

**LIFE SCIENCES
& HEALTHCARE**

**3DEXPERIENCE
PLATFORM ON CLOUD
RISK-BASED APPROACH
TO SOFTWARE
QUALITY ASSURANCE**





INTRODUCTION

Cloud computing represents a paradigm shift in how we do business. Organizations are running applications, managing data, and shifting operations to the cloud to benefit from the speed and simplicity of cloud provisions, as well as benefiting from the operational effectiveness of maintenance, IT services, and security from specialist providers.

Dassault Systèmes has been providing cloud-based services since the creation of the **3DEXPERIENCE®** platform in 2012. We have built a full cloud-based ecosystem, the **3DEXPERIENCE** Cloud platform that enables our clients to benefit from secure, flexible, scalable cloud resources. We position quality, security, and privacy at the heart of our **3DEXPERIENCE** platform operations. Our ISO certified management systems for Quality Management (ISO 9001:2015), Information Security (ISO/IEC 27001:2022, ISO/IEC 27017:2015), Information Privacy (ISO/IEC 27701:2019, ISO/IEC 27018:2019) together with our AICPA SOC 2 Type 2 attestation power our reliable and scalable cloud platform with state-of-the-art practices—critical enablers of your business success.

Cloud solutions provide an opportunity to be agile and respond quickly to customer requirements via shorter release cycles; on the other hand, these shorter release cycles introduce frequent changes and updates that require a robust change management system to maintain the systems in a validated state.

The implementation of computerized systems in regulated industries, such as pharmaceuticals, medical devices, and biotechnology, has significantly improved operational efficiency and data management. However, the use of computerized systems also introduces inherent risks, including data integrity, security breaches, and compliance failures. To help ensure the integrity, reliability, and compliance of computerized systems in a GxP (Good Practices) environment, a risk-based approach is essential.

Regulators are also increasingly expecting risk-based decision making to be incorporated into all facets of business processes throughout the product lifecycle. Appropriate controls help to manage risk and validate GxP systems for their intended use.

Typically, the same rigor is applied to all system changes

regardless of potential impact. If a universal change management approach is applied to all changes, it can repress system change with over-engineered, cumbersome processes. Managing the change is usually more involved than implementing the change itself, resulting in systems consistently lagging user needs. Without costly resources and time dedicated to steady state management, solutions may become stagnant—stuck on older software versions or configurations, and creating a growing gap between business needs and available software functionality.

By reducing the redundant, extraneous, and non-value-added change requirements, companies can better ensure a change management process that embraces system updates and continuously meets end-user requirements. The objective is to facilitate a streamlined change management process whereby there is no compromise to:

- The quality of the “product”
- The integrity of the software application’s validated state.

Life Sciences customers are seeking tools to support their business processes and must maintain GxP Compliance of all related operations:

- Consequently, Computerized System Validation (CSV) is required to assure GxP applications are fit for intended use and are compliant with applicable regulations. In the context of a cloud hosted GxP software or platform, the validation poses significant challenges when faced with initial validation and potential changes
- Every deployment or change to the system could potentially be a challenge to maintain the validated status
- As a Software supplier for Life Sciences companies, Dassault Systèmes helps enable Customer compliance with GxP regulatory requirements for its **3DEXPERIENCE** platform

In order to guide our Life Sciences customers, this white paper outlines the risk-based approach to software quality assurance followed for the evaluation of the Dassault Systèmes portfolio products and related changes based on GAMP 5 “*A Risk-Based Approach to Compliant GxP Computerized Systems*”.

The intent of this risk assessment process and associated validation artifacts is to expedite and support the customer’s validation process. Ultimately, it is the responsibility of the customer to validate the software for its intended use.

DASSAULT SYSTÈMES FUNCTIONAL RISK ASSESSMENT PROCESS

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ICH Q9: Quality Risk Management together with ICH Q8: Pharmaceutical Development and ICH Q10: Pharmaceutical Quality System are one of the ICH Quality topics that encourage further development of science-based and risk-based approaches to quality. The intention of ICH Q9 is to focus the behaviors of industry and regulatory authorities on the two primary principles of Quality Risk Management (QRM), which are:

- the evaluation of the risk to quality should be based on scientific knowledge and it should be ultimately linked to the protection of the patient;
- the level of effort, formality and documentation of the quality risk management process should commensurate with the level of risk

In the context of computerized software systems such as the **3DEXPERIENCE** platform, scientific knowledge is based upon the specifications and the business process being supported as explained in ISO 9001/Dassault Systèmes Quality Management System and GAMP5® Second Edition.

