

An Example Of Visual Six Sigma with JMP® Scripting: Fresenius Kabi plant, Cavezzo, Italy

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About the Project

Fresenius HemoCare Italia, a subsidiary of Fresenius Kabi located in Northern Italy (Cavezzo, MO), is committed to the development and production of medical devices (disposables), specifically of filters for leukocyte depletion, a critical component of transfusion sets.

Fresenius HemoCare Italia introduced JMP® at the end of 2011. This software became more widespread throughout the organisation at the beginning of 2014. In that same year, a new manufacturing line was installed and validated, which was quite challenging for such a relatively small organisation.

The equipment automates all manufacturing steps, from component assembly to filter packaging.

The automation embeds not only the manufacturing phases, but also the quality inspections that are mandatory for a medical device, for example the integrity (leak) test.

The line operates with minimal operator need and at high throughput, and has high innovation content. This was the first time that some of the technologies were integrated in a complex project, including one that was used for the first time ever in a medical device.

Despite the complexity of this scenario, the project we are presenting is feasible in a relatively short timeframe for anyone with a sufficiently mature organisation: project management, Six Sigma training, and available IT infrastructure (SQL server) are the prerequisites.

The key to our success was JMP® and its complete and flexible JSL scripting language. The debugger tool and interactive editor make it possible to approach complex programming projects modularly. The feasibility of the end result therefore becomes only a matter of resources and time.

About the Authors

The Fresenius team is composed of highly skilled engineers with backgrounds in physics, informatics, material sciences, chemistry, and mechanics.

After a customised 2-day training session on JSL, followed by a 2-day scripting workshop, the project's output, called "process supervisor," was delivered in six weeks, during which time none of the team interrupted his/ her other activities.

Three of the five Fresenius team members had never seen JMP® before January 2014 and had no previous experience in scripting. All team members are Project Managers and expert Six Sigma practitioners.

Since the very beginning, each JMP® training session was customised on typical datasets.

The trainer, Statcon's statistician Sebastian Hoffmeister, had previous experience in creating online SPC with JMP scripting.

Field of application: Medical disposables – Leukodepletion filter

During blood transfusion the patient receives a large number of allogeneic donor leukocytes (white blood cells - WBCs), which may lead the recipient's immune system to having several leukocyte-mediated adverse reactions.

To minimize such risks, leukodepleted (i.e. filtered) blood transfusion is required, which is why most countries have moved to a so-called "universal leukodepletion" policy.

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Blood transfusion technology (i.e. the devices and dedicated equipment) permits creating leukodepleted blood components from any single donation (plasma and red blood cell, and platelet concentrates).

Typical blood filtration figures:

- each donated whole blood unit contains 2-4 billion WBCs (in various families, specialized by function, which can be differentiated by size, appearance, and surface properties).
- WBCs/unit < 1million are allowed after leukoreduction in EU countries.
WBCs/unit <5 million are allowed after leukoreduction in US/Canada/UK.
- Typical values for red cell concentrates are close to currently available detection methods, usually below 15,000 WBCs/unit, which means 99.999% depletion (5 logs).

Each filter is designed as a result of a compromise between conflicting objectives:

- maximise leukoreduction;
- maximise red cells and plasma recovery;
- minimise filtration time.

Lean (&) Six Sigma

Lean Manufacturing and Six Sigma are among the most well-known techniques for achieving operational excellence.

Lean Manufacturing is usually associated to continuous improvement, a never-ending cycle that recalls Deming's cycle Plan-Do-Check-Act.

Six Sigma is associated to breakthrough improvement through the (D)MAIC phases: every project has a start and end where benefits are reckoned.

Some mature organisations integrate the two visions in the so-called Lean Six Sigma.

Indeed there are many mutually beneficial interactions.

Information management

When managing the launch, validation, or improvement of automated processes, it becomes clear that the flow of information throughout the process is a process itself.

Not uncommonly, information causes a bottleneck of the entire process because it flows in a push rather than in a pull mode. Lean Manufacturing considers time as one of the Muda's (types of waste).

Information often flows through stratified layers of different data sources and remains disconnected among the various phases. Flow is one of the guiding Lean Principles.

In other words, the vision of the process from an information perspective is often not customer (i.e. end-user) oriented. Data analysis must be adapted to and is limited by the existing database structure.

