BIOVIA

3DEXPERIENCE®

# BIOVIA
# QUALITY STATEMENT
## Datasheet


DASSAULT SYSTEMES

## COMPANY INFORMATION

Headquartered in San Diego, California, BIOVIA, Dassault Systèmes (BIOVIA) supports science-based industries by providing a scientific collaborative environment for advanced biological, chemical and materials experiences. With the goal of helping organizations develop better products faster and more cost effectively, BIOVIA supports customers in the Life Sciences and Materials Science & Engineering sectors to help them:

- Enhance product and process insight
- Facilitate collaboration, both internally and across externalized research networks, and
- Accelerate compliant product and process development from research through late-stage QC/QA, manufacturing and commercialization

Refer to the BIOVIA Brand Profile datasheet for more information and history.

## QUALITY MANAGEMENT SYSTEM

At BIOVIA, we are committed to offering our customers a complete solution for scientific software. Our products enable greater productivity, advancements and sharing. The BIOVIA software portfolio unifies our customers' research and development organization around a single system, and solves critical issues for scientists, management, information technology and intellectual property.

The BIOVIA software portfolio supporting the Life Sciences industry covers the following disciplines, which are developed under the BIOVIA Quality Management System:

- **Quality & Compliance**
- **Scientific Informatics**
- **Molecular Modeling & Simulation**
- **Data Science**
- **Laboratory Informatics**
- **Formulation Design**
- **Manufacturing Analytics**

Our BIOVIA Quality Management System (QMS) facilitates the objectives of our customers, that is, to reduce the cost, time and complexity of software validation. This quality system ensures that we follow good software development practices and that we create and release high quality products that enable our customers to meet regulatory requirements. Our business and development processes are designed around the Food and Drug Administration (FDA) requirements and guidelines for software development and validation, including those outlined in the Good Automated Manufacturing Practice (GAMP) guide published by the International Society for Pharmaceutical Engineering (ISPE). Customer feedback is incorporated into our quality system to ensure that our products meet or exceed customer expectations. The Quality Management System (QMS) at BIOVIA also incorporates key elements of ISO 9000 and the Institute of Electrical and Electronics Engineers (IEEE) standards for software engineering. The ISO 9000 standard from the International Standards Organization establishes a basis for the content of the quality system, and IEEE provides additional standards for processes, tools and documentation.

Dassault Systèmes, the parent company of the BIOVIA brand, has achieved ISO 9001:2015 for the Quality Management System for the 3DEXPERIENCE platform cloud applications. To request and download the certificate, go to https://www.3ds.com/about-3ds/ethics-and-compliance/quality-compliance/.

In addition, many of the world's leading pharmaceutical companies have audited the BIOVIA quality system and have approved BIOVIA as a quality strategic supplier.

Our system mandates quality procedures that are implemented during the product development process, such as periodic audits, the use of development and process document templates, executive approval of processes and plans, quality compliance oversight and on-line access to process documents. New employees receive quality system training as part of their new employee orientation, as well as on-going training on process changes for existing employees.

## DOCUMENT CHANGE CONTROL OF THE BIOVIA QUALITY MANAGEMENT SYSTEM (QMS)

The BIOVIA Quality Management System (QMS) is subject to formal change control. Change requests can be made through the internal tracking system. The software management team evaluates these requests and determines whether or not to make the changes. When changes are made, they are documented through a Change Order which requires formal Leadership Team approval. Employees are notified of the changes and required to indicate that they have reviewed and understand the changes.

The BIOVIA Quality Management System has pre-defined levels of approval for different project documentation. Release Plan Reviews require review and approval by the Leadership Team, as do Golden releases. Other documentation, such as Test Plans, requirements and design reviews, are approved by the cross-functional project teams, which include representatives from the development, software test, configuration management, documentation, product management, customer support and quality compliance organizations.

