DASSAULT SYSTEMES POSITION PAPER for

BIOVIA Quality Management

on the 3DEXPERIENCE Cloud

Version 1.0

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Version History

Version	Date	Description
1.0	30 May 2024	Original Version based on 2025 GA

Introduction

The purpose of this paper is to provide Dassault Systemes' (3DS) position on the criteria for electronic records and electronic signatures as defined in the United States Food and Drug Administration (FDA) Federal Code of Regulations Title 21 CFR Part 11 (21 CFR Part 11), European Union GMP Annex 11 (Annex 11) and relevant predicate rules for the intended use of the application.

Since 1997, with the introduction of 21 CFR Part 11, companies in the life sciences industry must consider whether or not their systems are compliant with these FDA and EU regulations. In this case, a system does not just refer to a software package, but to the Standard Operating Procedures (SOPs), processes, environment and software packages that store, retrieve, and file electronic records. The first step in deploying a system is to determine whether or not it meets the requirements of 21 CFR Part 11, Annex 11 and the predicate rules. You must then determine how to address the shortcomings of your system.

The following checklists for US FDA 21 CFR Part 11 EU Annex 11, and relevant predicate rules, identify the relevant requirements of the regulations. You can meet some of these requirements by subscribing to **BIOVIA Quality Management** in the 3DEXPERIENCE Cloud. Also refer to 'DASSAULT SYSTEMES Position for 3DEXPERIENCE Platform on the Cloud Based on: 21 CFR Part 11 Guideline for Electronic Records; Electronic Signatures, EU Annex 11 Guideline for Computerized Systems'. Other requirements will require you to collaborate with Dassault Systemes, and still others will require additional work on your part.

For more information, please contact BIOVIA customer support at biovia.support@3ds.com

21 CFR Part 11 Requirements

Requirement	3DS App	Customer SOP(s)	3DS Position for BIOVIA Quality Management
B/11.10 Controls for Closed Systems			
Persons who use closed systems to create, modify, maintain, or transmit electronic records shall employ procedures and controls designed to ensure the authenticity, integrity, and, when appropriate, the confidentiality of electronic records, and to ensure that the signer cannot readily repudiate the signed record as not genuine. Such procedures and controls shall include the following: (a) Validation of systems to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.	.X	X	The application is developed using good software practices and is thoroughly tested. Customers can either develop and/or implement the validation plans and protocols themselves or out-source these activities.
(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.	X	X	Electronic records and their associated history are maintained in a relational database. Users, with the appropriate authorization, can obtain human readable and electronic copies of records in user-selectable format with a range of content editors and viewers.
(c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.	X	X	Quality Management Records are captured in the Business Process service and data is held for the duration of the contract with Dassault Systemes

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(d) Limiting system access to authorized individuals.	X	X	Access to the application requires a user ID and password. The system does not accept redundant user IDs. The common name of the user is linked to the user ID. Configured privileges further control user access to application functionality for a Role. Access control changes are recorded in an audit trail. The 3DEXPERIENCE Passport functionality controls password aging, length, uniqueness and lockout management.

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(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.	X	X	All data collected for quality management is managed by the Business Process Service and retained for the length of the contract with Dassault Systemes. A comprehensive Audit History capability is included in the application, which contemporaneously records information about events and data transactions during system operation. A user can access the Audit History for any quality record by viewing the Change History of that record. A user with appropriate access can view the Package Management tab to inspect the history of updates to process models in use. All audit trail records include the following: • date and time stamp (from database server) • user unique identifier • action performed action object unique identifier • parameters associated with action object It is the customer's responsibility to establish policies and procedures to ensure that their records are retained for an appropriate length of time.

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(f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	X	X	Signature workflow is enforced for tasks authorizing a change to be made or a record to close by built in mechanisms.
(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.	X	X	Access control is described in section 11.10(d). Electronic signatures for experiment submission and witnessing employ a user ID and password. Only authorized users can execute an electronic signature. The combination of user ID and password is unique since the system enforces a unique user ID. Experiments can only be created or edited after authority checks, based on user ID and password against defined user privileges and record status.
(h) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.		X	It is the customer's responsibility to authenticate with the server, including web clients, print label clients, balance reader clients, and users of the API.

