StatSoft Validation Services

Headquarters: StatSoft, Inc. • 2300 East 14 Street • Tulsa, OK 74104 • USA • +1 (918) 749-1119 • info@statsoft.com • www.statsoft.com

Australia: StatSoft Pacific Pty Ltd.
Brazil: StatSoft South America Ltda.
Bulgaria: StatSoft Bulgaria Ltd.
Chile: StatSoft South America Ltda.
China: StatSoft China
Czech Rep.: StatSoft Czech Rep. s.r.o.
France: StatSoft France
Germany: StatSoft GmbH
Hungary: StatSoft Hungary Ltd.
India: StatSoft India Pvt. Ltd.
Israel: StatSoft Israel Ltd.
Italy: StatSoft Italia srl
Japan: StatSoft Japan Inc.
Korea: StatSoft Korea
Netherlands: StatSoft Benelux
Norway: StatSoft Norway AS
Poland: StatSoft Polska Sp. z o.o.
Portugal: StatSoft Iberica Ltda
Russia: StatSoft Russia
S. Africa: StatSoft S. Africa (Pty) Ltd.
Spain: StatSoft Iberica Ltda
Sweden: StatSoft Scandinavia AB
Taiwan: StatSoft Taiwan
UAE/Egypt: StatSoft Middle East
United Kingdom: StatSoft Ltd.
Contents
StatSoft Validation Services ................................................................. 1

1.1. Computer Systems Validation for STATISTICA Applications ................. 3
1.2. Relevance to STATISTICA Applications ........................................... 3
1.3. StatSoft Validation Services ............................................................... 4
1.4. Advantages .......................................................................................... 5
1.5. For More Information, Contact Us ..................................................... 5
1.1. Computer Systems Validation for STATISTICA Applications

As provider of the STATISTICA product suite, we are committed to partnering with our customers in meeting our mutual goal of designing and producing products of the highest quality and reliability. Many of our customers are in FDA-regulated industries, such as the design and manufacture of pharmaceutical and medical device products. These customers rely on STATISTICA as an integral software tool within their Research and Development and Quality Control processes.

StatSoft, through our Technical Services group, provides software validation services as an optional 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.

1.2. 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,
- optimize product formulations,
- inspect raw materials to be used in the manufacturing of products,
- make judgments about the efficacy of multiple product configurations,
- make predictions about product reliability,
- determine the most important process parameters within a multivariate product manufacturing application,
- determine the optimal product packaging for shipment, storage and delivery to consumers, and
- certify that particular lots of product conform to product specifications.
For each of these applications, STATISTICA can 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 regulations.

1.3. StatSoft Validation Services

StatSoft’s Technical Services Group provides services and validation documents that can be customized to suit the relevant STATISTICA application and needs of the customer. This is offered through a combination of a StatSoft team, a suite of services, and documentation.

The StatSoft Team: StatSoft provides a team of highly experienced 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 Services includes a full suite of installation and qualification services. The detailed scope depends upon the system, as well as the responsibilities of the StatSoft team. Our suite of services may include gathering and documentation of requirements, validation planning, system design, system installation and configuration, installation qualification, operational qualification, performance qualification, and documentation preparation.

Documentation: StatSoft offers a standard set of Validation deliverables. During the project planning activities, we will customize these deliverables to meet the project requirements. The documentation includes a User Requirements and Functional Requirements Specification, a Validation Plan, a System Design Specification, a Test Plan and Detailed Test Cases, a Traceability Matrix, an Installation Qualification Summary, and a Validation Summary. Additionally, numeric validation reports are available.
1.4. **Advantages**

StatSoft provides its Validation Services 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.

1.5. **For More Information, Contact Us**

Please contact StatSoft Technical Services at 918-749-1119 (email info@statsoft.com) for more information about the Validation Package to suit your STATISTICA application needs.