All BIOVIA Quality Management System and project documents are managed under the requirements of the "Quality System Document Management and Storage" procedure. This procedure details the requirements for the management, storage, maintenance and modification of documents within the BIOVIA Quality Management System. It applies to all contents of the BIOVIA Quality Management System, including documentation produced as a result of projects operating under the quality system. It is applicable to all departments at all locations within the BIOVIA organization that operate within the quality system.

All Software Development documents and associated procedures are BIOVIA Proprietary documents and can only be shared with customers during vendor audits.

## PERSONNEL AND ORGANIZATION

BIOVIA's commitment to hiring excellent people with industry-pertinent training is evidenced by the qualifications of our employees. Most of our technical employees have degrees in Chemistry, Biology and Computer Science. Many have post-graduate degrees. Continuous job development and training is encouraged through our tuition reimbursement program, attendance at professional development courses, the Dassault Systèmes 3DS University and attendance at on-site training seminars and coaching sessions. New employee orientation sessions introduce staff to our development process and our quality management system. Awareness training on the regulatory and compliance needs of the life science industry, such as 21 CFR Part 11 and Annex 11 regulations, is included as part of the curriculum for new employee orientation. Staff seminars and peer-to-peer educational opportunities flourish as a result of design reviews, code reviews, test planning discussions and other mentoring activities.

The BIOVIA work environment engenders a cross-functional approach to product development. Our product teams comprise representatives from Product Development, Product Management, Quality Assurance (Test), Documentation, Configuration Management, Customer Support and Quality Compliance. This team approach promotes frequent communication and synchronized effort between the groups that create and support our products.

## PRODUCT LIFECYCLE

The BIOVIA Product Lifecycle encompasses the overall lifetime of a product, from Initiation to end of product life through Obsolescence. The lifetime of the product also includes the maintenance of the product through product releases, which incorporates the Software Development Life Cycle (SDLC) for each product release. Each product release has clear distinct phases to incorporate the planning, requirements, design and testing of the product. The software development methodology at BIOVIA utilizes the more modern iterative development model. As a result, clear requirements are defined for specific functionality before programming begins. At defined points in the development process, requirements, design and test cases are re-evaluated and revised to allow for innovations and improvements to the plan. Customer-requested changes are built into the product, as needed by the iterative development model. When the development process is complete, the product is approved and released to customers for use. Maintenance and obsolescence processes are also defined to ensure the software is maintained throughout its viable lifetime and, when required, is discontinued via a controlled and predefined process.

The scope of the development process is dependent on the change and associated impact of a release. For example, full releases with new features that are delivered to all customers use the full development process. Service pack releases, which fix specific problems or introduce small updates to functionality for a small number of customers, use an abbreviated approved version of the process. The product team defines the scope of a release as per the predefined controlled process required for the release.

To ensure coding consistency, the development team defines and maintains coding standards. Formal code reviews by managers and peer reviews help developers follow and improve the standards. Code reviews are done on an as-required basis during the development phase. A risk-based assessment is used to determine if a code review is warranted, with more frequent code reviews conducted on high- priority or high-risk features, and more code reviews conducted later in the software development lifecycle where risks of regression and schedule impact are higher.

Peer reviews happen throughout the SDLC. Requirements reviews are conducted by a cross-functional team including product management, development, test, configuration management and documentation personnel. Prior to release, a review of the product is conducted by product management to help ensure that the product meets market and customer needs. Reviews of test plans and test scripts are done throughout the development and test cycle by peers in the test organization or by programmers working on specific features.