The initial assessment is based on in-depth knowledge of the industry business practices our solutions enable. This assessment is derived from user requirements, design specifications, operating procedures, regulatory requirements and known functional areas, as well as the involvement of subject matter experts from both the Dassault Systèmes R&D team and specialists from our Life Sciences and Healthcare Industries team.

For the **3DEXPERIENCE** platform, a '**Role**' includes a set of applications that enable users to cover a set of business activities corresponding to their job function. A '**Role**' is commercially available for customers to purchase. An '**Application**' provides a comprehensive set of features to the users to perform their job. A '**Feature**' corresponds to functionality within an application. A risk-based GxP impact assessment is conducted for each application that is available on cloud and is relevant to Life Science and Healthcare industries.

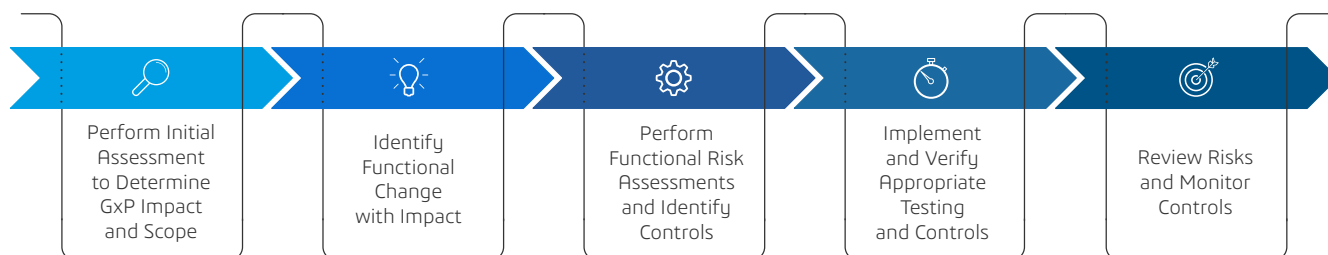
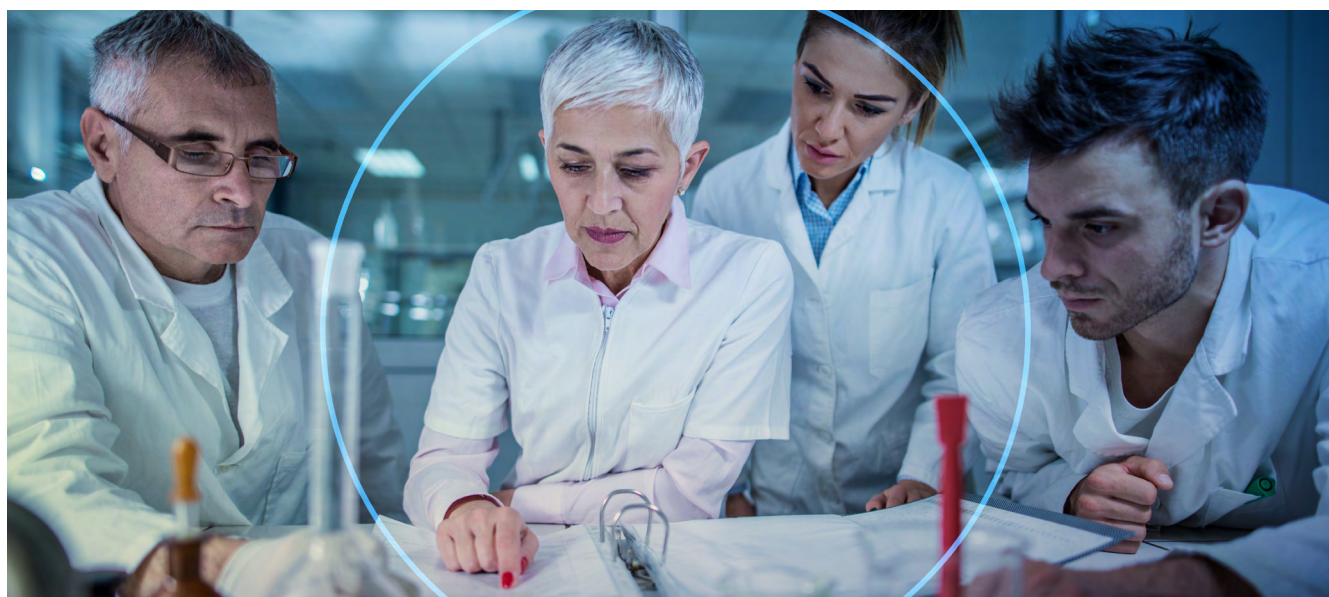


