StatSoft EUROPE

Use Case:

Continued Process Verification (CPV) digitalized at an international Pharma/Biotech company

By digitalizing the Continued Process Verification (CPV) Analysis and Reporting, our customer saves thousands of working hours and gives the users at different manufacturing sites the capability, to generate CPV reports (consisting of up to hundreds of pages) as a self-service. The company uses the same software-framework for their Stability and Shelf Live Analysis. And there is more to come.

Requirements and Motivation

When the customer launched their program to automate data science and data management processes for their Pharma manufacturing network in 2018, several requirements had to be met:

- Provide convenient access to process- and quality-relevant data from various IT-systems for the end-users.
- Allow automatic generation of GxP-relevant reports - in particular for CPV - to fulfil requirements from health authorities.
- Eliminate/minimize manual effort for data acquisition (copy and paste) and paper-based documentation to improve data integrity and compliance.
- Enable analytics which were not possible before to better understand and improve manufacturing processes and product quality.
- Focussing on one global centralized system allowing a gradual roll-out, making it available to various users and sites among the pharma manufacturing network.
- The system must be validated, but the validation efforts during the implementation of the solution, but also during Life Cycle Management, must be manageable.
- Leveraging former investments in data and knowhow.
- Design a solution that is future proof.

The solution used at customer side:

Low Code framework based on TIBCO Statistica / Data Science

A pre-requisition by our customer for this project was a Commercial Off-The-Shelf software (COTS) that can be implemented with as little programming and validation effort as possible and may be set up centrally, but which is scalable and can be used at different sites. For this the company has chosen the TIBCO Data Science Platform (Statistica), a low code solution that meets these requirements and includes functionalities that are a must in GxP-controlled environments and according to FDA CFR 21 Part 11 guidelines:

- Data Preparation as a process (Access, Transformation, Corrections, Upload).
- Automation of analytical capabilities to generate the intended insights repeatedly.
- Reporting functionalities by StatSoft to automate the output in MS-Word-format.
- User management functionalities including access rights to data, analysis, and reports.
- Centralized version control functionalities and an audit trail on every step.
- Possibility to capture paper-based data by a manual data-entry frontend, fulfilling data integrity requirements (separate sample approval, audit trail).
- Broad range of features for statistical analysis and visualization.

The TIBCO Data Science platform is used by many pharmaceutical and biotech companies.

The differentiators:

One platform: From data configurations to analysis and reporting, everything can be handled in one system.

Flexibility and enhancements: Change requests from the users can be implemented quickly due to the openness of the solution.

Meet regulatory requirements according to FDA CFR 21 Part 11 regulations and minimize validation effort: With the default implementation, low code software components are used that minimize the effort for validation. Programming is limited to special cases requiring specific customization.

"Thanks to the advantages of the software framework used at our customer combined with our implementation experience we were able to fulfil all of the customers needs and provide a sustainable platform with room for growth and upcoming projects."

Sören Schönfeld, Lead Data Engineer, StatSoft

Smart Data Architecture:

The foundation from a data point-of-view is the customers Data Lake in their own Private Cloud environment. The data lake – which is a validated IT-platform in itself – ingests data from multiple source-system depending on the plant's IT-infrastructure. Necessary transformations of the raw data are performed there to improve the performance of Statistica queries. Data sources that are not yet covered by the data lake (e.g. new systems or manual data entries) may be connected directly to the solution. The solutions is built with a future move to an AWS environment in mind.

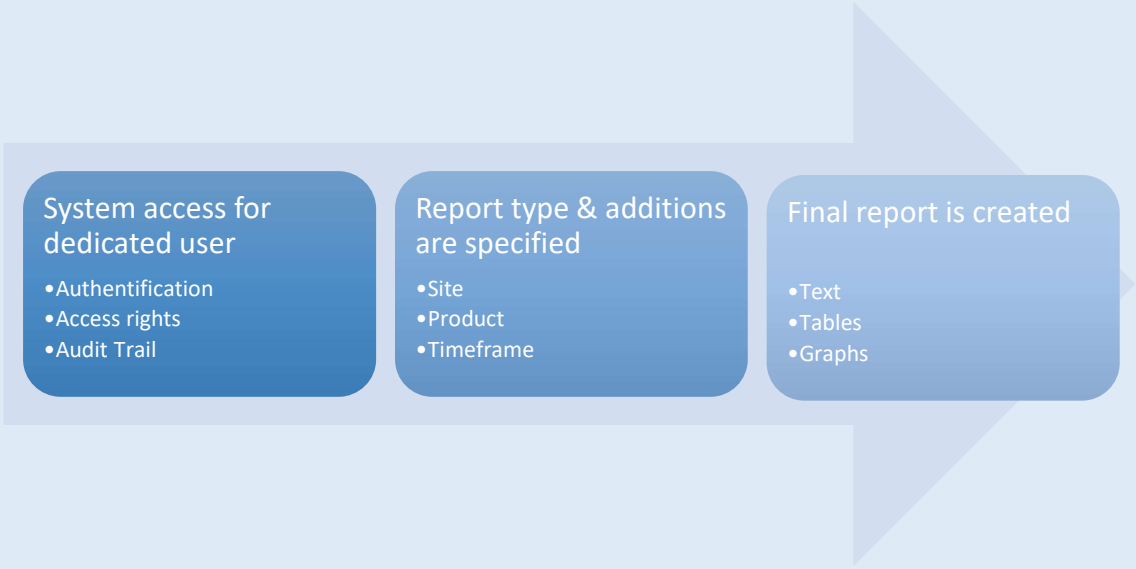
For the end-user nothing will change, as all the changes are happening in the background.