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(i) Determinations that the persons who develop, maintain, or use electronic record/electronic signature systems have the education, training, and experience to perform their assigned tasks.	X	X	3DS R&D personnel are well-qualified and are trained to follow established software development procedures. 3DS Customer Success personnel are trained to upgrade and maintain the system and are available to train software administrators. Customers ensure that all their employees, and other personnel, who work with a regulated system have the necessary levels of education, training, and experience to perform their assigned tasks.
(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.		X	Customers need to develop the policies and procedures that support the use of the applications with electronic signatures in a regulated environment.
(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.	X	X	3DS provides system operation and maintenance manuals for the software. Although customers are not responsible for control over the content of the system operation and maintenance manuals, they need to establish and maintain controls over the distribution of, access to, and use of the manuals.

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(2) Revision and change control procedures to maintain an audit trail that documents time-sequenced development and modification of systems documentation.	X		Revisions made to the manuals by 3DS follow a documented change control procedure. 3DS maintain these revisions in a secure database.
B/11.30 Controls for Open Systems			
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 under the circumstances, record authenticity, integrity, and confidentiality.	.	X	Customers need to develop procedures to support the use of software applications in a regulated environment.
B/11.50 Signature Manifestations			
(a) Signed electronic records shall contain information associated with the signing that clearly indicates all of the following: (1) The printed name of the signer	.X		Electronic signatures are stored with the audit trails for the records they apply to. All audit trail records include the unique identifier of the signer. Audit reports include the full name of the signer. The system displays and records the name of the signer.
(2) The date and time when the signature was executed	X		All electronic signatures include a System controlled date and time stamp. The system records and displays the date and time the signature was executed.

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(3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature.	X		All electronic signatures include fields that identify the meaning of the signature. For Quality Management, a signature confirms that the user completed the appropriate task.
(b) The items identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section shall be subject to the same controls as for electronic records and shall be included as part of any human readable form of the electronic record (such as electronic display or printout).	X		The name, date, timestamp, and signature role are data in the database and in the generated final report file (human-readable form).
B/11.70 Signature/Record Linking			
Electronic signatures and hand-written signatures executed to electronic records shall be linked to their respective electronic records to ensure that the signatures cannot be excised, copied, or other-wise transferred to falsify an electronic record by ordinary means.	.X	X	Each audit trail record and each electronic signature include the unique identifier of the signer that is linked to the specific activity. It is the customer's responsibility to establish policies and procedures that prevent unauthorized access to the relational database that contains the audit trail file.
C/11.100 General Requirements			
(a) Each electronic signature shall be unique to one individual and shall not be reused by, or reassigned to, anyone else.	.X	X	3DEXPERIENCE platform user credentials are unique to individual users and cannot be reused or reassigned.

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(b) Before an organization establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature, or any element of such electronic signature, the organization shall verify the identity of the individual.		X	Customers using the application in an FDA-regulated environment must verify the identities of the individuals that use electronic signatures.
(c) Persons using electronic signatures shall, prior to or at the time of such use, certify to the agency that the electronic signatures in their system, used on or after August 20, 1997, are intended to be the legally binding equivalent of traditional handwritten signatures. (i) The certification shall be submitted in paper form and signed with a traditional handwritten signature, to the Office of Regional Operations (HFC–100), 5600 Fishers Lane, Rockville, MD 20857. (ii) Persons using electronic signatures shall, upon agency request, provide addition-al certification or testimony that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.		X	Customers using the application in an FDA-regulated environment must certify to the agency that the electronic signatures in their system are intended to be the legally binding equivalent of traditional handwritten signatures.
C/11.200 Electronic Signature Components and Controls			
(a) Electronic signatures that are not based upon biometrics shall: (1) Employ at least two distinct identification components such as an identification code and password.	.X		3DEXPERIENCE platform access is provided by means of a configurable user ID and password. The user must reenter this information when applying an electronic signature.

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(i) When an individual executes a series of signings during a single, continuous period of controlled system access, the first signing shall be executed using all electronic signature components; subsequent signings shall be executed using at least one electronic signature component that is only executable by, and designed to be used only by, the individual.	X		No two users can have the same username and password. The passwords (one of the two components of electronic signatures) cannot be viewed by anyone To indicate the start of a continuous period of controlled system access, the user must use two distinct identification components to log into the software. All signatures during this period are recorded using both distinct identification components of the signature. During periods of inactivity, the user's session is automatically terminated. Additionally, it is the customer's responsibility to implement policies and procedures that require users to log out of the application during periods of non-use.
(ii) When an individual executes one or more signings not performed during a single, continuous period of controlled system access, each signing shall be executed using all of the electronic signature components.	X		All signings in the application use at least two distinct identification components at all times.

