Case study

Data Discovery – Medical Device Quality Improvement

Business Background & Context	**Rare event defects in medical devices resulted in high volumes of scrap and major supply chain interruptions at the customer.**
Problem & Goal	Medical devices were produced in large batches on very high volume manufacturing lines. Batches were sampled using a destructive test. Occasionally very low levels of defects (ppm level) were detected. Complete batches of suspect product had to be scrapped. The goal was to better understand the problem and to improve yield and OTIF.
What was Done	• Rigorous statistical analysis of historic test data (over half a milliion tests !!) to identify possible factors (e.g. production lines, products, components and test machines). • Design of Experiments to identify root causes • Changes to product design, manufacturing conditions, test machine calibration, sampling strategy
Business Impact	Scrapped batches and major supply chain disruptions were reduced by a factor of 3. Major cost savings and customer confidence was greatly increased