

Case Study - Medical Device Manufacturer



Background:

A medical device manufacturer has engineers and scientists routinely analyzing data on parameters that are critical to manufacturing quality. This is part of both ongoing analysis for monitoring as well as special case analysis for finding the root cause of potential quality issues. The teams use JMP as their “go to” data analysis tool, leveraging its flexibility and wide array of available analysis methods.

Problem:

The data for the parameters critical to manufacturing can be difficult and time consuming to access, join and clean. Data is often spread over multiple databases with a variety of conditions important to determining what data should be cleaned and how it should be cleaned. The follow through creation of Statistical Process Control (SPC) charts and subsequent analysis can then be overwhelming due to the large number of parameters involved. Documentation of results then forms a final burdensome step.

Necessary Parts of a Solution from the Engineers/Scientists:

- Give us a system that automates all the background data work.
- Make the system do the work of looking for violations and notifying us.
- When something happens, send us all the actual and relevant data so that we can dig in.
- Create documentation as part of the work flow, not as an afterthought.
- Require that charts in violation have a reset comment/reason associated with each specific point in violation.
- Create an overall dashboard.

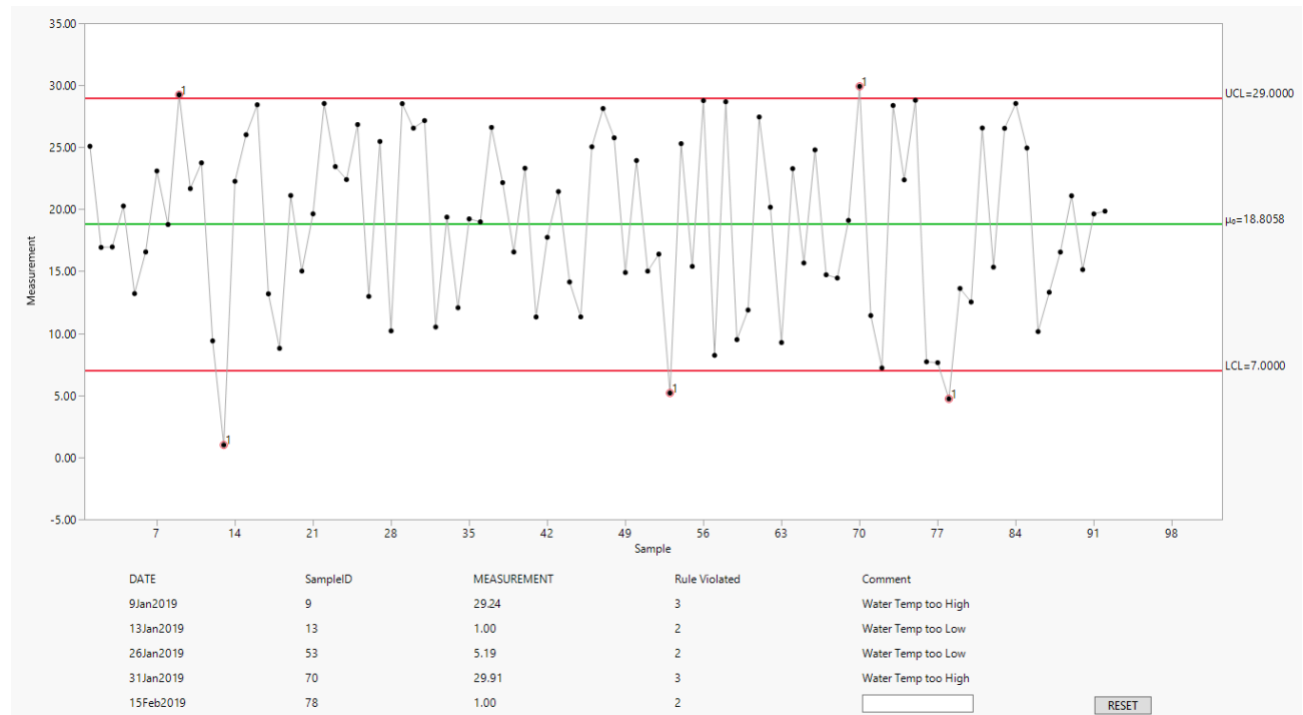
Preferred Elements of a Solution:

The Science and Manufacturing teams have JMP and are comfortable/prefer receiving and analyzing their data in JMP. Can we construct a system that leverages our JMP base but takes the burden off the teams? Any system must also be validated.

