

AtlaZ GxP software module

21 CFR Part 11 Statement



This document provides guidance on how to effectively incorporate the AtlaZ system into electronic records management systems, ensuring optimized workflows, high-throughput efficiency, and compliance with regulatory standards in GxP labs.

Section: 11.10 Controls for closed systems		AtlaZ GxP software module features
11.10 (a)	Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.	AtlaZ GxP software module is designed to provide accurate, reliable and consistent intended performance. It provides data integrity checks and a comprehensive audit trail to trace modifications of electronic records and to detect illegitimate altering of electronic records. Thus, enabling you to incorporate AtlaZ into your electronic records management system.
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. Persons should contact the agency if there are any questions regarding the ability of the agency to perform such review and copying of the electronic records.	AtlaZ GxP software module provides electronic records in human readable format, data integrity checks and a comprehensive audit log for said records, which can be imported into your electronic records management system. The system owner is, however, solely responsible for storage of those records.
11.10 (c)	Protection of records to enable their accurate and ready retrieval throughout the records retention period.	The system owner is solely responsible for storage of records throughout the record retention period.
11.10 (d)	Limiting system access to authorized individuals.	AtlaZ GxP software module runs on a PC with a Windows operating system. You can use Windows access rights and Active Directory to administer system access. The audit trail uses the current Windows user as active user for the audit log. The system owner is, however, solely responsible for limiting user access.
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.	AtlaZ GxP software module audit trail creates time-stamped logs if records are created, modified or deleted. The audit trail can be exported any time.
11.10 (f)	Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	AtlaZ GxP software module will only interface with an AtlaZ measurement device. A barcode scanner is available for plate scanning. Relevant user actions are recorded in the audit log.
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.	Any user logged into Windows can access the AtlaZ GxP software module. To ensure that only authorized individuals have access to the system, Windows access rights or Active Directory can be used. The system owner is, however, solely responsible for limiting user access.
11.10 (h)	Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.	Data Integrity checks assure that modifications of records outside of the AtlaZ software are detected. Hash values of records can be exported with the audit log, if the system owner wants to implement additional device checks for the electronic records management system.

Section: 11.10 Controls for closed systems (cont.)		AtlaZ GxP software module features
11.10 (i)	Determination that persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.	The system owner is solely responsible that the responsible personnel is qualified.
11.10 (j)	The establishment of, and adherence to, written policies that hold individuals accountable and responsible for actions initiated under their electronic signatures, in order to deter record and signature falsification.	The system owner is solely responsible for the establishment of these policies.
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.	User documentation is supplied with the AtlaZ system and can be access on the system. Once delivered, the system owner is solely responsible for access and use of the documentation.

Section: 11.30 Controls for open systems		AtlaZ GxP software module features
11.30	Persons who use open systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, as appropriate, the confidentiality of electronic records from the point of their creation to the point of their receipt. Such procedures and controls shall include those identified in 11.10, as appropriate, and additional measures such as document encryption and use of appropriate digital signature standards to ensure, as necessary integrity, and confidentiality.	Not applicable.

**Sections:
11.50, 10.70, 11.100, 11.200, 11.300**

These sections regulate the use of electronic signatures. AtlaZ does not provide electronic signatures.



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