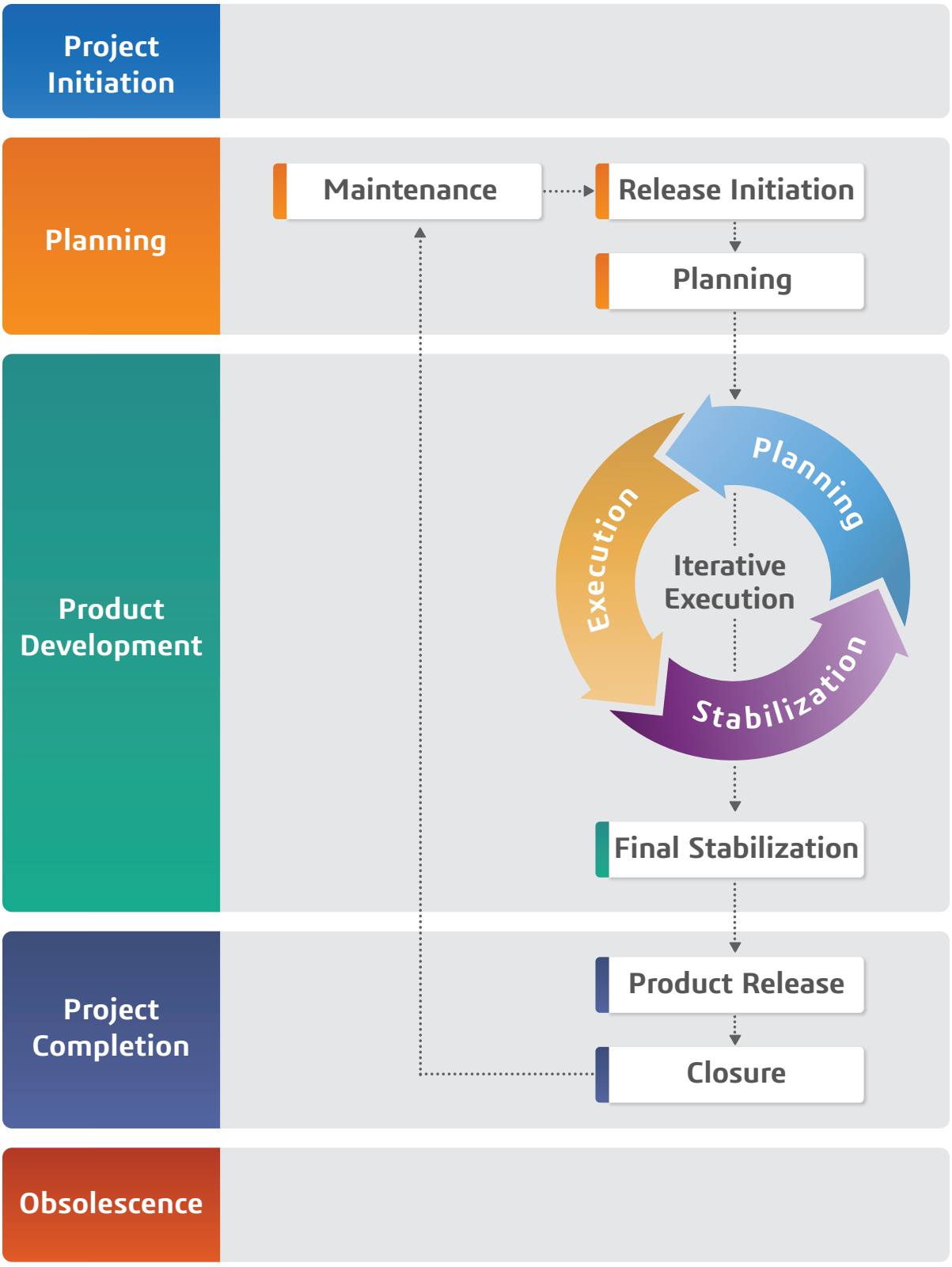
## SOFTWARE DEVELOPMENT LIFECYCLE

The overall purpose of the software development lifecycle is to transform a set of requirements into a viable software product or system. Input from customers and users is critical in defining these requirements for any given product. The system is designed and developed to meet customer requirements. The products are tested throughout the process to assure that the requirements are met and that the software functions as it was designed to function. The product is documented to ensure that users and customers can install, configure and use the software to accomplish the tasks it is designed to do.