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(2) Be used only by their genuine owners		X	Customers using the application in an FDA-regulated environment must ensure that their users are trained and aware that only their genuine owners use non-biometric electronic signatures.
(3) Be administered and executed to ensure that attempted use of an individual's electronic signature by anyone other than its genuine owner requires collaboration of two or more individuals.		X	Customers using the application in an FDA-regulated environment must ensure that their users are trained and aware that only their genuine owners use non-biometric electronic signatures.
(b) Electronic signatures based upon bio-metrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.		X	The 3DEXPERIENCE Platform and the application do not make use of Biometrics in place of eSignature. Customers in an FDA-regulated environment must ensure that their users are trained and aware that only their genuine owners use non-biometric electronic signatures.

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C/11.300 Controls for Identification Codes/Passwords			
Persons who use electronic signatures based upon use of identification codes in combination with passwords shall employ controls to ensure their security and integrity. Such controls shall include: (a) Maintaining the uniqueness of each combined identification code and password, such that no two individuals have the same combination of identification code and password.	.X		User IDs are unique; they cannot be deleted or reallocated. If a user ID has been deactivated, it can be re-activated. These Administrator actions are audit trailed.
(b) Ensuring that identification code and password issuances are periodically checked, recalled, or revised (e.g., to cover such events as password aging).		X	The rules regarding password aging, length, composition, and uniqueness apply to the 3DPassport service and the SLA defined between the customer and Dassault Systems.
(c) Following loss management procedures to electronically de-authorize lost, stolen, missing, or otherwise potentially compromised tokens, cards, and other devices that bear or generate identification code or password information, and to issue temporary or permanent replacements using suitable, rigorous controls.		X	Customers using the application in an FDA-regulated environment must employ controls to ensure the security and integrity of identification codes and passwords.
(d) Use of transaction safeguards to prevent unauthorized use of passwords and/or identification codes, and to detect and report in an immediate and urgent manner any attempts at their unauthorized use to the system security unit, and, as appropriate, to organizational management.	X	X	The 3DEXPERIENCE 3DPassport service can be configured to issue alerts after a pre-set number of unsuccessful login attempts. It is the responsibility of the customer to ensure that the SLA for the service identifies the number of attempts.

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(e) Initial and periodic testing of devices, such as tokens or cards, that bear or generate identification code or password information to ensure that they function properly and have not been altered in an unauthorized manner.		X	The use of Tokens or cards to gain access or to apply signatures is not supported.

Annex 11 Requirements

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Quality Management
General			
1. Risk Management Risk management should be applied throughout the lifecycle of the computerized system taking into account patient safety, data integrity and product quality. As part of a risk management system, decisions on the extent of validation and data integrity controls should be based on a justified and documented risk assessment of the computerized system.	.X	X	Risk management activities are required activities throughout 3DS software development life cycle (SDLC) for the development of the application. Customers using the application in a regulated environment must apply risk management on the validation and the data integrity controls with the use of the application.
2. Personnel There should be close cooperation between all relevant personnel such as Process Owner, System Owner, Qualified Persons and IT. All personnel should have appropriate qualifications, level of access and defined responsibilities to carry out their assigned duties.		X	Customers using the application in a regulated environment must have roles and responsibilities defined in procedures.
3. Suppliers and Service Providers 3.1. When third parties (e.g. suppliers, service providers) are used e.g. to provide, install, configure, integrate, validate, maintain (e.g. via remote access), modify or retain a computerized system or related service or for data processing, formal agreements must exist between the manufacturer and any third parties, and these agreements should include clear statements of the responsibilities of the third party. IT-departments should be considered analogous.	X	X	Customers using the application in a regulated environment must ensure service level agreements are in place with the application service supplier and/or service provider.

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3.2. The competence and reliability of a supplier are key factors when selecting a product or service provider. The need for an audit should be based on a risk assessment.		X	Customers using the application in a regulated environment must have a supplier assessment program.
3.3. Documentation supplied with commercial off-the-shelf products should be reviewed by regulated users to check that user requirements are fulfilled.		X	Customers using the application in a regulated environment must have a computerized systems validation program to ensure user requirements are mapped to supplier-provided documentation.
3.4. Quality system and audit information relating to suppliers or developers of software and implemented systems should be made available to inspectors on request.		X	Customers using the application in a regulated environment must have a supplier assessment program.
Project Phase			
4. Validation 4.1. The validation documentation and reports should cover the relevant steps of the life cycle. Manufacturers should be able to justify their standards, protocols, acceptance criteria, procedures and records based on their risk assessment.	.	X	Customers using the application in a regulated environment must have a computerized systems validation program.
4.2. Validation documentation should include change control records (if applicable) and reports on any deviations observed during the validation process.		X	Customers using the application in a regulated environment must have a computerized systems validation program.

