

# Continued Process Verification

## Real-time analytics for manufacturing insights

### BENEFITS

#### ACCESS DATA

Integrate all data sources, internal and external, throughout product lifetime.

#### MODEL KEY PERFORMANCE INDICATORS

Compare different models for critical quality attributes (CQA) and critical process parameters (CPP).

#### MONITOR IN REAL TIME

Monitor any and all attributes or parameters and distribute instantaneous alerts.

#### AUTOMATE AND REUSE

Create reusable templates and automate data prep, reporting and analytics workflows to reduce time spent on repetitive tasks.

#### USE INTERACTIVE AND AD HOC REPORTING

Drill down or modify existing reports on the fly, or produce one-off reports as needed.

#### KEEP CONTROL OF YOUR DATA

Meet global standards for security, documentation, and 21 CFR Part 11 compliance.

### BUSINESS CHALLENGE

Continued Process Verification (CPV) can be challenging, complex, and costly. Complex processes with multiple ingredients, containers, materials, people, machinery, and data in different formats and various locations make it a daunting task. What's needed is a secure, regulatory-compliant system that organizes the chaos, collects and analyzes the data, alerts to issues, and automates reporting.

### SOLUTION OVERVIEW

TIBCO Statistica™ is an analytics platform that lets you use CPV to prove final product quality in a collaborative, secure environment. Statistica connects to all data sources that contribute to the lifetime development of a product. It aggregates the data, analyzes the resulting information, monitors critical quality attributes, and automates reporting for both internal and external stakeholders.

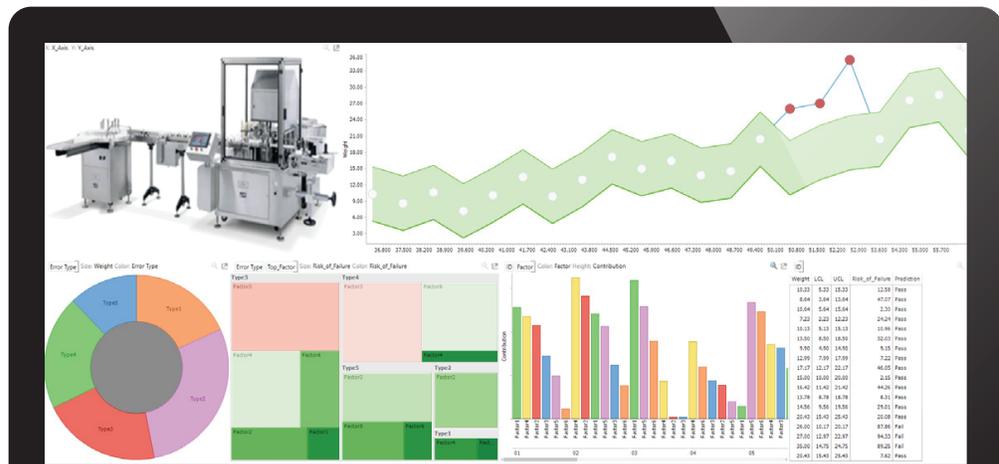


Figure 1: Real-time predictions of product quality and equipment failure.

### DESIRED OUTCOMES

Statistica simplifies the inherently complex task of implementing and maintaining a CPV solution. With Statistica, you can easily connect to all the varied data sources that contribute to a final product and easily create the analysis needed to verify that a system stays in control. Even more important, if any parameters are going out of control, the built-in processes of Statistica will alert you. Analysis and data prep templates can all be automated and reused to ease the burden of an already over-taxed production team.

Statistica is different in that it is available as a validated commercial off the shelf (COTS) software system. The burden of customization is lifted by using a platform that integrates all the necessary applications into one solution that does not need to be re-validated at different junctures. There is no vendor lock-in, no proprietary databases, data formats, or black boxes that prevent you from expanding or growing a successful product.

## CAPABILITIES

The Statistica solution for Continued Process Verification is structured around six key components:

### DATA ACCESS & AGGREGATION

Over the lifetime of any production cycle, disparate data is available from both internal and external sources. All of this data is required to successfully implement a CPV solution, but this is not an easy task. Statistica makes it easier by providing out-of-the-box solutions for accessing data from practically any data source, enabling aggregation and data cleansing for all CPV related activities and reporting requirements.

### ANALYTICS

Integrate external analytics within internal analytic workflows and embrace the app marketplace for models. Monetize your models and data or import models written by others. Import models from Algorithmia, Azure ML, Apervita, and others. Leverage open source technologies including R, Python, and Apache® Spark®. Connect these in a single workflow to drive interaction and collaboration.

### MONITORING

The flexibility of the Statistica platform enables you to use any model and monitor it for any requirement needed. Monitoring can involve any quality control chart (IMR, X-bar and R, EWMA, and more); any deviation from control limit, warning limit, or other custom specification, such as residuals from a regression model or misclassification rates from machine learning algorithms.

### STANDARDIZED, INTERACTIVE, AND AD HOC REPORTING

Within the realm of CPV, a wide variety of reports are required for annual product reviews (APRs), invalid trending reports (ITRs), and internal milestone reports. Many times, these reports are created manually and require an inordinate amount of effort to develop. Statistica enables you to automate this process and method of delivery. Statistica makes it easy to develop data sources, analyses, and reports on the fly, without costly customizations.

### SECURITY

CPV by definition assumes that strict guidelines are followed so that the results of a product lifetime analysis can be trusted. From documentation to verification of analyses, guidelines and standards must be followed so that people can rely on the quality of the product they are consuming. Statistica meets global standards for security and documentation to meet CPV requirements.

### AUTOMATION

Running and distribution of reports of all data acquisition, aggregation, data prep, and analytic workflows can be scheduled.



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