A diagram of the software development lifecycle is provided next page.

It is important to note that, while the diagrammatic view of this process indicates phases with clear starting and stopping points, the process at BIOVIA is meant to be iterative and meant to allow for flexibility to address changing business needs via a controlled process. Therefore, a given requirement might be defined, prototyped, evaluated technically and coded before one has reached the final list of requirements for a given release. However, each requirement will be traceable through the process to show that it has been defined, coded and tested appropriately. In addition, once the list of requirements for a complete release is defined, that list of requirements is tested in its entirety during the final stabilization phase and prior to release to the customer.

# BIOVIA Software Development Life Cycle (SDLC)



The Software Development Lifecycle is structured into different phases with checkpoints at the end of each phase. The phases include:

- **Release Initiation**
- **Planning**
- **Iterative Execution**
- **Final Stabilization**
- **Product Release**
- **Closure**
- **Maintenance**

Overlying these processes for each given project or product release is project management. All projects will travel through each phase, but the amount of activity, documentation and the speed of execution will vary depending on the type of project. It is the responsibility of the project lead to determine what activities apply to a given project as defined by release types in the Quality Management System based on the risk and scope of work associated with that project.

The purpose of the Release Initiation phase is to define and approve the objectives of a new project and to assign resources to that project. New product initiatives require approval by the Leadership Team. Product Management will develop a Release Plan Review including use cases or business requirements.

The purpose of the Planning phase is to develop an overall project plan, based on the high level product requirements and use cases that will be addressed by the project and on input from the various functional groups involved in the project. It includes defining deliverables and User Stories (requirements), defining and analyzing risks and scheduling the activities that occur within the project. The deliverables of the planning activities are agreed upon as project milestones and dates that are then tracked in the project management system.

The purpose of the Iterative Execution phase is to complete the actual coding, testing and documentation work required to accomplish the project's objectives. User Stories (requirements) are fleshed out and well understood, software is developed to meet those requirements and address the fundamental use cases. Test scripts are designed and executed, documentation is written and installers are created. Underlying all of this is the automated build system which manages all source code, builds the test-ready deliverables and executes any automated unit tests.

The purpose of the Final Stabilization phase is to conduct final testing, defect resolution and documentation activities. This phase may be conducted in release candidate cycles, an iterative approach to testing and defect resolution designed to work towards a releasable product. This is the final look at the software to assure it is of sufficient quality for release to the customer base. Only high priority bugs are fixed. Typically, reviews are done of those fixes. Risk assessments are made of those fixes so that the appropriate amount of testing for those fixes can be done. This phase brings all the components of the software together, including different modules, the database, the different supported operating systems, etc. The product is then regression tested, as defined in the test plan, to demonstrate that the product is stable and requirements are met, and that it is ready for release to end users. The deliverables, including software, documentation, installers, etc. may also be distributed to a wider audience within BIOVIA to allow for additional installation training/testing, or Customer Support Review.

During the Product Release phase, the Product Team prepares for the final release by conducting an Executive Call Meeting (Release Readiness Review) that provides the BIOVIA leadership team with sufficient information about the product quality and risks of release to allow for an appropriate decision about releasing the product and conducting other release-related activities. During this phase, the product and all its components (e.g., documentation and installers) are released to customers through a controlled mechanism. Supporting components are also created and maintained (e.g., third party components). The Product Release phase of the SDLC primarily covers the handoffs between the product team and the Business Operations organization, which is responsible for delivering product to the customer base through a download platform, as well as through BIOVIA ScienceCloud.

The purpose of the Closure phase is to formally terminate all project activities. This phase of the life cycle verifies that the SDLC is complete and that the project is finished. It includes the activities necessary to administratively close the project as well as evaluate the project's performance against its objectives. It provides the opportunity for the team to reflect on the project performance and determine what went well and what needs improvement on the next project.