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4.3. A current listing of all relevant systems and their GMP functionality (inventory) should be available. For critical systems a current system description detailing the physical and logical arrangements, data flows and interfaces with other systems or processes, any hardware and software pre-requisites, and security measures should be available.		X	Customers using the application in a regulated environment must have a computerized systems validation program.
4.4. User Requirements Specifications should describe the required functions of the computerized system and be based on documented risk assessment and GMP impact. User requirements should be traceable throughout the life-cycle.		X	Customers using the application in a regulated environment must have a computerized systems validation program.
4.5. The regulated user should take all reasonable steps, to ensure that the system has been developed in accordance with an appropriate quality management system. The supplier should be assessed appropriately.		X	Customers using the application in a regulated environment must have a computerized systems validation program and supplier assessment program.
4.6. For the validation of bespoke or customized computerized systems there should be a process in place that ensures the formal assessment and reporting of quality and performance measures for all the life-cycle stages of the system.		X	Customers using the application in a regulated environment must have a computerized systems program. The customer is responsible for the review, approval, and execution of any bespoke validation testing.
4.7. Evidence of appropriate test methods and test scenarios should be demonstrated. Particularly, system (process) parameter limits, data limits and error handling should be considered. Automated testing tools and test environments should have documented assessments for their adequacy.		X	Customer's using the application in a regulated environment must have a computerized systems program.

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4.8. If data are transferred to another data format or system, validation should include checks that data are not altered in value and/or meaning during this migration process.	X	X	Customers using the application in a regulated environment must have a computerized systems validation program. Any data transfer to or from the Business Process service used by the Quality Management application would need to be planned, risk-assessed, and validated (as a bespoke project). The nature of these activities is that each one is different with its risks, even within the same organization. Documentation shall be captured and stored to provide any evidence required.
Operational Phase			
5. Data Computerized systems exchanging data electronically with other systems should include appropriate built-in checks for the correct and secure entry and processing of data, in order to minimize the risks.	.X		Dassault Systemes' software development practices require that any data exchange between 3DEXPERIENCE applications include the required checks and prevent risks of error or security vulnerability. If a bespoke integration is required, there is a joint responsibility between the customer and the integrating organization to validate the design, execution, and delivery of that integration.

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6. Accuracy Checks For critical data entered manually, there should be an additional check on the accuracy of the data. This check may be done by a second operator or by validated electronic means. The criticality and the potential consequences of erroneous or incorrectly entered data to a system should be covered by risk management.	X	X	The QUALITY MANAGEMENT application includes a number of Business Process process models, which are used by the end users to manually capture data related to the quality incident being investigated. The process models include basic data validation (for example to check that an email address or phone number is in the right format) and make use of predefined lists of values to select from. However, it is still the responsibility of the user to select/enter the correct value and for other (customer-based) users in the process to check and request correction when necessary.
7. Data Storage 7.1. Data should be secured by both physical and electronic means against damage. Stored data should be checked for accessibility, readability and accuracy. Access to data should be ensured throughout the retention period.	X	X	Electronic records and their associated history are maintained in a database. Users with the appropriate authorization can obtain human readable and electronic copies of records with a range of content editors and viewers. Additionally, users can retrieve the history of the associated records with the application's Audit Report tool. Alternatively, a database administrator (with the appropriate authorization) can obtain copies of these records as structured documents with standard 3rd party data retrieval tools.

