BIOVIA

3DEXPERIENCE®

BIOVIA VALIDATION KIT

Datasheet

DASSAULT SYSTEMES

Products

- **BIOVIA Discoverant**
- **BIOVIA CISPro**
- **BIOVIA Compose and Capture**
- **BIOVIA Foundation**
- **BIOVIA Notebook**
- **BIOVIA Pipeline Pilot**
- **BIOVIA Workbook**

BIOVIA has developed each function in the products listed above for use in your regulated environment. Because BIOVIA documents and tests the core functionality of these products as part of our comprehensive quality system, only your product- and process-specific configurations and reports require validation on-site. BIOVIA performs extensive testing on all of its products using the same discipline to develop, execute and document test cases and product testing as required by FDA guidelines. Refer to the BIOVIA Quality Statement for more information.

To support your on-site validation, BIOVIA offers a Validation Kit containing key deliverables that will reduce the effort required to develop your validation approach. In addition to BIOVIA's internal test documentation, the kit includes:

- Validation Collateral Plan
- Feature Requirements Traceability
- Risk Impact Assessment
- Validation Test Runs (Executed Test Cases)
- Validation Test Cases (Unexecuted)
- Validation Summary Report

The Validation Kit does not include "Installation qualification (IQ) protocol and execution," which is available as a Services Offering.

Availability

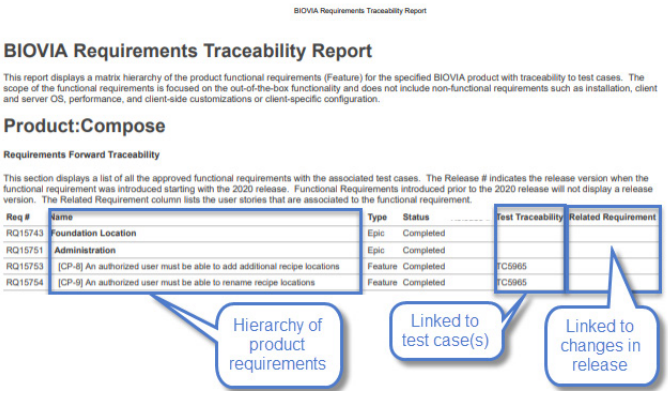
BIOVIA releases Validation Kits once a year as a general availability release. Customers with maintenance will have early access to Risk Impact Assessments with every product release.

Validation Collateral Plan

BIOVIA's Validation Collateral Plan provides a high-level view of the process of generating the validation kit deliverables, which are integrated into the BIOVIA QMS processes and tools for software development and testing.

Requirements Traceability

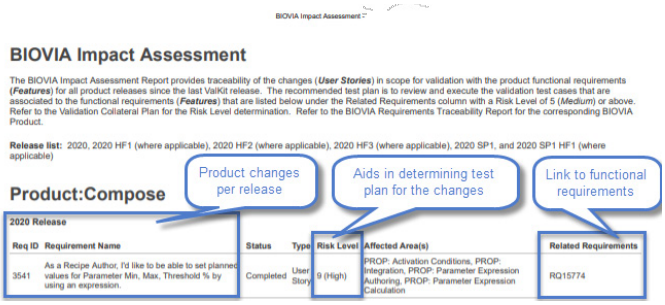
BIOVIA maintains a comprehensive set of product functional requirements with complete traceability to test cases. This provides the ability to help with mapping of the customer's User or Business Requirements to the out-of-the-box (OOTB) functionality of the BIOVIA product, which in turn maps to the test cases. The customer can then verify that the functionality is fully tested.