Once a product has been released, it must be maintained. These activities are part of the Maintenance phase. Information obtained from customers is fed back into the development process and becomes part of the list of requirements or goals considered for future releases.

The purpose of the Maintenance phase is to provide optimal support for released products. Product maintenance is an ongoing effort. Information obtained from customers is fed back into the development process and becomes part of the list of requirements or goals considered for future releases. There are several procedures in place that define how maintenance is to occur, including how customer issues for existing products are managed.

As new technologies become available, and as new user needs surface, it is sometimes necessary to declare a product "Obsolete" and move forward with the next generation product. The Obsolescence phase of the software development lifecycle is designed to allow

allow for adequate customer notification and support during their transition to new products. Procedures in the Obsolescence phase also cover changes to supported hardware and software and changes to the types of support provided for a given product.

## VALIDATION AND VERIFICATION ACTIVITIES

The Software Testing (QA) organization writes a test plan for each software release. The test plan outlines the scope of the testing as well as the software configurations. A full release includes functional, performance, stability and automated regression testing.

BIOVIA uses a software tool that provides a single repository in which User Stories (feature requirements) are tracked for each new software release. The test organization designs specific test scripts for each requirement, and there are links between the requirements and test cases. Test results are entered into this system along with information about which build the tests were conducted against and links to any new defects created as a result of executing the tests. Test results are subject to a review cycle.

Traceability between requirements, tests and test results are managed through this system, and a full report showing requirements, tests and test results by build (or final test results) is available.

## PROJECT CHANGE CONTROL

Change Control applies to projects underway, where changes to requirements must be managed. The BIOVIA Quality Management System calls for a planning phase early in a project where discussions of scope, resources, schedule and uses cases are laid out in the Release Plan Review document. Management approves the Release Plan Review, and the release plan is tracked at weekly management meetings.

Later in a project, change control becomes much more significant as the risk of introducing changes when the code is stabilizing is much higher. Change Control Board (CCB) meetings are called to discuss any changes proposed at this point. A CCB includes representatives from the development, software test, configuration management, documentation, product management, customer support and quality compliance organizations. Risks to project scope and schedule are communicated at the weekly management meetings, and management approval is only required if changes will affect either the project's ability to address the use cases laid out in the Release Plan Review or the schedule.

## CONFIGURATION MANAGEMENT

The Configuration Management (CM) department and industry-standard source code management (SCM) software manage and control changes to the source code and the software configuration. The CM department maintains the procedures for controlling, building and maintaining all source code.

The SCM software enforces the tagging of changes and branches to the source code, which guarantees the unique identification, reproduction and retrieval of each code version (or build). Additionally, SCM secures the source code by allowing access only to authorized personnel. Everyone with access to the SCM system receives training on the source code change procedures and the tagging conventions.

## RELEASE MANAGEMENT

BIOVIA uses software tools that provide a single repository in which User Stories, design, test cases, test results and defects are tracked for each new software release. When development and testing are complete, QA presents to the executive team a summary of product readiness, based on the release readiness criteria outlined during the planning phase, and makes a release recommendation. The product is released to customers only after it has passed the release readiness review.

## SECURITY

Secure IT and Facility Infrastructure. To ensure the security of the hardware, software and infrastructure used for the software development of BIOVIA products, the Global Information Technology (IT) department at Dassault Systèmes is responsible for managing and securing network, hardware and software resources. Site access and physical security are the responsibilities of the Security & Safety group at Dassault Systèmes. These groups are responsible for IT and Facilities processes across all Dassault Systèmes locations.

Please contact your Account Sales Representative for more information about Dassault Systèmes Information Security.

Secure Coding Practices. During the software development of our products, BIOVIA employs secure coding practices by conducting periodic code reviews by peers and automated systems. Vulnerability and penetration testing are done at pre-determined stages of the SDLC with the ability to stop deployment if a security risk is discovered. The SDLC process is continuously evaluated and updated to stay current with industry standards and best practices.