In many cases, the lack of information exchange throughout the various phases of a process results in a loss of information as it prevents efficient root cause analysis. A typical example is when process data are collected on a time-series basis while QC data are collected on single item or batch traceability.

What's more, what defines whether a product is good or bad is not the product itself but the information gathered both on the single item and from the process (population) it belongs to.

Offline release and process & product data evaluation is the kind of bottleneck that might be very expensive in cases of large throughput and fast automated processes with high value products. However, this vision can be extended and applied to other scenarios quite easily.

Design for Visual Six Sigma - DFVSS

Visual Six Sigma is the title of ground-breaking book co-authored by JMP® Europe marketing manager and Black Belt Dr. Ian Cox (*Visual Six Sigma: Making Data Analysis Lean* by Ian Cox, Marie A. Gaudard, Philip J. Ramsey, Mia L. Stephens, Leo Wright; Wiley). It focuses on the process of data analysis; its cyclical structure resembles that of Lean Manufacturing.

The way classic Six Sigma tollgates are usually presented emphasizes the "Model Relationships" phase, where statistics is used for inference.

In Visual Six Sigma, confirmatory data analysis is not always necessary and may thus be skipped; the "Uncover relationships" phase, where graphical tools are used for exploratory data analysis, is much more important.

Visual Six Sigma integrates the Lean Manufacturing pillar of Just in Time perfectly.

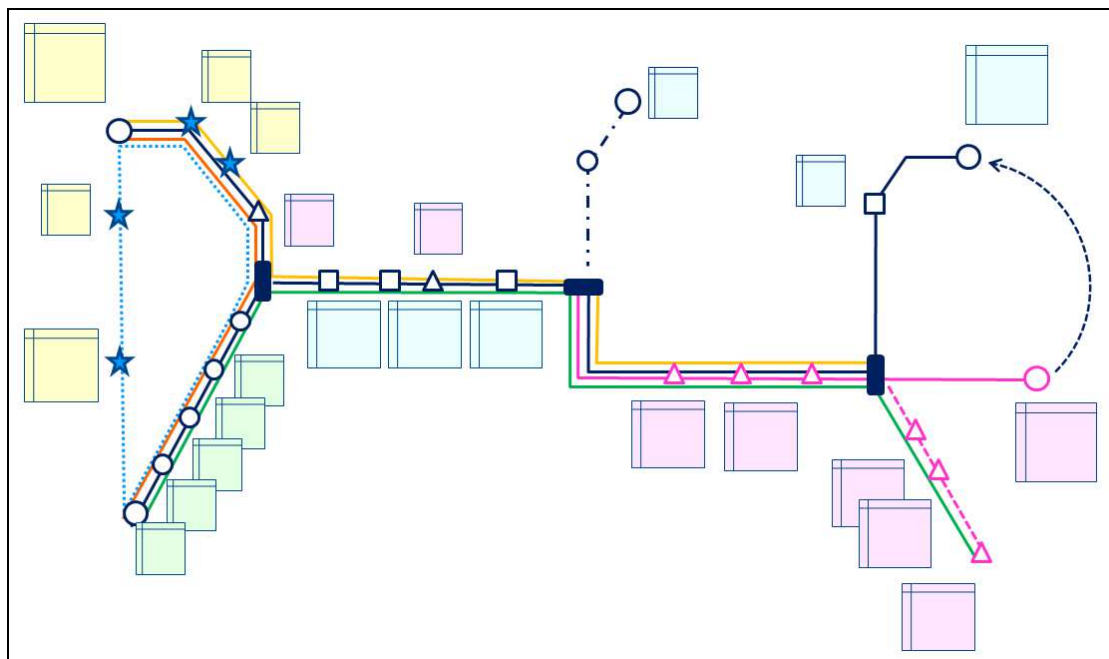
The interactivity makes JMP the ideal software for Visual Six Sigma, and the capability of analysis automation through JSL language is a further added value.

Process Map

The tube map below is an innovative way to visually explain the process without going into technical details. The coloured lines represent the type of flow (manufacturing, materials consumption, traceability, etc.). The various geometrical shapes represent the various process phases (e.g. welding), with each shape representing a specific type of phase (e.g. write information into database).

The coloured boxes are the datasets that every process phase updates in various databases.

The dark blue rectangles are frontiers between areas of the automation provided by different suppliers.



Each station produces datasets in its own format, according to its own Takt time; dataset requirements were designed together with the process specifications (design inputs).

