

## Continued Process Verification

Real-time analytics for manufacturing insights

### BENEFITS

- **Access data** - Integrate all data sources, internal and external, through the lifetime of the product
- **Model key performance indicators** - Compare different models for Critical Quality Attributes (CQA) and Critical Process Parameters (CPP).
- **Real-time monitoring** - 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.
- **Interactive and ad hoc reporting capabilities** - 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 and machinery and their accompanying data sources in different formats and locations make CPV a daunting task. A system is needed that can take all this inherent chaos and organize it in such a fashion that you can consume the data, analyze it, and create automated reports and alerts to lead in this industry. Moreover, it needs to occur while meeting security and regulatory guidelines.

### SOLUTION OVERVIEW

Statistica is an analytics platform that allows you to meet the complex needs of proving final product quality through CPV in a collaborative, secure environment. Statistica allows you to connect to all data sources that contribute to the lifetime development of a product, aggregate the data, analyze the resulting information, monitor critical quality attributes, and automate reporting for both internal and external stakeholders.

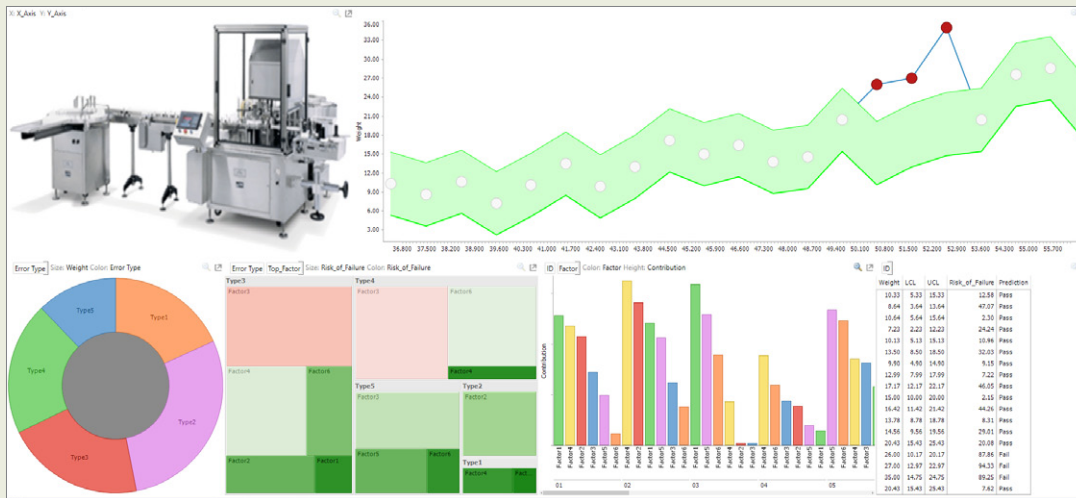


Figure 1: Real-time predictions of product quality and equipment failure.

## CHALLENGES

Meeting and maintaining product quality is difficult, complex and costly. However, not meeting and maintaining product quality is dangerous, even more costly and potentially deadly. Production processes are inherently complex. Ingredients, containers, materials, people and machinery represent just a few of the variables that constantly change, making it difficult to maintain established quality specifications. Moreover, each of these are represented by data in different formats and locations. To succeed in this environment, an organization must use a system that is able to consume all of this data, analyze it as needed, alert immediately if anything is amiss and automate reporting for decision-makers. In order to be successful, this all needs to be accomplished within strict security guidelines that meet industry standards.

## 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. With the functionality included in Statistica, you can 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 if the process is at risk of going out of control. The analysis and data prep templates created 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 are no proprietary databases, data formats or black boxes that prevent you from expanding or growing a successful product by locking you into one vendor.

## 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 these data are required to successfully implement a CPV solution, but this is not an easy task. Statistica makes this 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 Spark. Connect these in a single workflow to drive interaction and collaboration.
- **Monitoring:**  
The flexibility of the Statistica platform enables you to utilize any model and monitor that for any requirement that is needed. This can involve any quality control chart (IMR, X-bar and R, EWMA, and more) and monitoring for any deviation from control limit, warning limit or other custom specification. It can be monitored for residuals from a regression model. You can even monitor 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:**  
All of the data acquisition, aggregation, data prep, analytic workflows and reports can be scheduled to automatically run be distributed to everyone within the organization.

## ABOUT STATISTICA

Statistica's advanced analytics, big data and IoT offerings provide you endless possibilities to innovate your enterprise. Whether it's uncovering the genetic basis of a disease, reducing hospital readmissions, mitigating financial risk, or ensuring procedural validation, Statistica enables organizations to transform in new and exciting ways. By embedding analytics everywhere and empowering a wider community of citizen data scientists, you'll accelerate innovation, improve patient experiences, and streamline your enterprise for the future.

### Statistica

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If you are located outside North America, you can find local office information on our Website.

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