Executive Summary

Medical Device industries are moving rapidly within their manufacturing systems to adapt to relatively newer technologies like MES (Manufacturing Execution Systems) and SPC to integrate with existing PLM and ERP systems for Operations and Quality Assurance. Manual evaluation of data for process control has become a thing of the past thanks to the enormous availability of data. With this, key stakeholders like the Engineering Manager, Engineer and the CNC operator should be able to correctly know by looking at the chart / report generated by the SPC software if a manufacturing process is moving out of control.

But the pace with which technology is being absorbed seems to put to background a need to properly identify the right methodology for implementation. For example, many industries are still dependent on Shewhart’s SPC chart (Xbar-R and the IMR) for identifying an out of control variable even though current software features include advanced SPC methods.

This project studies the various SPC methodologies that can be applied to a Medical Device manufacturer. A preliminary research revealed about 15 relevant SPC methodologies are available. A paired comparison based on factors relevant to the Medical Device manufacturer narrowed down the selection to 2 SPC methodologies. Statistical tools were used within Minitab® to compare these with the existing method for identifying ‘out-of-control’ variables.

The results show that the CUSUM method of determining ‘out of control’ variables such as the coded dimension is statistically superior than using the current method of using I-MR chart.

Additionally, at least one of the software used to analyze SPC data seems to have a few limitations which could mask the underlying issue associated with an out of control variable. To evaluate this, a spreadsheet loaded with Excel formulae was built to verify if the number of out of control variables generated were higher. The results were statistically evaluated, but could not be proven that the spreadsheet based I-MR was superior.