

MEDICAL DEVICE MANUFACTURER ACHIEVES SIGNIFICANT SAVINGS & IMPROVEMENTS WITH WinSPC

“The flexible nature of the PDA data collection, coupled with the rich functionality in the WinSPC system provides us with a comprehensive SPC and Process Monitoring system which is essential to our business.”

Quality Director



Over the past 50 years, Our Client has grown to become the world's largest OEM and contract manufacturer of wire formed medical devices and components specializing in minimally invasive devices for cardio, endo and neurovascular applications.

CHALLENGE

Our Clients production facility in Ireland was capturing key process and product specification data manually on the shop floor and then transcribing the data to spreadsheet form for analysis by their Quality and Operations departments.

In addition to addressing the potential for data input errors, and the time consuming nature of the manual process, our Client required a solution that would

- Provide flexible data collection which would be aligned to their new cellular manufacturing processes,

- Comply with FDA 21 CFR Pt 11,
- Provide out of the box SPC charting and Process Monitoring capabilities.

DATAWORKS ROLE

TECHNOLOGY APPLIED

Dataworks designed a solution which utilises Wireless PDA units incorporating built in barcode scanning capabilities. The PDA Data Collection application enables users on the shop floor to collect the data in a quick and flexible manner while moving within the manufacturing cell. This method of data collection is quicker than the previous manual process and feeds real time data into WinSPC.

The full benefits of WinSPC are leveraged by users and supervisors on the shop floor, while at the same time providing real-time monitoring and reporting to management and quality personnel.

CORE BUSINESS BENEFITS

RESULTS

Our client is now capturing and storing key process and product data electronically and in a real-time manner. WinSPC enables greater control over their processes and captures data that is required by their customers and the regulatory authorities without the need for additional resources. WinSPC ensures the availability of real-time data in an intelligent format to decision makers focused on quality monitoring, product approval and compliance. WinSPC provides a cost effective solution to the collection and collating of critical data.

BENEFITS

Our Client is utilizing WinSPC primarily as an SPC package to ensure that their process is in control, but also as a data collection system for attribute data including defects.

- Enabler for continuous improvement initiatives
- No additional human resources required to operate
- “Plant Monitor” for Operations personnel.
- Full traceability on the who, what, where, why and when

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