Missing information or lack of traceability at any station is a type of defective, represented by the information line intersecting the manufacturing and quality lines.

Designing the primary keys of databases at the same time as the process is the only way to avoid the information loss that is typical of a multiphase, multi-frontier process, and is a prerequisite to our JSL scripting project.

Project Work Breakdown Structure (WBS)

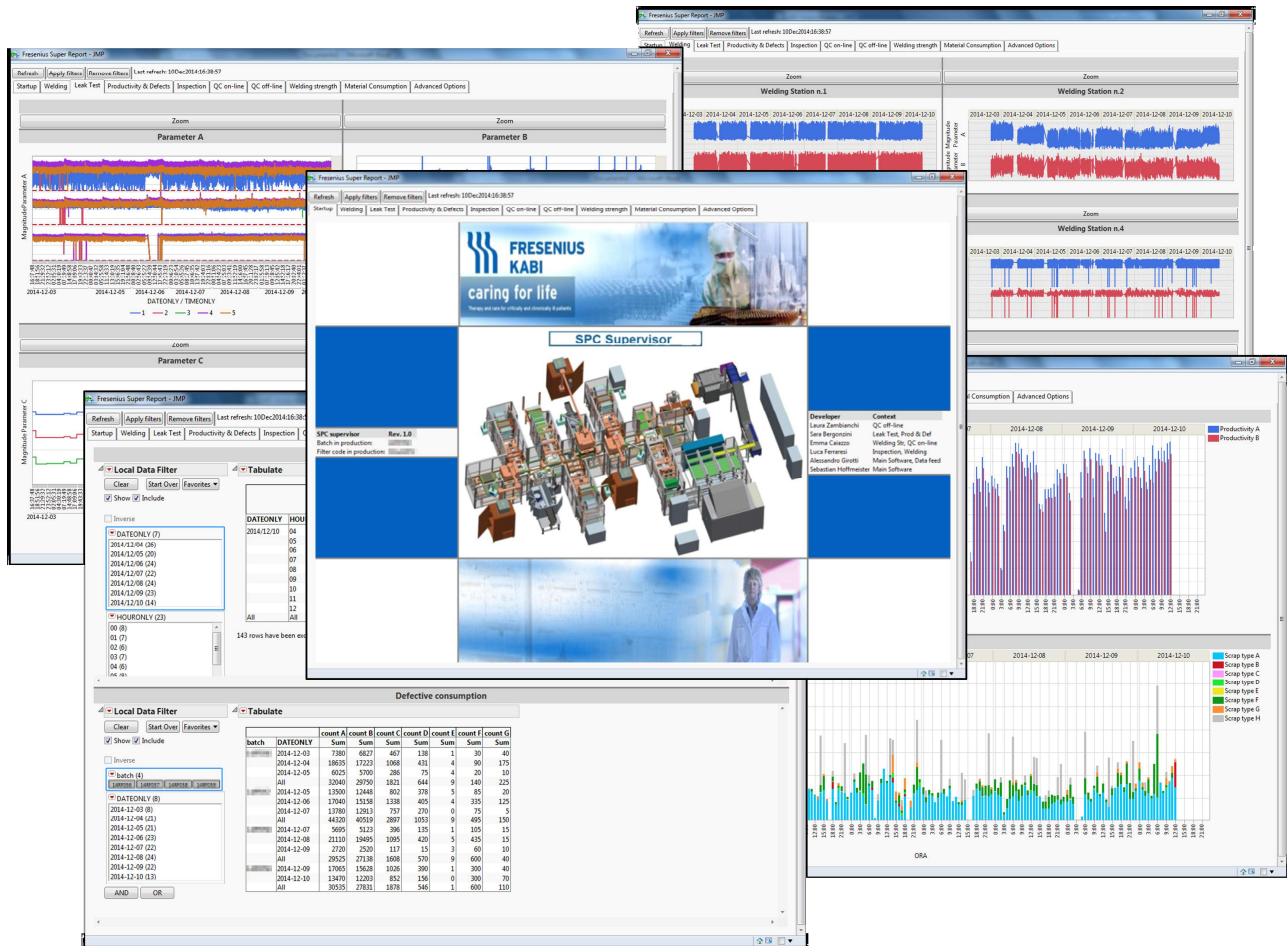
A complex SQL queries infrastructure links all datasets (including other offline QC databases) so that all the information is accessible and interlinked.

