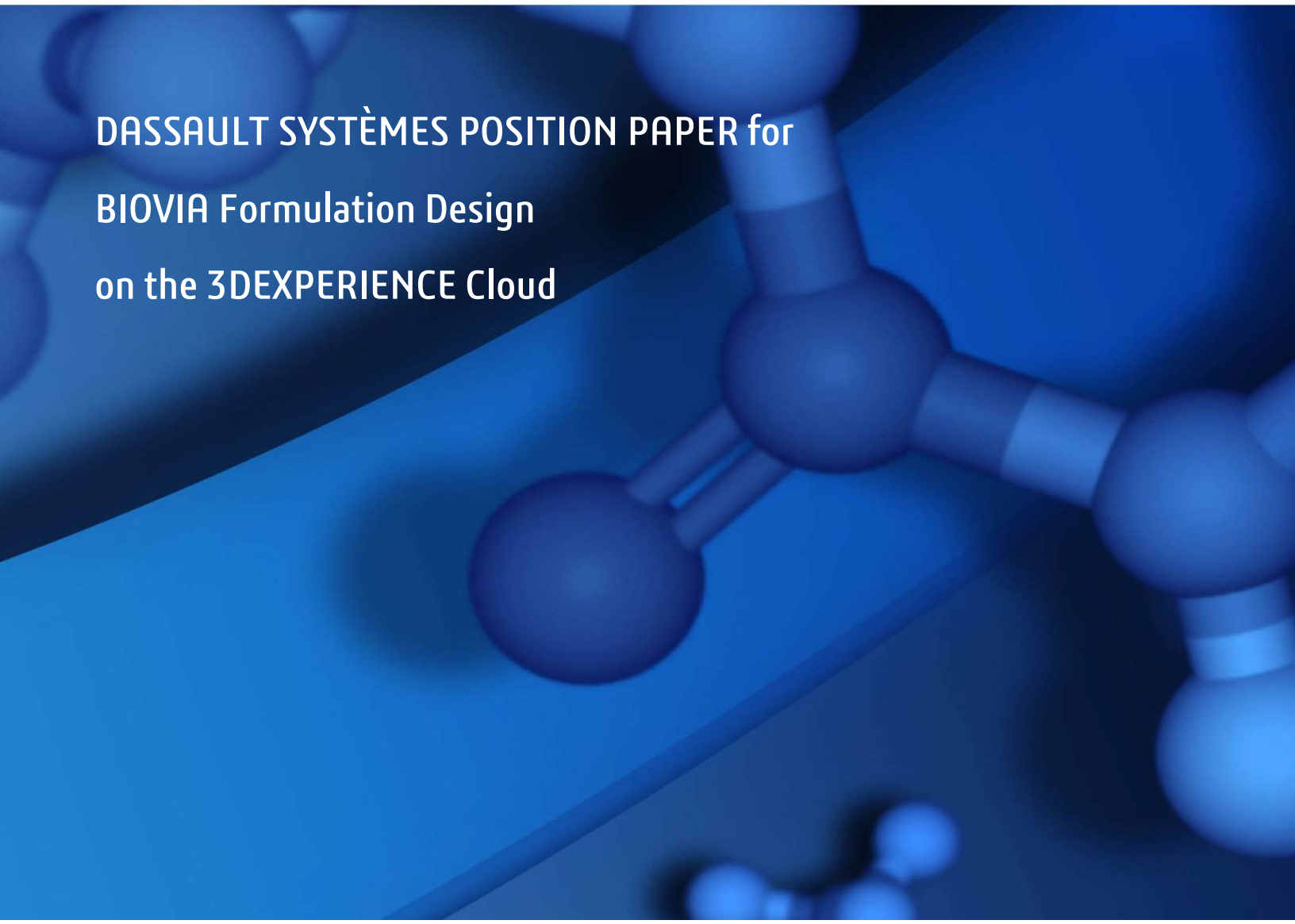

DASSAULT SYSTÈMES POSITION PAPER for BIOVIA Formulation Design on the 3DEXPERIENCE Cloud

Version 1.0

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Version History

Version	Date	Description
1.0	30 May 2024	Original Version based on R2025x GA

Introduction

The purpose of this paper is to provide Dassault Systèmes' (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 the BIOVIA Formulation Design application in the 3DEXPERIENCE Cloud. Also refer to 'DASSAULT SYSTÈMES 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 Systèmes, 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 Formulation Design
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 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. Review/ inspection is facilitated by the search function in BIOVIA Formulation Design, or by retrieving Formulations for a specific user or collection. Records include metadata (such as creation date/time, maturity state etc.)

