Case Study

# Medical device maker eliminates bottlenecks, enables yield increase with switch to digital records

A maker of implantable medical devices reduced risk of manual reporting errors, boosted quality assurance, reduced liability, and closed gaps in its supply chain by replacing paper-based processes with an agnostic digital data management and analytics platform.

A leading manufacturer of implantable medical devices came to Sciemetric with a problem. Their reliance on manual, paper-based processes for inspection and quality control of sub-components from its suppliers was becoming an issue. As growing customer demand called for increased production, it became clear that this manual process was a bottleneck impeding business growth.

The manufacturer was using electronic measuring and inspection tools such as digital micrometers, calipers, laser gauges and cameras to monitor production at each station, but numeric measurements were not recorded and stored by any digital means. Instead, inspectors would pencil them in on paper forms that would then be funnelled through another department for manual data entry and then filed in cabinets off the floor. Camera image files would be stored separately on a server.

The production line suffered from:

- **Lack of scalability:** That manual inspection process inhibited the output of the entire line. There was no way to work around it without seriously impacting quality or increasing costs with more inspectors and inspection stations.
- **High risk of error:** From bad handwriting to paper forms filled out incorrectly or the wrong value being recorded, the manual process was prone to human error.
- **No real-time insight:** Inspection data was not recorded or integrated for easy real-time analysis to spot trends or patterns that pointed to broader quality issues before sub-components were used in production.

## Automated data flow and quality control

With Sciemetric's system, data from measuring devices is fed directly into an inspector's tablet via Bluetooth. This eliminates the need for paper and the risk of human error.

Each tablet then uploads its data directly into a QualityWorX database for a streamlined and automated data entry process that is reliable and consistent.

Once in QualityWorX, the data can be analyzed with Sciemetric Studio 2.0 to identify quality issues and drive continuous improvement. A user-configurable real-time alerting engine also constantly monitors this data for Nelson Rule breaches and provides email alerts.

## Solution

The manufacturer turned to Sciemetric for its expertise in consolidating data from disparate sources and enabling the real-time analysis that can catch quality issues at source before they lead to larger and costlier problems.

Sciemetric worked with the manufacturer to modernize and digitize quality control and inspection of supplier sub-components by:

- **Scripting custom gateways** that could ingest data from a variety of inspection devices from third-party vendors, using whatever data output is available on a device. In other words, create a "universal translator" to transform this data into a standard digital format.
- **Creating a configurable tablet application** that would replace paper forms. Sciemetric designed this application to work on Windows, in response to the manufacturer's preference for Microsoft Surface Pro tablets. This application received measurements from inspection devices via Bluetooth.
- **Developing a best practice workflow** to manage data and address any issues with data quality.
- **Configuring a Sciemetric QualityWorX database** to be the single central repository of all inspection data. This included the digital forms from the tablet application, as well as integrating any other data files resident on other servers, such as machine vision image files. In QualityWorX, all of this data is combined and correlated by any combination of identifiers – date and time stamp, batch number, inspector, supplier, etc.
- **Conducting real-time analysis** from the QualityWorX database using Sciemetric Studio 2.0, to chart trends and spot anomalies that indicate quality issues.
- **Automating quality control** with Sciemetric Studio 2.0's SPC-enabled real-time alerting engine. This allowed the manufacturer to be able to configure their own features, apply statistical rules and set alerts for out-of-control data. The engine continuously scans the QualityWorX database for data anomalies, recording alerts in a user-controlled audit log, and has the option to send out real-time alerts via email.

## Benefits

By replacing manual paper processes with digital data management and analytics, the manufacturer has improved the efficiency, capacity and accuracy of this vital quality assurance process.

> **The manufacturer engaged with Sciemetric with the expectation that eliminating manual paper processes would reduce costs per plant by $2 million to $3 million a year. In addition to this operational cost saving target, the manufacturer is realizing other benefits key to its bottom line, liability risk and reputation in the market.**

In particular, the manufacturer valued how Sciemetric is a truly agnostic option that can collect, convert and integrate data from third-party devices into a single database. A conventional factory can become a true smart factory without a costly rip and replace of existing equipment.

Sciemetric's solution is now being deployed at seven plant sites across North America, Latin America, Europe and Asia. The manufacturer is also looking to extend use of the solution across the line of each plant, including end-of-line testing.

## Far-reaching impact

- **Improved quality, less scrap:** Faulty subcomponents are more accurately and quickly identified before they are used on the assembly line.
- **Reduced reliance on manual entry:** The likelihood of human error is drastically reduced.
- **Supply chain integrity:** Reduced risk related to supply chain disruption. In an industry where these products are critical and in high demand, improved overall yield and helped to ensure quality assurance of manufactured products.
- **Defensible results:** A data-driven audit trail with which to verify where responsibility for a quality issue rests – with the manufacturer, or with the sub-component supplier.

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