Figure 1—Quality Risk-Management Process



STEP 1: PERFORM INITIAL ASSESSMENT TO DETERMINE GxP IMPACT AND SCOPE

The primary objective of this initial step is to establish whether the application falls within the scope of GxP or lies outside it.

The assessment begins by focusing on role as the initial entry point, then progresses to each application within the role. Functional changes, including enhancements to existing features or the introduction of new features within an application, are managed via functions. Scenarios include test cases that validate these functional changes against their requirements and any regression impacts related to the change.

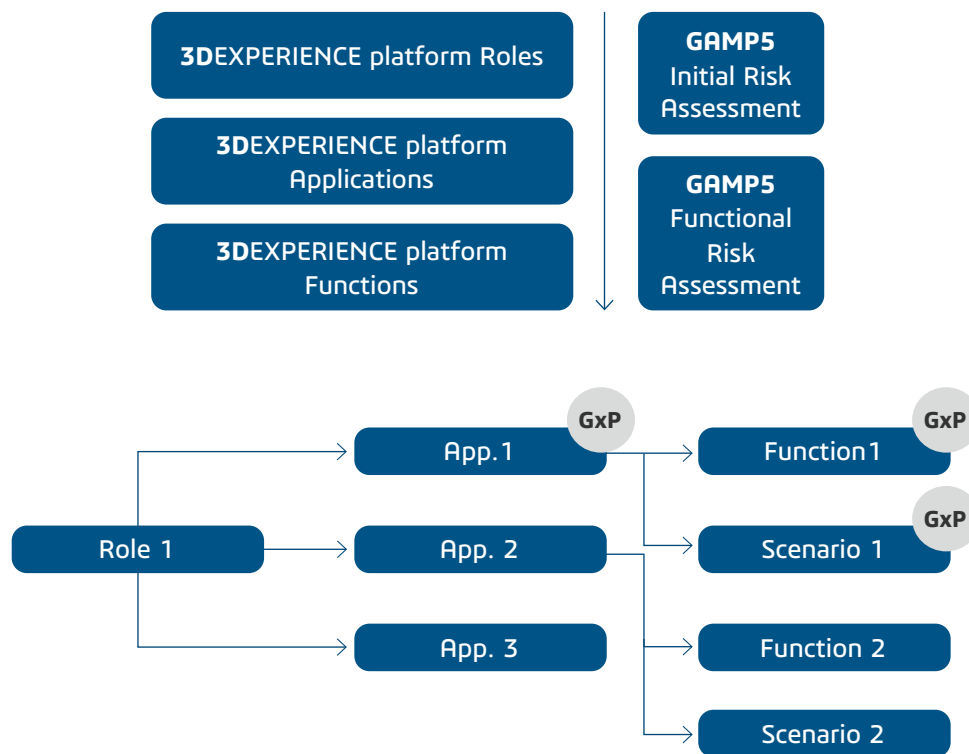


Figure 2—Levels of GxP impact assessment

The **GxP impact assessment** for an application is based on the response to the set of four questions in Table 1. Questions 1.1 and 1.2 are related to *direct* GxP impact and questions 1.3 and 1.4 are related to *indirect* GxP impact.

1.1 (Direct Impact)	1.2 (Direct Impact)	1.3 (Indirect Impact)	1.4 (Indirect Impact)
Does the application control a development, manufacturing and/or testing process that has a direct impact on product quality (drug or medical device)? Product quality attributes include identity, efficacy, strength, dosage, safety, and purity for example.	Does the application produce data that is used to “release” (batch release) drug or medical devices components or materials? (create, modify, maintain, archive, retrieve, or transmit data used to prove the safety, efficacy, and quality of product and formulations?)	Does the application provide information on which decisions are made affecting fitness for purpose of the drug or medical device product?	Does the application create, modify, maintain, archive, retrieve, or transmit records (data) that must be available for inspection by a regulatory agency, or data or reports that are sent to regulatory agencies?