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7.2. Regular back-ups of all relevant data should be done. Integrity and accuracy of backup data and the ability to restore the data should be checked during validation and monitored periodically.		X	The application is provided with the 3DEXPERIENCE Platform as part of a SaaS solution. Backup and Restore operations are provided as a part of the contracted SLA.
8. Printouts 8.1. It should be possible to obtain clear printed copies of electronically stored data.	X	X	The application includes functionality to export final reports of each quality record, tables of record summaries, and charts of metrics. In each case, provenance data is included to confirm who requested it, when, and from which system.
8.2. For records supporting batch release it should be possible to generate printouts indicating if any of the data has been changed since the original entry.	X	X	Provided that the records have been submitted no retrospective changes can be made. Any additions or alterations will be appended to the original record.
9. Audit Trails Consideration should be given, based on a risk assessment, to building into the system the creation of a record of all GMP-relevant changes and deletions (a system generated "audit trail"). For change or deletion of GMP-relevant data the reason should be documented. Audit trails need to be available and convertible to a generally intelligible form and regularly reviewed.	X	X	The application captures all data in the Business process service. This includes an immutable Audit trail to record who (GUID identifier) made what change to records including a system-controlled date & time stamp. The audit trail data is retained with the rest of the record for the duration of the contract. The Audit trail of a record can be inspected in the application and exported if required.

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10. Change and Configuration Management Any changes to a computerized system including system configurations should only be made in a controlled manner in accordance with a defined procedure.		X	Customers using the application in a regulated environment must have a change control program.
11. Periodic Evaluation Computerized systems should be periodically evaluated to confirm that they remain in a valid state and are compliant with GMP. Such evaluations should include, where appropriate, the current range of functionality, deviation records, incidents, problems, upgrade history, performance, reliability, security and validation status reports.		X	Customers using the application in a regulated environment must have a maintenance procedure to include periodic review of the system.
12. Security 12.1. Physical and/or logical controls should be in place to restrict access to computerized system to authorized persons. Suitable methods of preventing unauthorized entry to the system may include the use of keys, pass cards, personal codes with passwords, biometrics, restricted access to computer equipment and data storage areas.	X	X	Dassault Systemes 3DEXPERIENCE Platform is delivered as a SaaS Cloud-based solution. Access to servers and data storage is tightly controlled and inspected to ISO standards. Customer access to systems is only supported through the user interface which prevents unauthorized access elsewhere. Customers are responsible for ensuring that end users are trained in the importance of maintaining secure passwords.
12.2. The extent of security controls depends on the criticality of the computerized system.		X	Dassault Systemes 3DEXPERIENCE Platform is delivered as a SaaS Cloud-based solution. Access to servers and data storage is tightly controlled and inspected to ISO standards.

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12.3. Creation, change, and cancellation of access authorizations should be recorded.	X		Customers create and maintain user access authorizations using the 3DPassport service. All changes to records are audited and can be inspected/reported.
12.4. Management systems for data and for documents should be designed to record the identity of operators entering, changing, confirming or deleting data including date and time.	X		The application records the identity of the operator changing the data and the date and time of change is captured into the database.
13. Incident Management All incidents, not only system failures and data errors, should be reported and assessed. The root cause of a critical incident should be identified and should form the basis of corrective and preventive actions.	X	X	Customers using the application in a regulated environment must make use of a CAPA solution (which may be that provided by this product). Furthermore, Dassault Systemes provide a customer support mechanism to capture reports of any incidents, failures, or errors encountered along with the analysis and resolution activities. This is documented in our procedures, which are inspectable during an audit. Customers are responsible for accurately reporting any incident and providing data/evidence as requested to complete the analysis.

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14. Electronic Signatures Electronic records may be signed electronically. Electronic signatures are expected to: a. have the same impact as hand-written signatures within the boundaries of the company b. be permanently linked to their respective record c. include the time and date that they were applied	X	X	Each audit trail record and each electronic signature include the unique identifier of the signer that is linked to the specific activity. Customers need to train users in establish policies and procedures that prevent sharing passwords or account access.
15. Batch Release When a computerized system is used for recording certification and batch release, the system should allow only Qualified Persons to certify the release of the batches and it should clearly identify and record the person releasing or certifying the batches. This should be performed using an electronic signature.		X	Customers using the application in a regulated environment must have a policy or procedure on the use of electronic signatures.
16. Business Continuity For the availability of computerized systems supporting critical processes, provisions should be made to ensure continuity of support for those processes in the event of a system breakdown (e.g., a manual or alternative system). The time required to bring the alternative arrangements into use should be based on risk and appropriate for a particular system and the business process it supports. These arrangements should be adequately documented and tested.		X	Dassault Systemes 3DEXPERIENCE Platform is provided as a SaaS cloud based solution. As such provision for business continuity in the case of a breakdown is covered under the terms in the SLA contract.