The Solution:

Create a JMP based system that allows data and chart setup with a Graphical User Interface (GUI), pulls data on a scheduled basis, runs control charts, pushes charts to users and notifies users of issues.

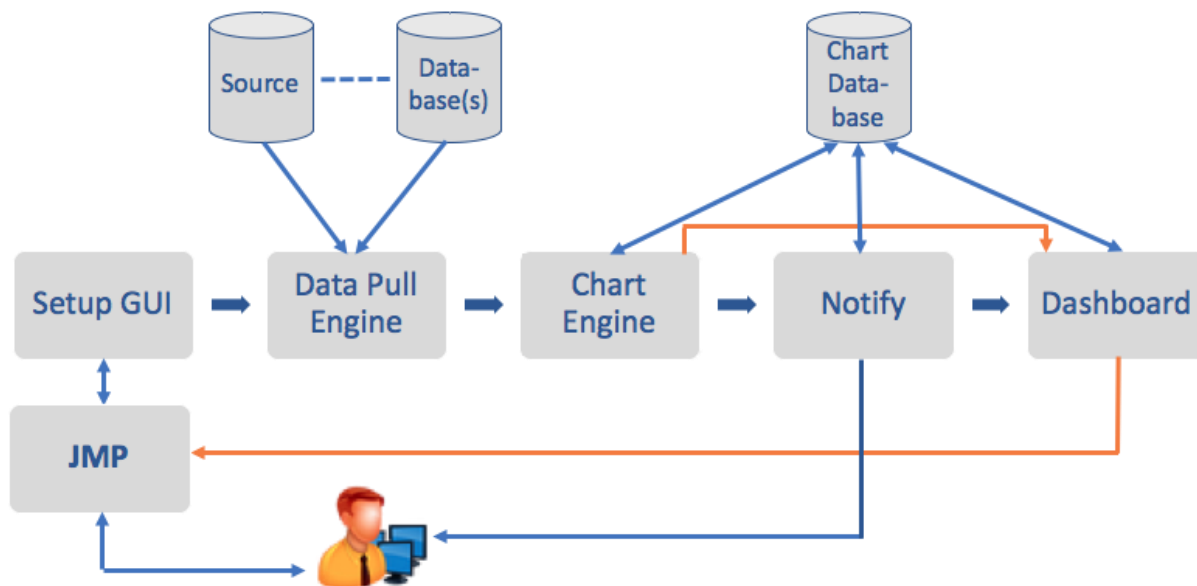
The diagram below shows a control chart from an example monitoring system. Out of control points are identified and details are captured below the chart as “chart history”. In this example the chart history indicates if the violation is open or has been reset. These chart and chart history screens are customizable to the workflow of the organization and can be sent by multiple delivery methods.



Key Elements:

- Graphical User Interface (Admin Panel) for Setting up Parameters, Data Sources, Limits and Rules.
- A data pull, join and Clean engine to access the data, clean and transform it for analysis.
- An engine to create charts and apply both standard and customer defined rules.
- A notification engine that sends EMAILs to users with charts embedded in the EMAILs.
- A system to track Out of Control conditions and document actions taken to address or reset them.
- Dashboards to show overall system health broken down in various ways; CpK, number and types of charts in violation, number of resets by user and chart type, stability and variability, etc.
- Validation of the system.

Medical Device Monitoring



The Impact:

- Saving greater than 4,000 hours of time per year for the Science and Engineering Teams.
- Provide a documentation trail for out of control conditions and the actions taken to resolve them.

Unforeseen Benefits:

- Identified areas and parameters with recurring, systematic problems.
- Facilitated cross-training and learning.
- Surfaced patterns in problem occurrence across multiple parameters when they were viewed together.
- Identified parameters with overly optimistic (loose) limits.
- The uncovering of new insights and many “Ah Ha!” moments.