Some queries contain several thousands of rows of code; this is necessary to align the information when it is collected with different granularity.

JMP® connects not to databases but to this SQL-queries substrate: such complex queries cannot be realised with JMP® interface, but need an expert of SQL language.

In other words, we created an interactive online data structure which makes it possible both to create the transfer function ($\bar{y} = f(x) + \bar{\epsilon}$) and to screen possible root causes in case of atypical events, the heart of both Visual and classical Six Sigma!
As the tool is online and user-friendly, it is also Lean.

The Scripting Project (s)



The starting point of the whole project was a customized JSL training session with focus on the specific requirements needed to develop the final Visual SPC-Report in JMP. The focus was mainly on:

- database access
- highly customized graphics
- user dialogs and customized reports

The most important aspect of the training was the direct connection to the real world problem.

Based on the training received, the team was able to formulate the requirements for the final program. This was a highly customisable report separated into sub-reports, each representing one of the different stages of the product line.

After the JSL backbone was programmed, each team member was able to extend the code and thus fill the reports with the relevant graphs and tables for the individual section.

The programmers worked simultaneously, while the project manager was in charge of the main routine and data feed through SQL programming.

Structure of the JSL

The typical JMP tool used to automate analyses is the Journal. However, advanced users know that JMP can also manage display boxes and graphs via scripting.

The backbone of our script is the display tool called "tab box," which creates a tabbed display panel in a display box window.

"Tab box" Function:

Tab Box ("page title1", contents of page 1, "page title 2", contents of page 2, ...)

Example:

```
New Window( "Example",
  Tab Box(
    "alpha",
    Panel Box( "panel", Text Box( "text" ) ),
    "beta",
    Popup Box( {"x", ex = 1, "y", ex = 2} )
  );
```

Our script is a local interface that loads data (i.e. results of the queries) dynamically from the SQL data server and uses functions and libraries which are made available on a shared (read-only) network folder on another server.

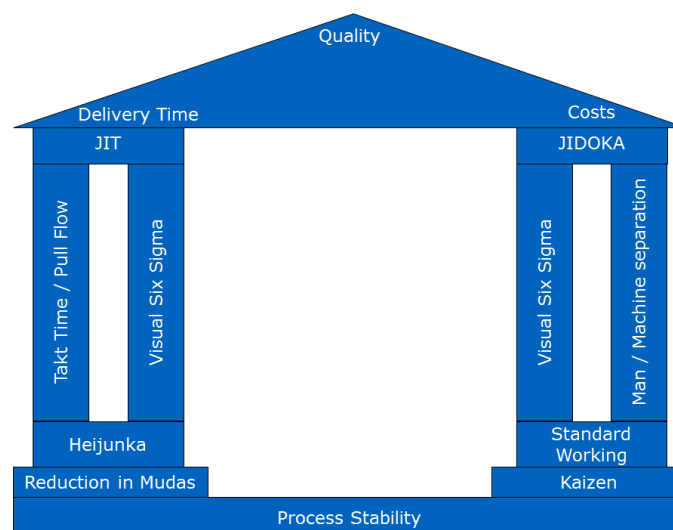
Thus, for validation purposes, all users are using the same version of the script and shared libraries and get a real-time picture of what is happening on the shop floor.

The zoom buttons allow the use of the transfer function as a root cause analysis tool, since the Ys and Xs are connected and aligned on the single item traceability.

Our Vision

Our script is used at various company levels:

- to validate the new line (reduce time to market)
- to improve process yield
- to conduct root cause analysis
- to track material consumption
- to track production costs and costs of poor quality
- to support product release
- for preventive maintenance



Adding the pillar of the management of the process and product information twice alongside the classical view of manufacturing contributes to achieving general enterprise objectives:

- as a Just-In-Time feature, easily available and understandable at any level to reduce Muda's.
- as a simple root cause analysis tool that moves towards Jidoka, a Japanese word that means *providing machines and operators the ability to detect when an abnormal condition has occurred and immediately stop work. This enables operations to build in quality at each process by eliminating the causes of defects* (see also <http://www.lean.org/Common/LexiconTerm.cfm?TermId=233>).

Excellence is never an accident. It is always the result of high intention, sincere effort, and intelligent execution; it represents the wise choice of many alternatives - choice, not chance, determines your destiny.

Aristotle