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17. Archiving Data may be archived. This data should be checked for accessibility, readability and integrity. If relevant changes are to be made to the system (e.g., computer equipment or programs), then the ability to retrieve the data should be ensured and tested.			Data captured in the Business Process service or attached as record sources in the Quality Management application are retained online for the duration of the contract – with Backup and Business continuity copies being taken and securely stored as required under the terms of the SLA. Customers can request a copy of any of this data – which would be negotiated and delivered as a part of a services engagement project.

Predicate Rule Requirements:

Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals

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21 CFR Part 211.100 (b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified.	Partial	X	The application provides a Deviation and CAPA process. If used (by the customer), this records the details of any deviation from the procedures in use and the subsequent analysis, disposition of impacted materials, approved resolution plans & actions. The CAPA process can be used to propose, approve, and document authorization to change production procedures to prevent the reoccurrence of issues. The customer is responsible for the approval and issue of all documentation and for training production staff in the correct operation and reporting procedures.
21 CFR Part 211.180 (a) Any production, control, or distribution record that is required to be maintained in compliance with this part and is specifically associated with a batch of a drug product shall be retained for at least 1 year after the expiration date of the batch or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, 3 years after distribution of the batch.	Partial	X	The application provides processes to manage quality issues if they arise. Any records captured are retained for the duration of the contract and can be exported if requested.

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(b) Records shall be maintained for all components, drug product containers, closures, and labeling for at least 1 year after the expiration date or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, 3 years after distribution of the last lot of drug product incorporating the component or using the container, closure, or labeling. (c) All records required under this part, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection. Records that can be immediately retrieved from another location by computer or other electronic means shall be considered as meeting the requirements of this paragraph. (d) Records required under this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records. Where reduction techniques, such as microfilming, are used, suitable reader and photocopying equipment shall be readily available. (e) Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or control procedures. Written procedures shall be established and followed for such evaluations and shall include provisions for: (1) A review of a representative number of batches, whether approved or rejected, and, where applicable, records associated with the batch. (2) A review of complaints, recalls, returned or salvaged drug products, and investigations conducted under § 211.192 for each drug product.			

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Quality Management
21 CFR Part 211.184 These records shall include the following: (a) The identity and quantity of each shipment of each lot of components, drug product containers, closures, and labeling; the name of the supplier; the supplier's lot number(s) if known; the receiving code as specified in § 211.80; and the date of receipt. The name and location of the prime manufacturer, if different from the supplier, shall be listed if known. (b) The results of any test or examination performed (including those performed as required by § 211.82(a), § 211.84(d), or § 211.122(a)) and the conclusions derived therefrom. (c) An individual inventory record of each component, drug product container, and closure and, for each component, a reconciliation of the use of each lot of such component. The inventory record shall contain sufficient information to allow determination of any batch or lot of drug product associated with the use of each component, drug product container, and closure. (d) Documentation of the examination and review of labels and labeling for conformity with established specifications in accord with §§ 211.122(c) and 211.130(c). (e) The disposition of rejected components, drug product containers, closure, and labeling.	Partial	X	The application provides a number of Processes for the management of Quality issues. This would include the details of items impacted by any issue and their disposition. These records are retained for the duration of the contract and can be exported.
21 CFR Part 211.192	X	X	The application provides a number of Processes for the management of Quality issues. This would include the details of items impacted by any issue and their disposition. These records are retained for the duration of the contract and can be exported.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Quality Management
All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and follow-up.			
21 CFR Part 211.198 (a) Written procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed. Such procedures shall include provisions for review by the quality control unit, of any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for an investigation in accordance with § 211.192. Such procedures shall include provisions for review to determine whether the complaint represents a serious and unexpected adverse drug experience which is required to be reported to the Food and Drug Administration in accordance with §§ 310.305 and 514.80 of this chapter.		X	It is the customer's responsibility to establish policies and procedures for handling written and oral complaints relating to products offered, including the investigation, review, reporting and information security of the complaint to the FDA.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Quality Management
(b) A written record of each complaint shall be maintained in a file designated for drug product complaints. The file regarding such drug product complaints shall be maintained at the establishment where the drug product involved was manufactured, processed, or packed, or such file may be maintained at another facility if the written records in such files are readily available for inspection at that other facility. Written records involving a drug product shall be maintained until at least 1 year after the expiration date of the drug product, or 1 year after the date that the complaint was received, whichever is longer. In the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, such written records shall be maintained for 3 years after distribution of the drug product. (1) The written record shall include the following information, where known: the name and strength of the drug product, lot number, name of complainant, nature of complaint, and reply to complainant. (2) Where an investigation under § 211.192 is conducted, the written record shall include the findings of the investigation and follow-up. The record or copy of the record of the investigation shall be maintained at the establishment where the investigation occurred in accordance with § 211.180(c). (3) Where an investigation under § 211.192 is not conducted, the written record shall include the reason that an investigation was found not to be necessary and the name of the responsible person making such a determination.			

