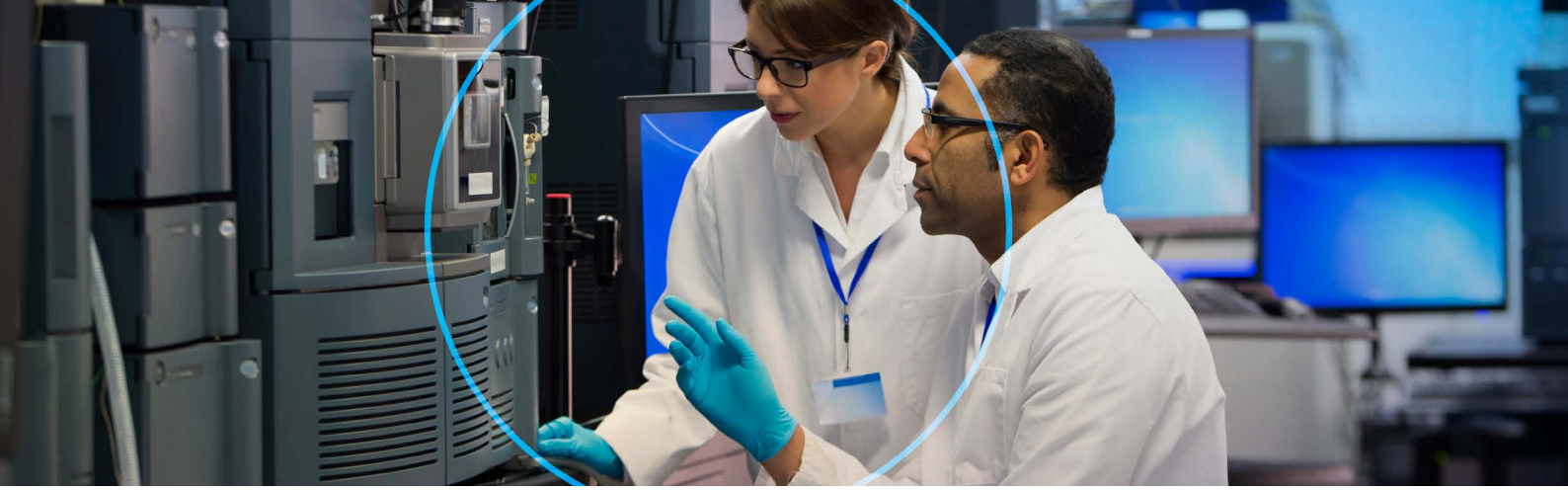
LIFE SCIENCES
& HEALTHCARE

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

DASSAULT SYSTEMES



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 (3DS) has been providing cloud-based services since the creation of the **3D**EXPERIENCE platform in 2012. We have built a full cloud-based ecosystem, the **3D**EXPERIENCE Cloud platform that enables our clients to benefit from secure, flexible and scalable cloud resources. We position quality, security and privacy at the heart of our **3D**EXPERIENCE platform operations. Our ISO certified management systems for Quality Management (ISO 9001:2015), Information Security (ISO/IEC 27001:2017) and Information Privacy (ISO/IEC 27701:2019) 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 behind 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 ensure 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 cloud-based services supplier for Life Sciences companies, 3DS supports its customers compliance with their GxP regulatory requirements for its **3D**EXPERIENCE 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 **3D**EXPERIENCE 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 customer's responsibility to validate the software for its intended use.

3DS FUNCTIONAL RISK ASSESSMENT PROCESS

The International Conference on Harmonisation of Technical Requirements for Registration of 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 be commensurate with the level of risk

In the context of computerized software systems such as the **3D**EXPERIENCE platform, scientific knowledge is based upon the specifications and business process being supported as explained in ISO 9001 / 3DS Quality Management System and GAMP®5 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 3DS R&D team and specialists from our Life Sciences and Healthcare industries team.

For the **3D**EXPERIENCE 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 for the users to perform their jobs. A 'Feature' corresponds to functionality within an application. A risk-based GxP impact assessment is conducted for each role that is available on the cloud and is relevant to Life Science and Healthcare industries.

