CERTARA INTEGRAL PLUGIN 22.4.1 VALIDATION STATEMENT

As a provider of software that is used by regulated customers, Certara develops software platforms/products/toolkits in accordance with a documented software development methodology. During execution of this methodology, documentation deliverables are created, including the following: Software Requirements Specifications, Software Design Specifications, Test Plan, Test Cases, Traceability Document, Testing Summary Report and Release Readiness Assessment. These documents serve to document the development and testing of a software version. At the end of the software development process, Certara Quality Assurance approves the release of the platform/product/toolkit version, completing Certara's validation of the software version. Certara Integral Plugin 22.4.1 was released by Certara on 15 April 2022.

Software development documentation is available for review during an on-site vendor audit at the Raleigh, North Carolina, USA facility, or through a remote/online audit.

Customers that use software in the implementation of computer systems in regulated environments must, to be compliant with regulatory expectations, validate the computer system, of which the software is but one component (along with the hardware (servers and workstations), network and operating systems environment, interfaces with other computer systems, and policies/standard operating procedures). Validation of the computer system must occur in the user's environment and must account for the user's unique set of requirements. Certara's validation of the developed software provides the foundation for the user's computer system validation activities, but does not replace or complete the user's computer system validation that is expected by the FDA and other regulatory authorities.

Please contact me if you have any questions.

Best regards,



Electronically signed by:
Phillip M Strickland
Reason: I have reviewed and approve this document as Quality Assurance
Date: Apr 18, 2022 13:23 EDT

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