Risk Impact Assessment

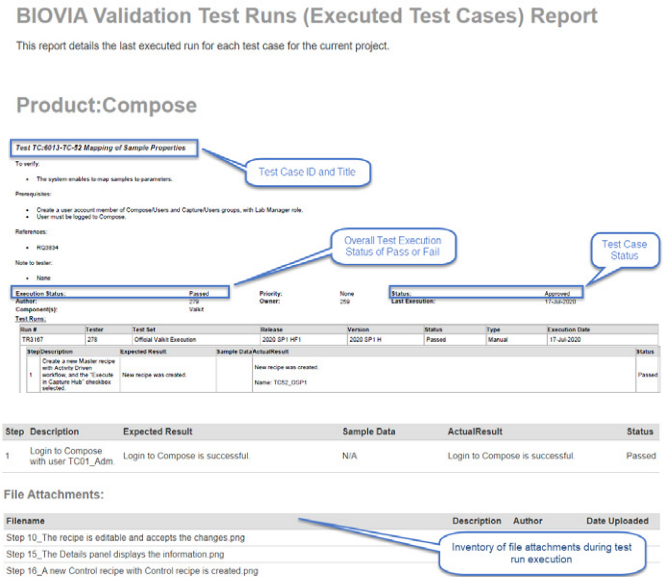
With the FDA's new guidance for Computer Software Assurance, BIOVIA has built a robust Risk Management process into the software development lifecycle to enable critical thinking when product changes occur. With every change and fix, development teams assess for impact and probability, which calculates to a Risk Level. This Risk Level appears in the Product Release Document (PRD), a document published with every product release. The Risk Impact Assessment included in the Validation Kit goes a step further and assesses each change against its impact on product functional requirements. Through the Requirements Traceability, the customer can identify impacted test cases and provide a recommended test plan for re-test, as needed, for the product upgrade, supporting the customer's change control procedures.

BIOVIA will generate a Risk Impact Assessment for every product release and will give customers early access to this document so that it can be useful in the customer's assessment and decision to upgrade.



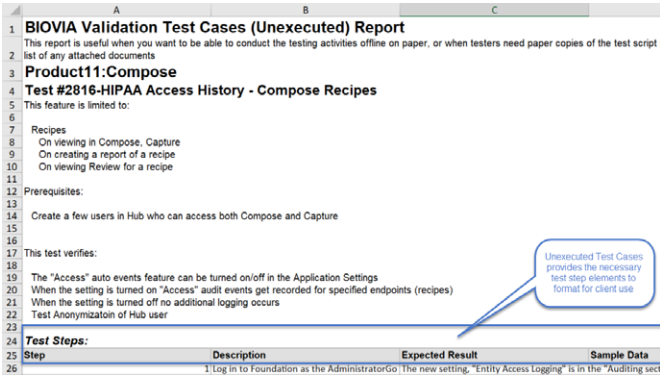
Validation Test Runs (Executed Test Cases)

To reduce the Operational Qualification (OQ) efforts at the customer site significantly, the customer can leverage the executed validation test runs during product testing. These validation tests focus on product functional testing of the user interface. Although non-functional requirements such as installation, performance, operating system, database and negative path testing are not included in these validation test runs, these are well integrated into the BIOVIA QMS process for software testing of the overall BIOVIA product. The Validation Test Run reports provide evidence of the executed test steps and test results.



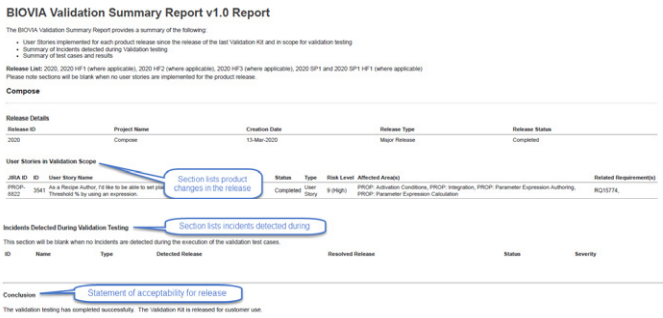
Validation Test Cases (Unexecuted)

Unexecuted versions of the Validation Test Cases will be available in Microsoft .xls and .doc formats if customers would like to re-use the test cases for change control efforts related to product upgrades. Customers can also modify the Validation Test Cases to support Configuration Qualification (CQ) or User Acceptance Test (UAT) efforts to verify customer-specific configured workflows or business requirements for their specific use.



Validation Summary Report

The Validation Summary Report provides a summary of the validation test runs against the product requirements listed in the Requirements Traceability. The report identifies the product changes for every product release since the last Validation Kit, the open known issues in the product and any detected incidents found during validation test runs.



Summary

IIn summary, the BIOVIA Validation Kit reduces the validation effort for testing product functionality, so that customers can focus on business-specific requirements and workflows to ensure that they are appropriate for their intended use.

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Dassault Systèmes, the **3D**EXPERIENCE Company, is a catalyst for human progress. We provide business and people with collaborative virtual environments to imagine sustainable innovations. By creating 'virtual experience twins' of the real world with our **3D**EXPERIENCE platform and applications, our customers push the boundaries of innovation, learning and production.

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