



StatSoft®

data analysis • data mining • quality control • web-based analytics

***STATISTICA* for Validated Applications**

A Compliance Statement from StatSoft Executive Management

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Introduction

StatSoft Inc. has a long history of partnering with our customers in FDA-regulated industries to deliver the highest quality data analysis, data visualization, and data mining software solutions. For example, StatSoft maintains working relationships with Pharmaceutical companies that span more than ten years and continue to branch out in terms of applications, integration of *STATISTICA* as a core business system, and adoption by users.

At present, StatSoft's commitment to regulated industries includes working relationships with organizations in the Pharmaceutical, Biotechnology, Consumer Products, Nutritionals, and Food/Beverage Manufacturing. For example, four of the top ten largest Pharmaceutical companies have significant commitments to *STATISTICA*. The applications of *STATISTICA* are varied, including Research & Development, Quality Control, QbD (Quality by Design), and Process Analytical Technology (PAT) applications. One global Pharmaceutical company, for example, has a global license to utilize *STATISTICA* by all personnel throughout its R&D and manufacturing sites worldwide. Another company configured *STATISTICA* to be tightly-integrated with its LIMS repositories for the automation of ongoing compliance reporting for all of its product formulations. These are just a few representative examples. StatSoft looks forward to speaking with your organization about its application objectives and the optimal *STATISTICA*-based solution to meet your requirements.

StatSoft has invested in an ongoing commitment to enhance the utilization of *STATISTICA* for validated applications and to ease the efforts involved in the validation of *STATISTICA*. This document summarizes the relevant factors for any organization in a regulated industry considering *STATISTICA* for a validated application, including the benefits of:

- *STATISTICA* as commercial off-the-shelf (COTS) software, and
- Specific compliance-related features of the *STATISTICA* software

Validation of STATISTICA

The FDA provides guidelines for Computer Systems Validation (CSV). The guidelines for validation provide a framework to fit a wide variety of objectives, software types, environments, and applications. As such, no software can be said to be “validated,” except through the application of validation procedures that are specific to its intended use, risks, and architecture being implemented – in other words, only specific applications of software implemented at a customer site can be validated. That being said, StatSoft has invested significant energy and resources in areas designed to make it easier for organizations to validate *STATISTICA* applications.

STATISTICA Commercial Off-the-Shelf Software

StatSoft has been categorized by our customers as a top-tier supplier for commercial off-the-shelf (COTS) software. Selecting *STATISTICA* has the advantage that StatSoft's documented Quality Management program and *STATISTICA*'s worldwide user base can be taken into consideration in the judgment of the level of application-specific validation testing to be performed.

StatSoft's Software Development and Quality Assurance Procedures

StatSoft's procedures for software development and quality assurance testing are mature and well documented. StatSoft supports periodic audits of its procedures by its customers or their representatives, as part of the due diligence process. StatSoft has passed every audit inspection conducted by its customers. StatSoft values these interactions with quality assurance and compliance professionals as one part of our ongoing commitment to quality management and continuous improvement.

Scope of StatSoft Global Support

StatSoft is among the world's largest data analysis software vendors, with a network of 24 offices worldwide delivering support and services. StatSoft is uniquely qualified to support our customers' regional user communities as part of a worldwide roll-out of *STATISTICA* for use in validated applications such as data analysis systems for quality control.

Validation Package and Services

StatSoft partners with the customer on each project to define a validation plan and approach that conforms to the intended use of the *STATISTICA* application, the customer's unique Computer Systems Validation SOPs, and the customer's available QA resources. StatSoft provides implementation and configuration services for *STATISTICA* software.

StatSoft collaborates with your team to define the roles and responsibilities and augment your team with StatSoft personnel as necessary to deliver validation services as a complete project solution from the Validation Plan to the final, approved Validation Report. StatSoft's validation services conform to your organization's CSV SOPs and documentation standards. These services begin with the training of our personnel on your SOPs for Computer Systems Validation and documentation templates.

In addition, StatSoft provides an optional Validation Package for the *STATISTICA* software. The Validation Package streamlines our customer's validation planning and documentation activities by providing specifications, IQ (Installation Qualification) and Operational Qualification (OQ) test scripts, and numerical validation reports certifying the accuracy of the statistical data analysis routines, as validated by StatSoft's internal validation procedures for each release.

STATISTICA Compliance Features

StatSoft invests much more in ongoing research and development of the *STATISTICA* suite than the software industry average. These ongoing enhancements and augmentations include compliance-specific features, again easing and streamlining the use of *STATISTICA* for validated applications. These software features include:

- Central Configuration and Management.** All configurations are managed in a central *STATISTICA* Configurations Database. Changes to a Data Access configuration, an Analysis configuration, and/or a Report template are made in one place. These are subject to object-specific access control permissions for editing and utilizing the configurations, are logged in the Audit Trail, and are immediately deployed to all Users with the requisite permissions. This level of configuration control is important for users in regulated environments.

- **Security/Access Control.** Deploying functionality to users according to their roles/responsibilities, training, experience level, and security level is one component of an exemplary validation plan. *STATISTICA* makes it possible through integrated security and access control.
- **User Administration.** The *STATISTICA* suite includes System Administration tools for the users with requisite permissions to manage the *STATISTICA* Users / Groups and their permissions.
- **Audit Trails.** *STATISTICA* provides a central audit trail for login/logout, system use (e.g., running analyses, reports, or queries), and editing configurations. For each activity record, the Audit Log includes the User's name, the Date/Time, the description of the activity performed, and a reason for the activity (if necessary).
- **Integrated Electronic Document Management.** StatSoft provides the *STATISTICA* Document Management System (SDMS) as an important component of the *STATISTICA* suite. SDMS is an electronic document management system, compliant with 21 CFR Part 11 requirements.

Summary

STATISTICA is uniquely suited for validation applications in regulated industries. Our customers enjoy streamlined validation by leveraging the status of *STATISTICA* as commercial off-the-shelf software, the exemplary software development and Quality Assurance procedures employed by StatSoft, the *STATISTICA* Validation Package and Services, and the specific compliance-related features of *STATISTICA*.



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