retrieve (search) prior knowledge. The accuracy of the product depends on writing the prompts well and specifically. How do you deal with the changing ontologies across prior knowledge? How do you deal with that LLM’s cannot interpret data graphs?

One firm started with public literature published only by that one particular firm.

A totally different application example was automation of airborne particle count analysis. Can use that for monitoring of operators and enhance training. Or detect anomalies and correlate with operator actions. Also just understanding workflows and improving efficiencies in how people work.

Application of AI in quality control setting, eg. connecting an OOS subvisible particle result to root cause. Image analysis - - AI trained on subvisible particle image analysis to distinguish silicone oil droplets from protein aggregates.

Similar application to visual inspection. Issue is that often the AI behind image analysis is a “black box” and it gets down to the pixel level but the explainability is rather low.

Applications to supply chain analysis.

Major concern with hallucinations. The critical aspect is then to do the prompt engineering to reduce the probability of hallucination, to ensure the answer that you get is appropriate and accurate.