Table 1—GxP Assessment Questions

The responses are then consolidated and used to classify the applications into three broad categories as indicated in Table.2.

Category	Response
GxP direct impact	Q1.1 or Q1.2 or both = "Yes"
GxP indirect impact	Q1.1 and Q1.2 = "No" Q1.3 or Q1.4 or both = "Yes"
Non-GxP	Q1.1, Q1.2, Q1.3 and Q1.4 = "No"

Table 2—GxP Impact Assessment Classification

STEP 2: IDENTIFY FUNCTIONAL CHANGE WITH IMPACT

This step focuses on identifying functional changes that impact GxP. In Dassault Systèmes terminology a function expresses what the system or application should provide to fulfill a requirement. An enhancement to an existing feature(s), or introduction of new feature(s) are delivered and tracked via functions. GxP classification status of the application, as determined in step one helps in identifying the functional changes with GxP impact.

STEP 3: PERFORM FUNCTIONAL RISK ASSESSMENTS AND IDENTIFY CONTROLS

A risk assessment is performed for all functional changes with GxP impact that were identified in step two. Risk is determined by analyzing the complexity of modifying the software (*high, medium, low*) along with the potential impact(s) (*major, moderate, minimal*) of the software change to the overall operation of the software as indicated in Figure.3.

Complexity

Complexity	Low	Medium	Low	Low
	Medium	High	Medium	Low
	High	High	High	Medium
		Major	Moderate	Minimal
		Impact		

Figure 3—Level of Risk



STEP 4: IMPLEMENT AND VERIFY APPROPRIATE TESTING AND CONTROLS

The risks and level of risk determined in the previous steps are used to develop appropriate preventive and detective controls. The risk information is also used to prepare the development and testing strategy, testing effort and schedule.

Well-established operational controls are in place across the software development lifecycle to manage risk related to specification, design, development, testing and release phases. Development and testing controls are designed to supplement each other in the reduction of risks. Large or medium level changes with significant impact expand the testing scope to include new test scenarios for the change and the affected existing tests. Low level changes, with little impact, limit the testing scope to new scenarios for the change as indicated in Table.3.

The primary goal of change management is to provide a high degree of assurance that the change was implemented as intended with no unexpected consequences. In line with ICH Q9 recommendations, when executing risk-based change management, the level of applied controls should correlate directly to the potential risk and impact i.e., the control should be sufficient to mitigate the risk. Or, if the risk has minimal impact on the resulting quality, an acceptable level of control may provide visibility without mitigation.

The table below describes the typical risk mitigation approach used to determine the most appropriate test coverage based on the scope of the changes introduced in a Software release.

		Testing Approach	
		Regression tests	New tests
Risk levels	High	Required	Required
	Medium	Required	Required
	Low	See note	See note

Table 3—Testing Approach for Risk Mitigation

Note

An assessment at the time of delivery is performed:

- to ascertain the scope (new and/or regression tests are necessary)
- to proceed with the testing approach outlined in Table.3 or to customize/alter the test approach based on the change being introduced for a given software version

STEP 5: REVIEW RISKS AND MONITOR CONTROLS

Risk controls are constantly applied and monitored throughout the software development lifecycle process to ensure appropriate decisions and measures are taken to reduce the risks and maintain it at acceptable levels. In line with ICH Q9 recommendations the controls are continuously evaluated to ascertain those controls are adequate to maintain the risks at acceptable levels. New or residual risks identified as a part of the ongoing risk assessment process are evaluated and additional controls are developed and implemented as required.

The results from each stage of the functional risk assessment process, coupled with their validation status, are collated as artifacts and assembled into a validation kit for distribution to our customers. A comprehensive breakdown of the validation kit's contents is provided below.



VALIDATION KIT

To expedite and facilitate the customer validation process, Dassault Systèmes has developed a collection of deliverables aligned with the GxP impact classification within the portfolio. These deliverables are detailed in Table 4.

The Functional Validation Kit provides documented evidence of the functional testing performed by Dassault Systèmes on GxP-impacted applications for a particular release.

The functional validation kit contents are detailed below.

GxP Impact	Deliverables
GxP Direct	Functional Validation Kit
GxP Indirect	Dassault Systèmes standard QMS is followed, no specific deliverable.
Non-GxP	Dassault Systèmes standard QMS is followed, no specific deliverable.