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
(c) Protection of records to enable their accurate and ready retrieval throughout the records retention period.	X	X	All records are protected in secure storage locations and are readily retrievable. The application provides access to create or edit Formulations based on roles, for retention of changed records, for the audit trail of records and user actions, and for query and the accurate, ready retrieval of information. Formulations can be retrieved using the BIOVIA Formulation Design application, or using APIs (application programming interfaces) providing ready retrieval throughout the record retention period.
(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.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
(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	A comprehensive Audit History capability is included in the application, which contemporaneously records information about Formulas after the Draft maturity state. A user can access the Audit History for any Formulation by generating the Formula Audit report. The Audit History also contains information about the status of the data object as it moves through its various states. A date-time stamp and user attribution identifies each change. The application automatically records Audit History information in the system database. A user or system administrator cannot use either the API or the user interface to apply changes to the information in the Audit History. The application presents the Audit History information in a system report. A user can access the Audit History for any object by selecting the relevant Audit function. 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.
(f) Use of operational system checks to enforce permitted sequencing of steps and events, as appropriate.	X	X	The application provides customers the means to manage workflows that enforce the sequencing of steps and events, as appropriate.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
(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 signature is not a capability in the application.
(h) Use of device (e.g., terminal) checks to determine, as appropriate, the validity of the source of data input or operational instruction.	N/A	X	The Formulation Design application does not support connecting to devices. It is the customer's responsibility to authenticate with the server for any connected devices.
(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. Regulatory Awareness training is provided to 3DS R&D personnel. 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	Electronic signature is not a capability in the Formulation Design application, however, is available in other 3DS applications. Customers need to develop the policies and procedures that support the use of the applications with electronic signatures in a regulated environment.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
(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 administrative 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.
(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 maintains 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			

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
(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 (2) The date and time when the signature was executed (3) The meaning (such as review, approval, responsibility, or authorship) associated with the signature. (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).	N/A		Electronic signature is not a capability in the BIOVIA Formulation Design application.
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.	N/A	X	Electronic signature is not a capability in the BIOVIA Formulation Design application. It is the customer's responsibility to establish policies and procedures that prevent unauthorized access to the database that contains the electronic records and 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.	N/A	X	Electronic signature is not a capability in the BIOVIA Formulation Design application, however, is available in other 3DS applications. The electronic signature is based on the 3DEXPERIENCE platform user credentials, which are unique to individual users and cannot be reused or reassigned.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
(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.	N/A	X	Electronic signature is not a capability in the Formulation Design application, however, is available in other 3DS applications. 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.	N/A	X	Electronic signature is not a capability in the Formulation Design application, however, is available in other 3DS applications. 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			

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
(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. (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. (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. (2) Be used only by their genuine owners (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.	N/A	X	Electronic signature is not a capability in the Formulation Design application, however, is available in other 3DS applications. 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. 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.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
(b) Electronic signatures based upon bio-metrics shall be designed to ensure that they cannot be used by anyone other than their genuine owners.	N/A	X	Electronic signature is not a capability in the Formulation Design application, however, is available in other 3DS applications. 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.
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		Electronic signature is not a capability in the Formulation Design application, however, is available in other 3DS applications. 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.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
(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.
(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 Formulation Design
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.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
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	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.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
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.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
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 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.
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 Systèmes' 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.
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 application is developed using good software practices and is thoroughly tested. BIOVIA Formulation Design includes features that enable the review of actions taken in the application through validation checks. Customers using the application in a regulated environment must have a computerized systems validation program, and must implement policies and procedures to ensure the review and verification of manually entered data.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
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 Formulation Design'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.
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	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.
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.	N/A		Formulation Design does not generate records for batch release.
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 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.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
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 Systèmes 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 Systèmes 3DEXPERIENCE Platform is delivered as a SaaS Cloud-based solution. Access to servers and data storage is tightly controlled and inspected to ISO standards.
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.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
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 have a CAPA program. Furthermore, Dassault Systèmes 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.
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	N/A	X	Electronic signature is not a capability in the BIOVIA Formulation Design application, however, is available in other applications on the 3DEXPERIENCE Platform. Each audit trail record includes the unique identifier of the actor that is linked to the specific activity. Customers need to establish policies and procedures and train users to 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	Electronic signature is not a capability in the Formulation Design application, however, is available in other applications on the 3DEXPERIENCE Platform. Customers using the application in a regulated environment must have a policy or procedure on the use of electronic signatures.

