Warwick Analytics helps to reduce impurity levels at pharmaceutical manufacturer with automated root cause analysis

In the production of a major pharmaceutical companies product, used in the treatment of haemorrhoids, a higher-than-expected impurity formation required a solution.

The Site Operational Excellence Lead at the plant where the product is made says: "The product is formed from a complex series of reactions from intermediate chemicals. It is very sensitive to many factors and has been a challenge to control the impurities for a long time.

"Clearly it is imperative to better understand the factors which drive impurity formation so that we can maximise the quality and avoid rejections. Not only does this save on the expensive raw materials and process, but it is also better for the environment reducing waste product and energy."

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WARWICK ANALYTICS　**SigmaGuardian**

So the company introduced SigmaGuardian software from Warwick Analytics, an automated root cause analysis tool, to identify where the underlying reasons for the impurity formation lay.

Although the initial dataset was small and contained some inaccuracies, SigmaGuardian was able to employ its Information Retrieval technology to extract as much information from the data as possible, including logical inferences and derivative variables. From the first iteration, its 'non-statistical' predictive algorithm was able to generate and validate some strong signals without any hypotheses. Some of the results were expected and some were a surprise to the team. This led to a second iteration with more data. Warwick Analytics generated root causes to explain the factors which predicted both high yields as well as low yields. A Design of Experiments ("DoE") was created from the results to validate the results. These concurred with the findings from SigmaGuardian and the relevant process changes could be implemented.

The Site Operational Excellence Lead continues: "The pharmaceutical industry is highly regulated and we have to verify and document everything we do. So finding and validating the root causes which drove yield improvements was a key advancement and we are very pleased with the analysis that SigmaGuardian provided.

"We did not expect the results to be as good as they were, particularly with limited data we provided. Also the speed of calculation and the ease of interpreting the results was impressive too."

Warwick Analytics has developed their SigmaGuardian automated root cause analysis and Y Predictive Analytic software following a decade of academic research originating from Warwick University.

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