Table 4—Validation Kit Deliverables

Functional Change Risk and Impact Assessment provides the list of functional changes and a corresponding risk and impact assessment for each functional change.

Brand	Application/ Role	Function ID	Function Title	Quality Assessment	Risk Complexity	Risk Impact	Change Risk Exposure	IR	IR Title
BIOVIA	Controlled Document Management	FUN111	Formulation Design— Bakers 100 and PHR in Formulation Design	GO	Medium	Moderate	This function adds new calculation support Bakers 100/PHR. These are new calculations and have minimal impact on the current calculators. These are covered with new unit tests.		

Table 5—Functional Change Risk and Impact Assessment

Scenario and Scenario Replay Status provides detailed test scenarios and their respective test replay status and case titles.

Brand	Application/ Role	Scenario ID	Scenario Title	Replay ID	Replay Date	Replay Status	No of Cases/ Nb of Steps	Case ID	Case Title	IR	IR Title
BIOVIA	Controlled Document Management	SCN112	QUC_ Widget_ Valkit_ GxP_ Compliance	RSC1082171	2026– Apr–29 / 09:54:52 AM	GO	17/57	1	Create Two Quality System Documents		

Table 6—Scenario and Scenario Replay Status

Remaining Open Issues includes the list of severity one (P1) incidents that remain open at the close of the release linked to functions and scenarios test performed in the context of the validation kit.

Brand	IR	IR State	IR Severity	IR Title	Functional Risk Assessment and Impact
BIOVIA	IR-111111	Open	Sev.1	R2026x_FD02 PPD2 CSTF CAFET Editing the DCCL Conformance Values are KO for the imported data	This issue is specific to the data; i.e. multivalued custom attributes, does not impact the entire functionality

Table 7—Remaining Open Issues & Impact Assessment

VALIDATION ENVIRONMENT

In addition to the validation kit(s), Dassault Systèmes provisions validation environments for its customers to

perform pre-production validation. The provision these validation kit(s) and environments are based on the contractual agreement between Dassault Systèmes and its customers.



CONCLUSION

Implementing a risk-based approach to compliant GxP computerized systems is crucial for maintaining the validated state of system and enabling the regulatory compliance of our customers. By adopting a structured risk management framework and following best practices for risk assessment,

mitigation, and documentation, organizations can effectively identify and manage risks throughout the computerized system's lifecycle. A risk-based approach supports proactive decision-making, allocation of resources, and continuous improvement to maintain compliance in a rapidly evolving regulatory landscape.

GLOSSARY

Role	A 3DEXPERIENCE 'Role' includes a set of applications enabling users to cover a set of business activities corresponding to their job function.
Application	An application provides a comprehensive set of features to the users to perform their job.
Feature	A feature corresponds to functionality within an application.
Function	A function expresses what the system or application should provide to fulfill a requirement. An enhancement to an existing feature, or introduction of new feature, is tracked via functions
Scenario	A scenario describes the steps to perform in order to test a particular aspect of a role/application
Test Case	A test case provides a brief description of the test to be performed, while the detailed test steps are organized within the test case
Scenario replay	A scenario replay records the execution of a list of steps for a scenario.
Scenario replay status	A scenario replay status represents the assessment provided by the Quality Assurance Engineer for every replay based on the status of each scenario step replayed.
Incident report (IR)	An incident report is used to record a defect (bug) that was detected in the role/application

REFERENCES

1. GAMP 5 "A Risk-Based Approach to Compliant GxP Computerized Systems".
2. The International Council for Harmonisation guidelines ICH Q8, ICH Q9, ICH Q10.
3. Food and Drug Administration (FDA) Guidance for Industry Part 11, Electronic Records; Electronic Signatures—Scope and Application.
4. Food and Drug Administration (FDA) General Principles of Software Validation; Final Guidance for Industry and FDA Staff.
5. Food and Drug Administration (FDA) Computer Software Assurance for Production and Quality System Software; Draft Guidance for Industry and Food and Drug Administration Staff.

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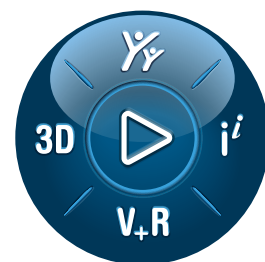
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With Dassault Systèmes' **3DEXPERIENCE** platform, 370,000 customers of all sizes, in all industries, can collaborate, imagine and create sustainable innovations that drive meaningful impact.

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