BIOVIA

3DEXPERIENCE®

BIOVIA
COMPLIANCE READINESS
Datasheet

DASSAULT SYSTEMES

Compliance Readiness for:

- **Unified Lab**
- **Manufacturing Analytics**
- **Quality and Compliance**

DESIGNED FOR 21 CFR PART 11 AND ANNEX 11 READINESS

Many BIOVIA solution features specifically address the needs of regulated environments. This includes security features mandated by FDA regulation 21 CFR Part 11 and EU Annex 11 such as access controls, electronic signatures, audit trails and ensuring data integrity, which enables customers to be compliant with 21 CFR Part 11 and Annex 11. The Regulatory Checklist document provided with each product release lists these required features. Meeting each compliance requirement is a shared responsibility between the customer and BIOVIA. Customer organizations can use the results provided by BIOVIA products to support critical process and product decisions without the need for alternative validated confirmation.

BIOVIA QUALITY MANAGEMENT SYSTEM AND TRAINING

Because BIOVIA documents and tests the core functionality of BIOVIA products as part of our comprehensive quality system, only the customer's business workflows, data models and data capture forms (reports) require qualification on-site. BIOVIA extensively tests all of its products using the same discipline to develop, execute and test as required by FDA guidelines. Refer to the BIOVIA Quality Statement for more information.

RISK IMPACT ASSESSMENT OF PRODUCT CHANGES

Using 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. Development teams assess every change and fix for impact and probability, calculating a Risk Level that appears in the Product Release Document (PRD). The PRD can aid customers in conducting a risk assessment against their business requirements.

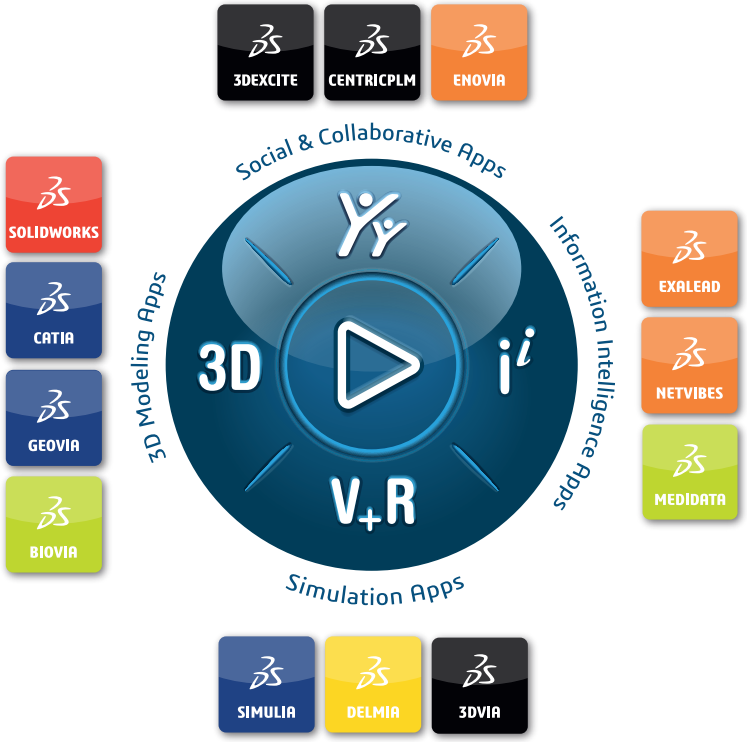
BASELINE VALIDATION AND CHANGE CONTROL

BIOVIA Services offers Installation Qualification (IQ) documentation with the installation of BIOVIA product(s) in the customer's IT environment.

To support on-site validation, BIOVIA offers a Validation Kit containing key deliverables that will reduce the effort required to develop a customer's validation approach. For example, customers can reduce the Operational Qualification (OQ) effort for testing product functionality, so that they can focus more on business-specific requirements and workflows for their intended use. See the BIOVIA Datasheet – BIOVIA Validation Collateral Kits for further information.

SUMMARY

- BIOVIA products are designed for 21 CFR Part 11 readiness
- BIOVIA employees are trained on regulatory compliance and skilled in Software Development Life Cycle (SDLC) activities
- Regulatory Checklists for risk assessment and reduction of validation efforts are released with the following products:
  - **BIOVIA Workbook**
  - **BIOVIA Notebook**
  - **BIOVIA Compose and Capture**
  - **BIOVIA CISPro**
  - **BIOVIA Discoverant**
  - **BIOVIA Foundation**
- Product Release Documents (PRDs) for risk assessment and reduction of validation efforts (released with product)
- Installation Qualification (IQ) as part of Services Engagement (Installation and IQ documentation)
- BIOVIA Validation Collateral Kits (Val Kits) for impact assessment and functional tests (Operational Qualification (OQ) provided as a separate product offering for:
  - **BIOVIA Discoverant**
  - **BIOVIA CISPro**
  - **BIOVIA Compose and Capture**
  - **BIOVIA Foundation**
  - **BIOVIA Notebook**
  - **BIOVIA Pipeline Pilot**
  - **BIOVIA Workbook**



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Europe/Middle East/Africa
Dassault Systèmes
10, rue Marcel Dassault
CS 40501
78946 Vélizy-Villacoublay Cedex
France

Asia-Pacific
Dassault Systèmes K.K.
ThinkPark Tower
2-1-1 Osaki, Shinagawa-ku,
Tokyo 141-6020
Japan

Americas
Dassault Systèmes
175 Wyman Street
Waltham, Massachusetts
02451-1223
USA

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