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
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 Systèmes 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.
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.	X	X	Data captured or attached as record sources in the 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:

Good Laboratory Practice (GLP)

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
21 CFR 58.130 Audit trails on electronic records.	X		The application maintains audit trails for electronic data. All audit trail records include a date and time stamp and the unique identifier (GUID) of the user.
21 CFR 58.190 Storage and retrieval of records and data.	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 through the Audit History.
21 CFR 58.195 Retention of records.	X	X	The GLP regulations define record retention periods as two to five years following the submissions of different permits. Given the length of time between beginning a study and submitting an application, record retention periods can be for many years. The application provides migration options for your records as the software is expanded and improved, assuring that your archived data is available. Records can be retrieved using the application throughout the record retention period defined in the contract with Dassault Systèmes. Customers need to establish policies and procedures to ensure their records are retained for the appropriate length of time.

Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals

Requirement	3DS APP	Customer SOP(s)	3DS Position for BIOVIA Formulation Design
21 CFR Part 211.68 (b) Appropriate controls shall be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Input to and output from the computer or related system of formulas or other records or data shall be checked for accuracy. The degree and frequency of input/output verification shall be based on the complexity and reliability of the computer or related system. A backup file of data entered into the computer or related system shall be maintained except where certain data, such as calculations performed in connection with laboratory analysis, are eliminated by computerization or other automated processes. In such instances a written record of the program shall be maintained along with appropriate validation data. Hard copy or alternative systems, such as duplicates, tapes, or microfilm, designed to assure that backup data are exact and complete and that it is secure from alteration, inadvertent erasures, or loss shall be maintained.	X	X	The application enables customers to ensure changes are made only by authorized personnel. It is the customer's responsibility to ensure that only authorized personnel are granted the permissions to make those changes. It is the customer's responsibility to check that formulas they create are accurate. The system can produce reports of the formulas that are created by the customer. 3DEXPERIENCE Cloud operations manages backup of the customers data.

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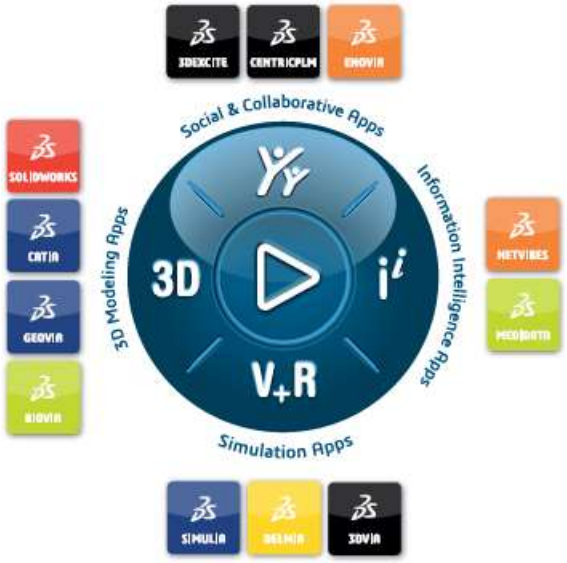
Dassault Systèmes brings value to more than 300,000 customers of all sizes, in all industries, in more than 150 countries. For more information, visit **www.3ds.com**.



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