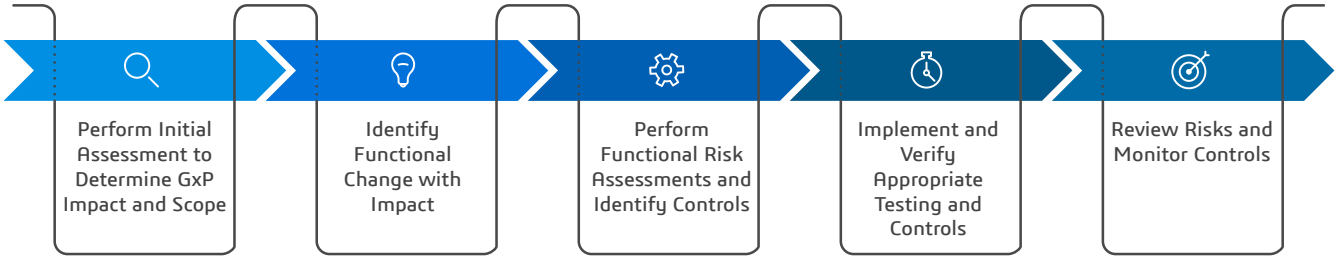


Figure 1- Quality Risk-Management Process

Step.1: Perform Initial Assessment to Determine GxP Impact and Scope

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

The GxP impact assessment is conducted at three levels — Role, Application and Feature — as indicated in Figure 2. The assessment begins by focusing on role as the initial entry point, then progresses to each application within the role, and finally dives into the feature available within each impacted application. Functional changes to an existing feature(s) or the introduction of a new feature(s) are managed via functions. Scenarios include test cases that validate these functional changes against their requirements.

The GxP impact assessment for each level 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 while questions 1.3 and 1.4 are related to indirect GxP impact.

