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White Paper

Facilitating 21 CFR Part 11 Compliance with Bio4C™ ProcessPad

Executive Summary

To promote the use of state-of-the-art technologies while ensuring that these new software solutions meet the safeguards and regulations of traditional paper-based record keeping, the FDA issued 21 CFR Part 11 regulations to establish standards under which new electronic documentation and electronic signatures are regarded trustworthy, reliable, and generally equivalent to paper records and handwritten signatures on paper.

Bio4C™ ProcessPad software is a data visualization, analytics, and process monitoring platform that securely acquires and stores batch processing and analytical testing data and makes the data available for continuous process verification, investigations, reporting, and process benchmarking operations for the pharmaceutical and biopharmaceutical industry.

Bio4C™ ProcessPad is used within organizations on applications where 21 CFR Part 11 is applicable. It aids organizations in their compliance efforts by meeting applicable requirements of 21 CFR Part 11. Additionally, software validation services are provided as part of a Bio4C™ ProcessPad deployment.

21 CFR Part 11 Compliance

The sections that follow provide a summary as to how Bio4C™ ProcessPad software assists in compliance with relevant 21 CFR Part 11 sections. Excerpts from the regulation are provided in bold text. This summary is for information purposes only and is not comprehensive. Contact a representative if further detail is required.

§ 11.10(a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.

Bio4C™ ProcessPad was developed following Software Development Life Cycle (SDLC) practices for software development and validation in which each stage of product development is carried out with the associated documentation. Moreover, we provide validation services as part of its installation and qualification of the Bio4C™ ProcessPad application.

§ 11.10(b) The ability to generate accurate and complete copies of records in both human readable and electronic form suitable for inspection, review, and copying by the agency.

Records include data associated with batch records and analytical records. Bio4C™ ProcessPad stores this information in a secure database which may be accessed in human readable form through the Bio4C™ ProcessPad user interface. Data can be downloaded from the system in the form of charts and reports in image, PDF or Microsoft® Word format.

§ 11.10(c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.

All records and their metadata are stored securely within the Bio4C™ ProcessPad database. Bio4C™ ProcessPad doesn't automatically create, modify or delete any of the data associated with these records. Also, the on-premise client hosted system needs to have mechanism and access controls in place to gain access to the server hardware and system software.

§ 11.10(d) Limiting system access to authorized individuals.

The system has multiple levels of security. User profiles with associated roles must be granted by the system administrator before access to the software is possible. Each user is assigned an account with a unique username and password, both of which are required to log in to the system. The user's identity and role are combined to determine whether access to a feature within Bio4C™ ProcessPad is permitted or denied.

§ 11.10(e) Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, or delete electronic records. Record changes shall not obscure previously recorded information. Such audit trail documentation shall be retained for a period at least as long as that required for the subject electronic records and shall be available for agency review and copying.

Each action performed in the system including modifying, creating, and deleting data are written automatically to audit trail tables in the system's database.

§ 11.10(g) Use of authority checks to ensure that only authorized individuals can use the system, electronically sign a record, access the operation or computer system input or output device, alter a record, or perform the operation at hand.

Bio4C™ ProcessPad uses a combination of a username and password to authorize user access to the application. The access to various features such as records creation, modification, and deletion is controlled by assigning roles to the user. Role specific permissions exist for each of the roles. Only a user belonging to the specific role will have access to the features specific for that role. Regarding the rights to electronically sign a record, this is not applicable to Bio4C™ ProcessPad because it is not the primary source of data or record.

§ 11.10(k) Use of appropriate controls over systems documentation including: (1) Adequate controls over the distribution of, access to, and use of documentation for system operation and maintenance. (2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.

The Bio4C™ ProcessPad system documentation is updated and distributed with each version of the software. Each set of documentation, including, user manuals and administrator manuals, are uniquely identifiable as applying to a specific version.

For additional information

please visit **MerckMillipore.com/Bio4CProcessPad**

To place an order or receive technical assistance

please visit **MerckMillipore.com/contactPS**
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