



StatSoft®

business intelligence • 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 has current working relationships with Pharmaceutical companies that span more than ten years and continue to grow 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, 5 of the top ten largest Pharmaceutical companies have significant commitments to *STATISTICA*. The applications of *STATISTICA* are varied, including Research & Development, Quality Control, and Process Engineering (PAT) applications. One major Pharmaceutical company, for example, has a global license to utilize *STATISTICA* by all Quality Control and Process Engineering personnel throughout its manufacturing sites worldwide. Another company configured *STATISTICA* to be tightly-integrated with its LIMS repositories for 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 its 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 major relevant factors of the utilization of *STATISTICA* for validation computer applications. The document covers 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 the specific to its intended use, risks, and architecture being implemented - in other words, only specific applications of software, implemented at customer site can be validated. That being said, StatSoft has invested significant energies and resources in general 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. Validation of *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 their due diligence. StatSoft has passed every audit inspection conducted by its customers. StatSoft values these interactions with Quality Assurance and Compliance professionals as one part of its 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 twenty 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 the *STATISTICA* software.

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.

StatSoft has a network of partners for delivering complimentary 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.

***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.** Important for a validated application is that configurations are managed in a central *STATISTICA* Configurations Database. Our customers in regulated industries value that changes made to a Data Access configuration, an Analysis configuration, and/or a Report template are made in one place, 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.
- **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. Users with User Administration permissions are able to utilize the User Administration application.
- **Audit Trails.** *STATISTICA* provides a central audit trail for login/logout, system use (Running analyses, running Reports, running 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. The SDMS is an electronic document management system, compliant with the 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 COTS 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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