Quality System Regulation (QSR) for Medical Devices

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Quality Management
21 CFR Part 820.70 Production and Process Controls (i) Automated processes. When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented.	X	X	The application is developed using good software practices and is thoroughly tested. Customers using the application in a regulated environment must have a computerized systems validation program.
21 CFR Part 820.90 (b) **Nonconformity review and disposition.** (1) Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented. Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.	X		The application includes a process to manage nonconformance analysis, containment confirmation, solution proposal, and disposition activities once authorized. An electronic signature is required to authorize the recovery actions and final closure. The nonconformance process automatically provides a full report including an audit trail to document who completed each task with a system-controlled timestamp. All records are retained for the duration of the contract and can be exported.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Quality Management
21 CFR Part 820.100 (a) Each manufacturer shall establish and maintain procedures for implementing **corrective and preventive action**. The procedures shall include requirements for: (1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems; (2) Investigating the cause of nonconformities relating to product, processes, and the quality system; (3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems; (4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device; (5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems; (6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and (7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review. (b) All activities required under this section, and their results, shall be documented.	X		The Quality Management application includes a process to manage CAPA analysis, solution proposal and correction activities once authorized and effectiveness review. Electronic signature is required to authorize the correction actions and final closure. The CAPA process automatically provides a full report including audit trail to document who completed each task with a system controlled timestamp. All records are retained for the duration of the contract and can be exported.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Quality Management
21 CFR Part 820.180 All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably **accessible** to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up. (a) Confidentiality. Records deemed confidential by the manufacturer may be marked to aid FDA in determining whether information may be disclosed under the public information regulation in part 20 of this chapter. (b) Record retention period. All records required by this part shall be retained for a period of time equivalent to the design and expected life of the device, but in no case less than 2 years from the date of release for commercial distribution by the manufacturer. (c) Exceptions. This section does not apply to the reports required by § 820.20(c) Management review, § 820.22 Quality audits, and supplier audit reports used to meet the requirements of § 820.50(a) Evaluation of suppliers, contractors, and consultants, but does apply to procedures established under these provisions. Upon request of a designated employee of FDA, an employee in management with executive responsibility shall certify in writing that the management reviews and quality audits required under this part, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken.	Partial		The Quality Management Analyst application provides a number of Processes for the management of Quality issues. This would include the details of items impacted by any issue and their disposition. These records are retained for the duration of the contract and can be exported.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Quality Management
21 CFR Part 820.198 Complaint Files (a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that: (1) All complaints are processed in a uniform and timely manner; (2) Oral complaints are documented upon receipt; and (3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting. (b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate. (c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.	X		The Quality Management Analyst application provides a number of Processes for the management of Quality issues – including Quality Complaint. This would include the details of items impacted by any issue and their disposition. These records are retained for the duration of the contract and can be exported.

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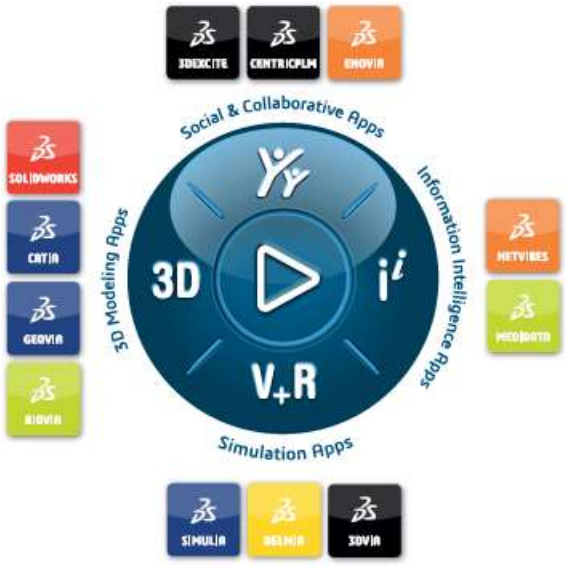

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