For BIOVIA products, such as Pipeline Pilot, Notebook, Foundation, Compose and Capture, Workbook and CISPro in the ScienceCloud, the ScienceCloud's Security and DevOps Teams work closely with the development teams to ensure secure configuration and policy enforcement. Fully autonomous environments are maintained for Development, Test and Production.

Secure Cloud Environment. ScienceCloud is a cloud-based information management and collaboration workspace designed to support globally networked life science companies. ScienceCloud allows customers and partners to efficiently access, share and communicate critical information in a secure and timely manner.

ScienceCloud has achieved and maintains ISO/IEC 27001:2013 Certification. ISO 27001 is the most widely recognized and internationally accepted standard for an independently verified Information Security Management System (ISMS). ISO 27001 enables ScienceCloud to identify security risks and implement appropriate controls to preserve confidentiality, integrity and availability of information assets. ScienceCloud ISMS includes the business processes and technology that guide the development and support of the ScienceCloud platform.

For more information about the ScienceCloud Security Best Practices, download the Whitepaper: ScienceCloud Security.

Secure Data. BIOVIA cares about your personal information, hence BIOVIA employs a privacy policy. See BIOVIA, Dassault Systèmes: Privacy Policy. All BIOVIA employees as well as Dassault Systèmes and Business Partners are required to follow the 3DS Data Protection Guidelines and HR Data Privacy Policy to ensure that our customers and their clients' data are safeguarded and follow the guidelines for General Data Protection Regulation (GDPR).

## CUSTOMER SUPPORT AND HANDLING CUSTOMER REPORTS

BIOVIA offers support contracts to all of our customers. We do this to facilitate customer satisfaction and to give our customers a way to report and resolve product queries or issues.

Customer reports of defects or enhancement requests are entered through the Dassault Systèmes customer portal and handled according to the product development, change request and customer support processes. We use metrics to monitor our response and resolution time so that we can continually meet and improve customer satisfaction.

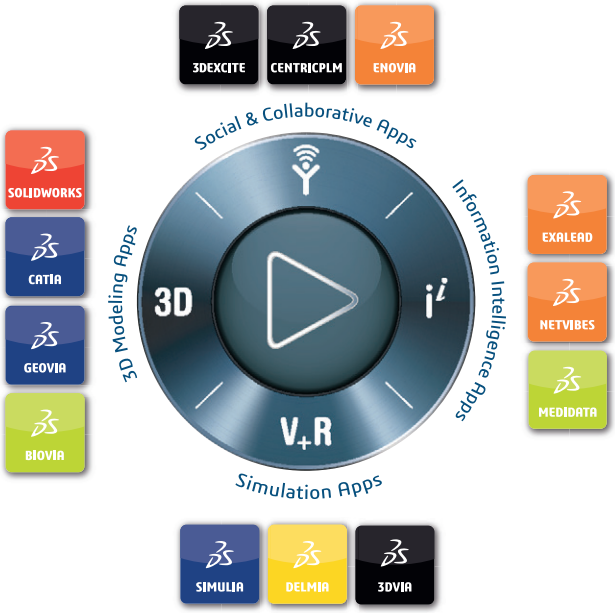
Each week, product teams review and prioritize work on any new defects or enhancements. A customer support representative attends these meetings as a customer advocate, and, when necessary, escalates customer issues. If critical issues arise, BIOVIA can issue Service Packs or Special Releases to resolve the issues.

## SUMMARY

BIOVIA software is built using best practices. BIOVIA understands our customers' need to use well-engineered, thoroughly tested software in highly regulated environments and to validate BIOVIA claims of high quality. To schedule an audit of the BIOVIA Quality Management System, please contact your Account Sales Representative.

### Our **3D**EXPERIENCE® Platform powers our brand applications, serving 11 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3D**EXPERIENCE® Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes' collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 250,000 customers of all sizes in all industries in more than 140 countries. For more information, visit **www.3ds.com**.



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