"By implementing Statistica in combination with our in-house GxP Data Lake, we've created a solution which allows compliant end-to-end reporting by creating GxP-relevant reports such as CPV at the "push of a button", but which is at the same time flexible enough to allow statisticians and process experts to explore relevant data using customized analysis workflows."

A Scientific Sr. Manager and Project Lead Scientific Data Management

The solution from a user's point of view:

Once the system is rolled-out to a manufacturing site, users can autonomously set-up new CPV reports/templates and configure them in the system. This process is free of coding, so it can be handled by business representatives (typically from local Quality Management or PharmaTech function) not requiring IT interaction. The general framework of the CPV-logic is globally harmonized which also fosters knowledge exchange and ensures comparability of results between individual sites.
Below, an exemplary process for the preparation of the report is outlined:



To generate a CPV report a user must log on at the system, choose the predefined template (site, product, time-range etc.), execute it and the report in MS-Word-format will be generated automatically. Depending on the complexity and size of the report, the generation will take approx. 20 to 60 minutes Reports may consist of hundreds of pages including tables, graphics, and text. After the report has been automatically generated, the user may review the content and supplement it. This process is a huge boost in performance in comparison to the labour intensive report building the users had to perform previously.

Besides the utilization of pre-defined, often highly customized reports such as CPV, all users have the possibility – provided they received the appropriate training – to use Statistica directly to perform Ad-Hoc investigations leveraging its data-access and analytical capabilities. Several initiatives have been supported this way already resulting in substantial knowledge gain and business benefits.

"The highly automated data queries from various GMP systems such as TrackWise, GLIMS and SAP significantly reduced the manual effort to do the complex batch-mapping among the process chain and associated trend reviews. This makes a big difference to my daily work. It has been also a pleasure working with the project team. So, THANK YOU and your TEAM for your continued efforts!"

A Site Process Lead of one of the customers production sites

"Initially the goal of the Statistica implementation in our site was the creation of GMP CPV reports. In my opinion, the strength of Statistica is the ability to connect all available data in data lake and to use workspaces to perform the extraction of connected data and create charts for example. In this way, the site was able to increase our knowledge on products and processes. As a consequence, the assessment of the product quality is faster as well as the trouble shooting process to understand and resolve potential gaps."

A Analytical, Cleaning and Process Review Manager

Outlook on future activities

The company will continue to further roll-out Statistica to increase the reach of its successful CPV solution. The solution is in use today at all European Pharma manufacturing sites within its manufacturing network. Sites in China and LATAM are supposed to follow in the future.

In addition, new applications have and will be designed and rolled out, which will further support the companies employees at their daily work. One good example already in use, is the automated report to perform Stability and Shelf Live Analysis according to ICH Q1E guidelines.

The initial implementation of the solution was primarily aiming at the automation of GxP reports, the elimination manual effort for data handling improving data integrity and compliance. However, the future ambition is to use Statistica to monitor quality and manufacturing processes in a more time-efficient and continuous manner allowing to detect and react earlier in case of trends or changes. Such an initiative has been launched recently with expected GoLive in the coming year.

Furthermore, by leveraging data from other “real-time” sources such as Data-Historian or PAT-measurements (Process Analytical Technology), an end-to-end transparency of relevant data and information is intended, giving our customer the chance to move from a currently reactive to a proactive way of monitoring their manufacturing processes.

Finally, the “people”-aspect must not be neglected. Applicability and continuous improvements regarding user-friendliness as well as proper communication, training & upskilling activities are key to ensure that such a system is applied in an efficient and sustainable way.

The role of StatSoft

We support the customer in the role of a solution provider, from the design specifications to the implementation and documentation. A unique advantage the StatSoft-team brings to the project is the knowledge of the technology in use and the experience from other similar projects.

Worth mentioning as well is the integrated reporting-node developed by StatSoft that allows to automatically generate the reports with up to hundreds of pages in MS-Word-format.

"The collaboration with StatSoft has decisively advanced this project. In addition to StatSoft's competence, the professional manner of communication contributes to the success of the project. We look forward to continuing this cooperation. "

A Scientific Sr. Manager and Project Lead Scientific Data Management

About us

StatSoft is a specialised consulting company and solution provider in the field of Data Science, Machine Learning (ML) and Artificial Intelligence (AI).

We support our clients from identification to implementation of Data Science and ML/KI projects. By doing this we generate competitive advantages, added value and knowledge in cooperation with our customers.

Analytics and reporting as „validated applications ", required in the (bio)pharma industry, is one of our core competences.

You may find out more about this case study and similar projects by contacting:

Sasha Shirangi
Sales Director

StatSoft (Europe) GmbH
Phone: +49 40 2285900-65
Mobile: +49 160 99802576
Fax: +49 40 2285900-77
Email: sshirangi@statsoft.de
www.statsoft.de
Axel-Springer-Platz 3
20355 Hamburg, Germany