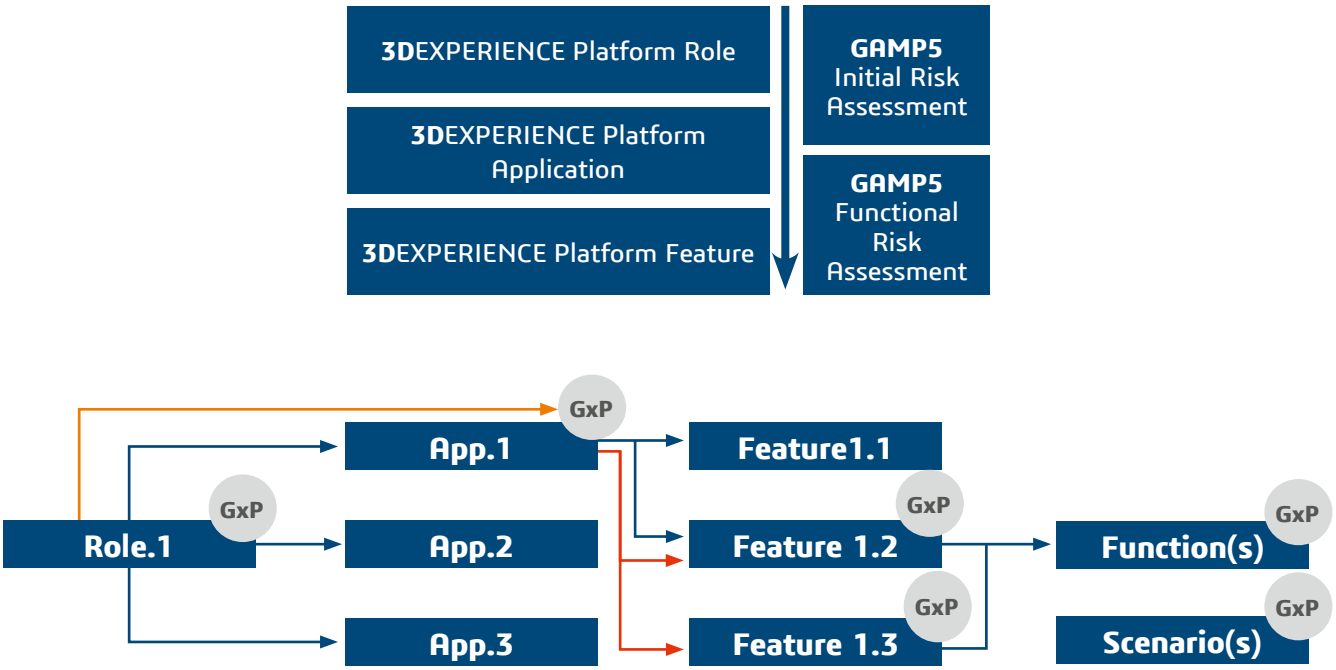


Figure.2- Levels of GxP Assessment

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

Table 1- GxP Assessment Questions

The responses are then consolidated and used to classify the role, application and feature 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 3DS terminology, a function expresses what the system or application should provide to fulfill a requirement. An enhancement to an existing feature(s) or an introduction of a new feature(s) is delivered and tracked via functions. Each function is associated with a feature, and the GxP classification status of the feature from step one helps identify 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 change on the overall software operations, as indicated in Figure 3.

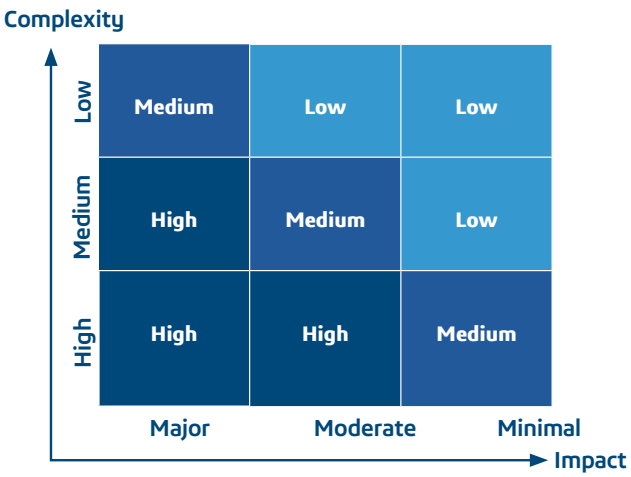


Figure 3- Level of Risk

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 3DS 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)
- Proceed with the testing approach outlined in Table 3 or 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 and maintain risks at acceptable levels. In line with ICH Q9 recommendations, the controls are continuously evaluated to ascertain that those controls are adequate to keep 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, 3DS has developed a collection of deliverables aligned with the GxP impact classification within the portfolio. These deliverables are detailed in Table 4.

GxP Impact	Deliverables
GxP direct	Functional Validation Kit ER/ES Validation Kit
GxP indirect	ER/ES Validation Kit
Non-GxP	None. 3DS standard QMS is followed.

Table 4- Validation Kit Deliverables

The Functional Validation Kit provides documented evidence of the functional testing performed by 3DS on GxP-impacted application and feature for a particular release. Additionally, the Electronic Records and Electronic Signatures (ER/ES) Validation Kit provides documented evidence of functional testing performed by 3DS to validate electronic record and electronic signature functionality — as defined in the United States Food and Drug Administration Code of Federal Regulations Title 21 Part 11 (21 CFR Part 11) and European Union GMP Annex 11, guideline for computerized systems.

The Functional Validation Kit contents are detailed below:

GxP-Impacted Feature(s) and Related Scenarios provide the list of the GxP-impacted role, application and feature, along with test scenarios linked to the validation scope.

3DS Role Brand: DELMIA		3DS Application Name: DELMIA Manufacturing Items Management		
Discipline	Feature Group	Feature	Scenario ID	Scenario Title
Process Planning	DELMIA Manufacturing Items Management	MFN Advance Duplicate	SCN0001	MFN Core Scenario

Table.5- GxP Impacted Feature(s) and Related Scenarios

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

Function Brand	3DS Application	Feature Impacted	Function ID	Function Title	Function Risk Impact	Function Risk Probability	Function Risk Exposure	Quality Assessment
DELMIA	DELMIA Manufacturing Items Management	MFN Advance Duplicate	Fun0001	Integration of advance duplicate command	High	Medium	Replacing an existing command with a new command that is based on a new architecture framework.	GO

Table.6- Functional Change Risk and Impack Assessment

Scenario and Scenario Replay Status provide detailed test scenarios and their respective test replay status for the GxP-impacted feature(s) and functional changes.

