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## Introduction

The xBxBio application is a predictive modeling engine for drug discovery and development. It is facilitated by the innovative and proprietary data mining and assemblage technology based on structure and chemical properties, both from predictive Software, empirical data, and published data to develop a multidimensional modeling system to improve the accuracy of the model and, in turn, increase successes designing new pharmaceutical agents and applications.

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In order to allow customers of xBxBio to utilize the data and results from xBxBio to support drug development and clinical trials, and to minimize the time and burden on customers to validate the system prior to deployment, the application shall be developed to meet the highest quality standard and comply with all requirements from global regulatory bodies governing software applications that support discovery, development, clinical trials, and manufacturing of biologics, pharmaceuticals, and medical devices (Software-as-Drug (SaD), Software-as-Medical Device (SaMD)) using acceptable Software Platforms (SaaS).

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## Prerequisite: Precertification from FDA in the Software Pre-Cert Program

Software Precertification (Pre-Cert) Program is envisioned as a voluntary pathway that embodies a regulatory model more tailored than the current regulatory paradigm to assess the safety and effectiveness of software technologies without inhibiting patient access to these technologies. The program's goal is to provide more streamlined and efficient regulatory oversight of software from

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manufacturers who have demonstrated a robust culture of quality and organizational excellence (CQOE) and are committed to monitoring real-world performance.

The program concept is based upon the precertification of software manufacturers who have demonstrated a culture of quality and organizational excellence based on five (5) CQOE principles: Product Quality, Patient Safety, Clinical Responsibility, Cybersecurity Responsibility and Proactive Culture.

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The vision of the Software Pre-Cert Program can be achieved by applying a Total Product Lifecycle (TPLC) approach to the regulation of software products. TPLC would allow for the evaluation of organizations and their software application throughout the lifecycle of the organization and products. A comprehensive quality management system (QMS) shall be in place to achieve and maintain TPLC.

Under the model of TPLC, not only will the objective of a true Quality-by-Design (QbD) concept be satisfied, the quality and reliability of the application will be maintained throughout the entire system

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design, development, testing, operation/maintenance, and change management processes. The team behind the xBxBio applicable consists of a group of experienced and diverse professionals and subject matter experts assembled based on these guiding principles and is fully capable of realizing true TPLC and QbD concepts.

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## Total Product Lifecycle (TPLC)

A comprehensive system requirement document that outlined the intended uses of xBxBio and compliance requirements shall be developed. Specifications for the IT infrastructure, including hardware, software, network, and database components to effectively support all use cases of xBxBio, shall be developed and maintained throughout the life cycle of the application.

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Artificial Intelligence (AI) / Machine Learning (ML) algorithm development involves learning from data and hence prompts unique considerations that embody Good Machine Learning Practices (GMLP). GMLP is those AI/ML best practices (e.g., data management, feature extraction, training, and evaluation) that are akin to good software engineering practices or quality system practices. The algorithm designed by xBxBio shall be trained by sample datasets to achieve highly reliable and accurate predictions. The system will also allow continuous improvement based on collected structured and unstructured data.

Besides these core functional requirements, the system shall be designed with the highest level of data

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integrity and security as an objective to achieve regulatory compliance and maintain the security of highly confidential and proprietary data. The data scientists and software developers in the xBxBio team develop the algorithm to satisfy these objectives.

Independent Quality in xBxBio shall work hand-in-hand with data scientists and developers and oversee the design and build process to ensure compliance. Codes and algorithms shall be strictly version-controlled, unit testing and integration testing shall be performed and documented with quality oversight.

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Design Review shall be performed periodically at a different stage of the life cycle to ensure that the design is adequate to support the system requirements and intended uses. With the QbD concept realized, and the algorithm and codes strictly controlled, the risk of design flaws will significantly be lowered, and an accurate risk-based approach for system validation based on GAMP5 can be utilized.

The GAMP5 methodology focus on Quality Risk Management (QRM), which is a systematic approach for the assessment, control, communication and review of tasks to patient safety, product

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quality and data integrity throughout the system life cycle. QbD, with quality involvement and proper documentation in development testing (unit and integration testing), shall be leveraged, and as a result, significantly reduce the validation effort required to ensure accuracy, reliability and repeatability to consistently deliver results.

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## Validation Considerations and Approach

The system will be supported by a state-of-the-art infrastructure that enhances the performance of the highly sophisticated data mining mechanism and algorithm with consistency and minimal downtime. Qualification shall be completed to ensure the hardware, software and network infrastructures are built to specifications to support the system's reliability and performance. Controls in physical security and backend database security shall also be ensured.

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A full functional risk assessment based on the FMEA approach shall be performed against the system requirements. Based on the result of risk assessment, the scope of validation shall be defined. Areas with the highest risk shall be the focus of system testing and performance.

Predictive application is built on data; quality of the data is key to reliability and accuracy of the outcome. The data mining mechanism and the algorithm to identify a target and predict an outcome shall be subjected to the most rigorous testing to ensure the most reliable and acceptable outcome. Based on

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predefined parameters and requirements constructed by xBxBio's board of scientists and subject matter experts, the data mining mechanism shall be challenged to ensure, 1) comprehensiveness and efficiency of extraction of empirical data and unstructured data, and 2) cleansing of data to achieve the highest data quality. Datasets shall be developed for the training of the algorithm by multiple data model validation methods. Repeatability of the system to provide the accurate outcome shall be demonstrated and challenged by vigorous testing with multiple iterations of test data sets.

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System U/I shall be tested to ensure data integrity and controls against unauthorized access in accordance with international regulations and guidelines. The system is compliant with all international regulations for electronic records and electronic signatures (e.g., US 21 CFR Part 11, EU Annex 11).

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## Conclusion

By deploying a TPLC approach that is supported by a strong team of scientists and quality professionals in the regulated industries, together with a robust quality management system, quality of the xBxBio application will be assured in the entire product life cycle to ensure accuracy and reliability.

Not only will xBxBio provide the best and most innovative predictive application that will significantly accelerate the drug discovery/development processes and clinical trials in the regulated

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industries, but this ideology is also further enhanced by the tremendous reduction of timeline and resources with the deployment of an out-of-the-box application that is fully validated with comprehensive documentation package that will withstand audits from any global regulatory agencies. Customers of xBxBio will be able to leverage the robust QMS and validation package during supplier qualification and validation, which will significantly minimize the roadblocks and timeline to deploy the application to any customer.

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