



SPC prevents quality defects in processes and products

Proficy Shopfloor SPC (Statistical Process Control) is a versatile quality control tool that enables production companies to collect, calculate and illustrate all the quality-related aspects of their processes and products. Proficy SPC prevents quality defects and deviations before they arise, ensuring optimal production and consistently stable product quality.

Targeted use of Proficy SPC improves the whole production process, increases customer satisfaction and strengthens the company's image and competitiveness. Proficy SPC is a flexible quality control and process validation tool that uses statistical data from the production

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Mark Kaare Poulsen, Validation Supervisor,
Unomedical, Denmark

process to ensure that all internal and external quality targets are met.

In medical equipment and pharmaceutical production, the tiniest quality defect can have fatal consequences for the company and the patients who depend on flawless products. Leading drug companies use Proficy SPC's versatility to meet the industry's very strict quality requirements, including the FDA's 21 CFR Part 11 regulations.

The following cases show how the Danish medical equipment industry uses Proficy SPC to control the quality of its processes and products in various ways.

SPC VIA RANDOM SAMPLE MEASUREMENTS

RANDOM SAMPLE STATISTICS SAVE SAMPLES

To Unomedical in Hundested, Denmark, producer of catheters for a wide range of medical uses (e.g. catheters for the throat and urinary tract, suction and feeding tubes), watertight quality control is crucial. The company produces vast quantities of catheters every hour. Random samples are tested every 15 minutes on a tensile test bench. Proficy SPC measures the strength needed to detach the funnel from the tube, and illustrates this as a graph accompanied by the permitted margins with green, amber and red fields on the operator's display screen.



FEWER REJECTS

The tensile test bench replaces a manual test where the product was weighted and hung vertically until it became detached. About one million catheters were tested annually – then thrown out. With Proficity SPC installed at the tensile test bench, monitoring of the product quality is better and faster. Because Proficity SPC illustrates the stability of the process it is possible to reduce the quantity of samples.

HUMAN SAMPLING ERRORS ELIMINATED

After every tensile test, all Proficity SPC data is transferred to an easy-to-understand screen which dynamically displays the last 20 measurements. The traffic-light analogy with red, amber and green fields allows the operator to assess the quality immediately. If the amber light shows three times or the red light shows once, production is stopped.

PREDICTS OVERALL PRODUCT QUALITY

Calculations using the Proficity SPC data from two random tests can with great probability predict the margins for all products from the intervening period. Data from relatively

few random tests can then be extrapolated to a large scale that represents the whole production.

REVEALES TRENDS AND RANDOM EVENTS

Unomedical uses Proficity SPC to calculate relevant key figures that are used to identify every deviation.

The company also uses Proficity SPC to differentiate between deviations that constitute a trend that needs to be adjusted, or random deviations, when the process parameters do not need adjusting. For example, Proficity SPC can quickly ascertain how a testing process with a sequence of one amber, two green and one amber light deviates from a measurement sequence with one green, two amber and one green light.



Mark Kaare Poulsen,
Validation Supervisor, Unomedical.

“In our mass production it is important always to have our finger on the pulse in terms of product quality.

SUMMARY

COMPANY

Unomedical, Denmark

SOLUTIONS

Production Management

- Quality control of processes and products with Proficity SPC

PRODUCTS

- Proficity Shop floor SPC

BENEFITS

- High product quality
- Stable processes
- Waste reduction
- Total system integration
- Complete traceability
- Real-time decisions
- Full data openness
- Countless applications

With Proficity SPC we now have a tool that will identify deviations before they become too big.

We also make major savings in the production process because Proficity SPC tells us straight away whether deviations are trends or random occurrences, thereby avoiding unnecessary production shutdowns.”

For more information on our smart solutions, please visit our website www.novotek.com

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