3DS Scenario Brand	3DS Role	3DS Application	Scenario Feature	Scenario ID	Scenario Title	Scenario Replay ID	Last Execution Date	Replayed By	Scenario Replay Status
DELMIA	Manufacturing Items Management (MFN)	DELMIA Manufacturing Items Management	MFN Advance Duplicate	SCN0001	MFN Core Scenario	RSC0001	01/01/24	xxx	GO

Step ID	Step Title	Tested Feature	Step Execution Instructions	Scenario ID	Scenario Replay status
001	Advance Duplicate	MNF Advance Duplicate	Select "Advance Duplicate" option in the duplicate window	Advance duplicate panel is displayed with the text and advance options	PASS

Table.7- Scenario and Scenario Replay Status

Consolidated Scenario Replay Summary provides an overall test scenario replay summary.

3DS Scenario Brand	Scenario ID	3DS Application	Scenario Feature	Scenario Title	Scenario Replay ID	Last Execution Date	Replayed By	Steps Replay Pass/Failed/ Blocked/Not Replayed/ Total	Scenario Replay Status
DELMIA	SCN0001	DELMIA Manufacturing Items Management	MFN Advance Duplicate	MFN Core Scenario	RSC0001	01/01/24	xxx	43/0/0/0-[43]	GO
DELMIA	SCN0002	DELMIA Manufacturing Items Management	MFN Revision	MFN Revision Scenario	RSC0002	01/01/24	xxx	33/2/1/0-[36]	NOGO
DELMIA	SCN0003	DELMIA Manufacturing Items Management	MFN Change Management	MFN Change Scenario	RSC0003	01/01/24	xxx	93/0/0/0-[93]	GO

Table.8- Consolidated Scenario Replay Summary

Change Related Open Issues outline problems that remained open at the close of the release linked to tests performed in the context of the validation kit.

Issue ID	Issue Abstract	Issue State	IR Severity (1-4)	Concerned Change ID	Concerned Change Title
ISU0001	Refresh issue in the dialog panel	Open	2	FUN0001	Integration of advance duplicate command

