

StatSoft®
Business White Paper

StatSoft's Validation Services: Computer Systems Validation for *STATISTICA* Applications

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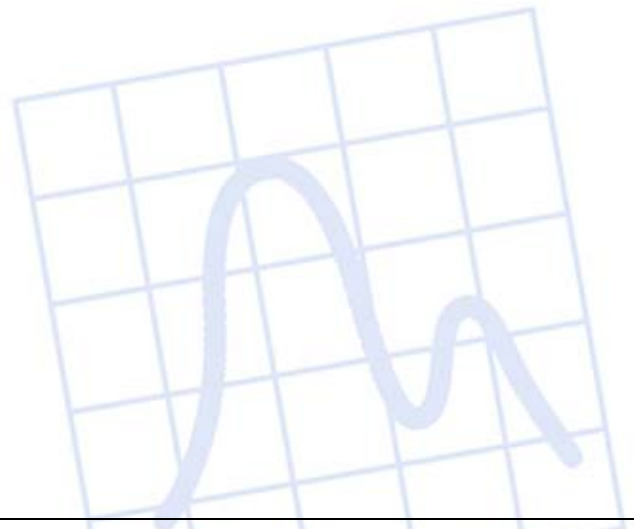
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Overview

StatSoft, provider of the **STATISTICA** product suite, is committed to partnering with our customers in meeting our mutual goal of the design and production of products of the highest quality and reliability. Many of our customers in FDA-regulated industries, such as the design and manufacturing of pharmaceutical and medical device products, rely on **STATISTICA** as an integral software tool within their Research and Development and Quality Control processes.

StatSoft, through its Technical Services group, provides software validation services as part of the deployment of **STATISTICA** applications. The following sections provide an introductory overview to our standard Validation Package for **STATISTICA** applications deployed within your environment. These services include requirements gathering and documentation, validation planning, installation qualification, operational qualification and performance qualification.

Relevance to **STATISTICA** Applications

STATISTICA is used for many applications where computer systems validation is relevant. For example, **STATISTICA** is used by organizations:

- To test the characteristics of new products,
- To optimize product formulations,
- To inspect raw materials to be used in the manufacturing of products,
- To make judgments about the efficacy of multiple product configurations,
- To make predictions about product reliability,
- To determine the most important process parameters within a multivariate product manufacturing application,
- To determine the optimal product packaging for shipment, storage and delivery to consumers, and
- To certify that particular lots of product conform to product specifications.

For each of these applications, **STATISTICA** may be used for any combination of the following activities:

- To store data and documents,
- To perform data management and cleaning tasks,
- To produce tabular and graphical output, and
- To produce summary reports of those analytic results.

Depending upon the application, the data and results used for these purposes may be subject to the rules of the 21 CFR Part 11 regulation.

The **STATISTICA** Validation Package

StatSoft's Technical Services Group provides a standard Validation Package that can be customized to suit the relevant **STATISTICA** application. Our Validation Package is a combination of a StatSoft team, a suite of services, and a set of documentation. Each of these components is covered in more detail below.

- **The StatSoft Team:** StatSoft provides a team of highly-experience and skilled professionals to perform the planning, implementation and validation services. The specific number and type of resources depend on the project scope. Our team structure includes the following typical roles: a Project Manager, a **STATISTICA** Technical Consultant, and a Validation Engineer.
- **Scope of Services:** Our Validation Package includes a full suite of installation and qualification services. The detailed scope depends upon the system and the responsibilities of the StatSoft team. Our suite of services may include requirements gathering and documentation, validation planning, system design, system installation and configuration, installation qualification, operational qualification, performance qualification, and documentation preparation.
- **Documentation:** StatSoft provides a standard set of Validation deliverables. During the project planning activities, we will customize these deliverables to meet the project requirements. The documentation set includes a User Requirements and Functional Requirements Specification, a Validation Plan, a System Design Specification, Test Plan and Detailed Test Cases, a Traceability Matrix, Installation Qualification Summary, and a Validation Summary.

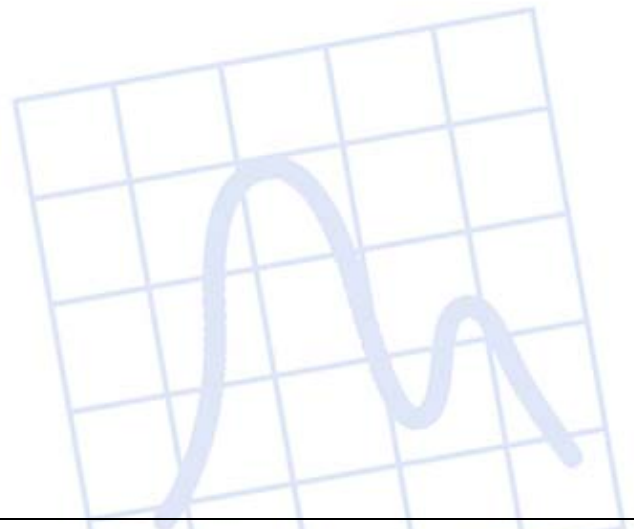
Advantages

StatSoft provides its Validation Package as an integrated set of services to augment our standard system design and deployment methodology. We standardized the Validation Package to provide an enhanced suite of services to our clients in regulated industries.

Your organization is able to leverage our combination of **STATISTICA** expertise and validation expertise. What this means to you is a streamlined approach to validation with significant cost and time savings.

For More Information, Contact Us

Please contact StatSoft Technical Services at 918-749-1119 for more information about our Validation Package to suite your **STATISTICA** application needs.



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