BLA REGULATORY

PHARMAFOCUS

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About Us

BLA Regulatory is located in the State of Maryland, conveniently close to the FDA's headquarters. We offer U.S. agent services for all types of FDA-regulated products, including drugs, cosmetics, medical devices, and more. Our team can guide you through the entire application and registration process to ensure FDA compliance. Please visit our office website for more information or if you need any assistance.

Navigating the Future: AI in the Drug Product Life Cycle and Regulatory Landscape

The use of artificial intelligence (AI) in the drug product life cycle has increased significantly in recent years, offering the potential to accelerate drug development and enhance patient care. AI is increasingly utilized in the biopharma industry, contributing to regulatory sciences such as reducing animal studies, predictive modelling, integrating diverse data sources, analysing large datasets, identifying post-marketing adverse drug experiences, and optimizing manufacturing conditions. However, the implementation of AI presents unique challenges, including concerns about data quality, bias, and model reliability. The complexity of AI models can make it difficult to understand how they function and interpret their results, underscoring the need for transparency.

In January 2025, FDA issued a new guidance: Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products: Draft Guidance for Industry and Other Interested Parties, that addresses key considerations for the use of AI throughout the drug product life cycle. It proposes a risk-based credibility assessment framework for evaluating AI models and emphasizes the importance of maintaining the credibility of AI outputs across the product life cycle. It outlines multiple avenues for sponsors and other stakeholders to engage with the FDA regarding AI model development.

Risk-Based Credibility Assessment Framework

The framework provides a seven-step process for evaluating the credibility of AI model outputs in drug product as listed below:

1. Defining the questions the AI model will address,
2. Determining its context of use (COU),
3. Assessing associated risks,
4. Developing a credibility assessment plan,
5. Executing the plan,
6. Documenting results and any deviations,
7. Determining the model's adequacy for its COU.

This structured approach ensures that AI models are properly validated for regulatory decisions throughout the drug product life cycle.

Life Cycle Maintenance of AI Models

This life cycle maintenance process of drug development is critical, as a model's performance may change over time or across different deployment environments. For AI models used in drug manufacturing, continuous monitoring is essential to ensure their ongoing effectiveness, as they may be sensitive to input variations. A risk-based approach is recommended for assessing the impact of changes, with oversight proportionate to the model's risk and context of use. This approach involves evaluating changes in model performance and making necessary adjustments, such as retraining or retesting the model. Additionally, life cycle maintenance plans should be integrated into the pharmaceutical quality system and included in marketing applications.

Early Engagement with Sponsors and Stakeholders

The FDA encourages early engagement with sponsors and stakeholders to set expectations for AI model credibility assessment activities, based on model risk and context of use (COU), and to identify potential challenges and solutions. Sponsors can engage with the Agency through formal meetings depending on the AI model's intended use.

Additional Engagement Options with the FDA

In addition to formal meetings, sponsors have various engagement options with the FDA based on the intended use of the AI model. These include

1. The Center for Clinical Trial Innovation (C3TI)
2. The Complex Innovative Trial Design Meeting Program (CID)
3. Drug Development Tools (DDTs)
4. Innovative Science and Technology Approaches for New Drugs (ISTAND)
5. The Digital Health Technologies (DHTs) Program
6. The Emerging Drug Safety Technology Program (EDSTP)
7. CDER's Emerging Technology Program (ETP)
8. CBER's Advanced Technologies Team (CATT)
9. The Model-Informed Drug Development Paired Meeting Program (MIDD)
10. The Real-World Evidence (RWE) Program

Example of application of AI in drug development: Defining the question of interest and the Context of Use (CoU) for the AI Model during use of AI in drug development-Commercial Manufacturing of a Drug:

Drug A is an injectable medication dispensed from a multidose vial, and its fill volume is critical for release. The manufacturer proposes using an AI-based visual analysis system for automated, 100% fill level assessment to improve performance and detect any deviations. The central question in this case is: Do the vials of Drug A meet the required fill volume specifications?

To answer the question, various types of evidence may be used, including in vitro testing, animal studies, clinical trials, or manufacturing validation, along with data from the AI model.

In the manufacturing example for Drug A, an AI model will analyze visual images of vials to detect fill volume deviations. However, independent verification of the fill volume on a representative sample will still be conducted as part of release testing. Thus, the AI model will not be the sole factor in determining product release, defining its scope and context of use (COU).