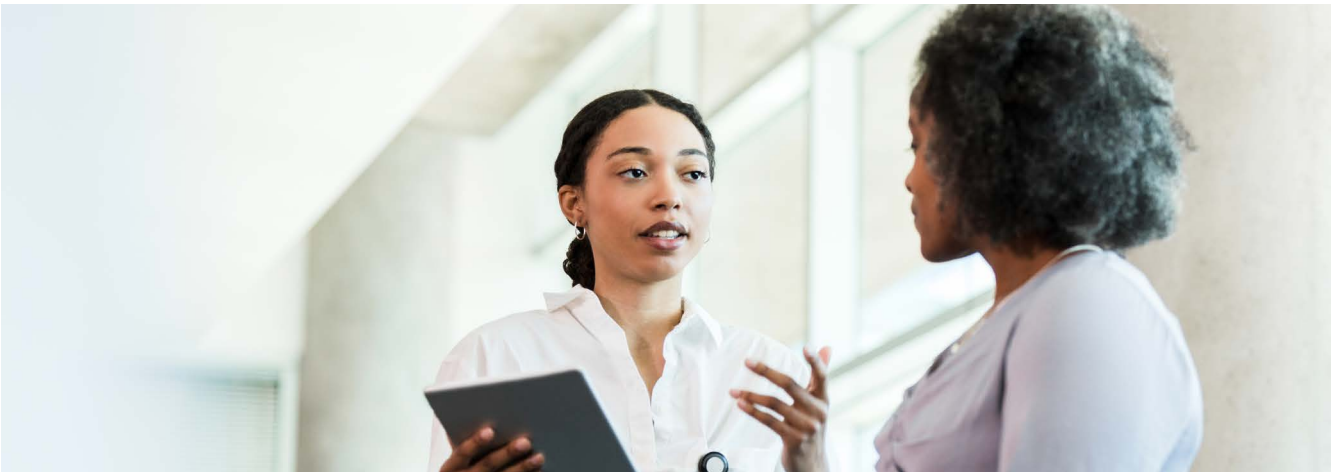
Table.9- Change Related Open Issues

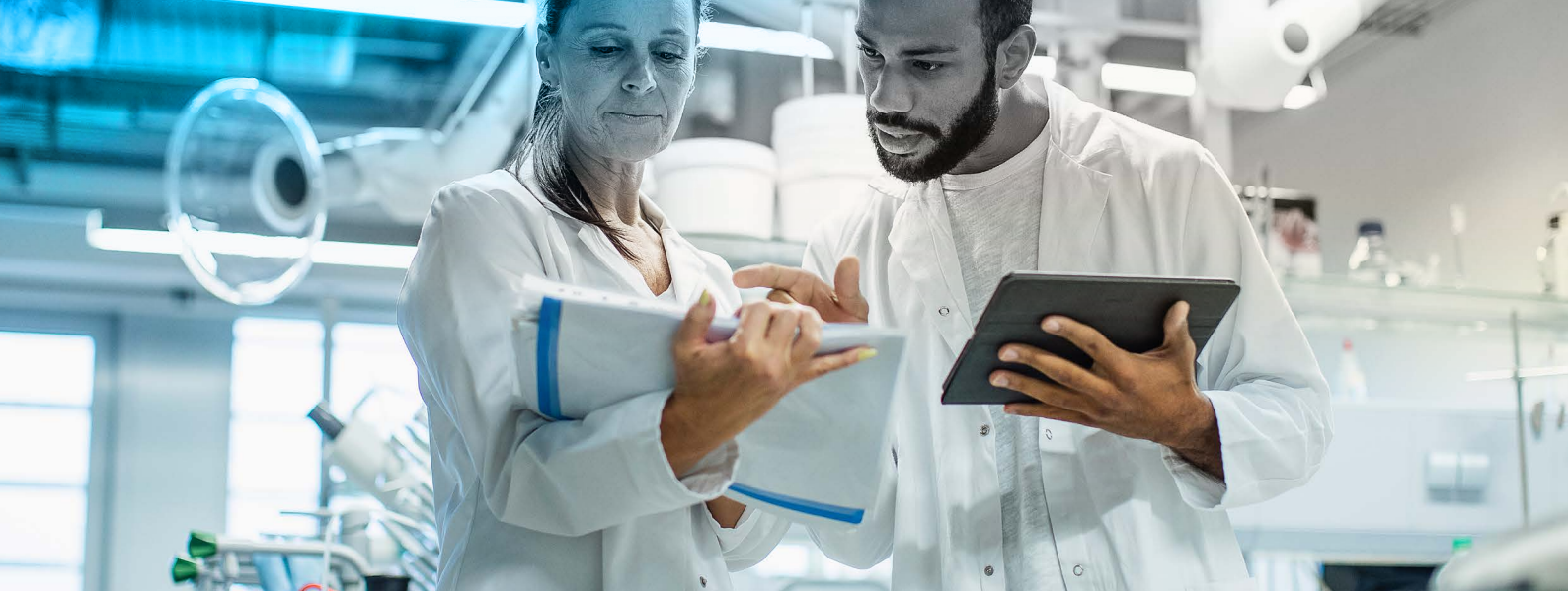
Supplemental information to the Functional Validation Kit, an Electronic Records and Electronic Signature (ER/ES) Validation Kit is provided wherever applicable. The ER/ES Validation Kit contents are detailed below.

- **Scenario and scenario replay status** provide detailed test scenarios and their respective test replay status for ER and ES
- **Consolidated scenario replay summary**, which provides an overall test scenario replay summary
- **Open issues** that stayed open at the close of the release linked to tests performed in the context of the validation kit

VALIDATION ENVIRONMENT

In addition to the validation kit(s), 3DS provisions validation environments for its customers to perform pre-production validation. These validation kit(s) and environments are based on the contractual agreement between 3DS and its customers.





CONCLUSION

Implementing a risk-based approach to compliant GxP computerized systems is crucial for maintaining the validated state of systems and helping our customers' regulatory compliance. 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 **3D**EXPERIENCE 'Role' includes a set of applications enabling users to cover business activities corresponding to their job function.
Application	An application provides a comprehensive set of features for users to perform their jobs.
Discipline	A discipline is a collection of related feature groups.
Feature Group	A feature group is a collection of related features.
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 an introduction of a new feature is tracked via functions.
Scenario	A scenario describes the steps to test a particular aspect of a role/application.
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 replayed scenario step.
Incident report	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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