



## Case Study

### Medical Devices Manufacturer gets Lean with Shopfloor-Online

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## Introduction

Data collection and analysis have always played a vital role in manufacturing and with strict regulations and legislation becoming commonplace; manufacturers are required to look at ways of improving their production processes to ensure increased customer satisfaction, operational efficiency and product quality.

The stringent requirements of the Food and Drug Administration (FDA) have been influencing changes in many production processes, and to comply with the new regulations, manufacturers have turned to more advanced integrated solutions which in turn will benefit their customers.

Bringing data together from a wide range of sources, Shopfloor-Online from Lighthouse Systems is a standard software suite that can be configured to fit into manufacturing environments to provide accurate, real-time information to speed up decision making at all levels of Operation.

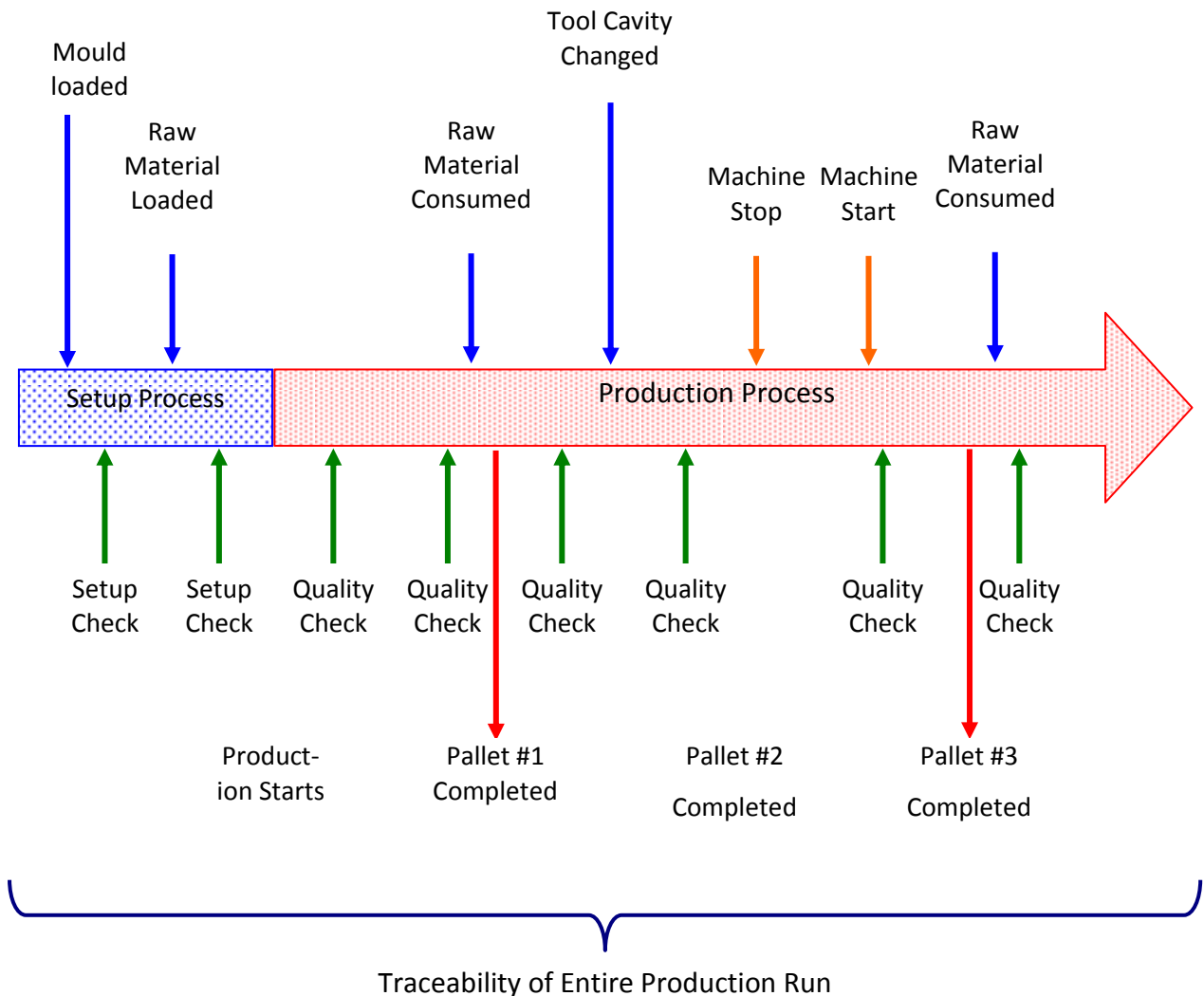
## Shopfloor-Online overcomes challenges

The issues facing a leading manufacturer in the medical devices industry were challenging in a number of ways.

### Traceability

Traceability Driven by FDA regulations, the end-user specified that the entire production process had to be tracked in detail. For any given production run it was necessary to determine:

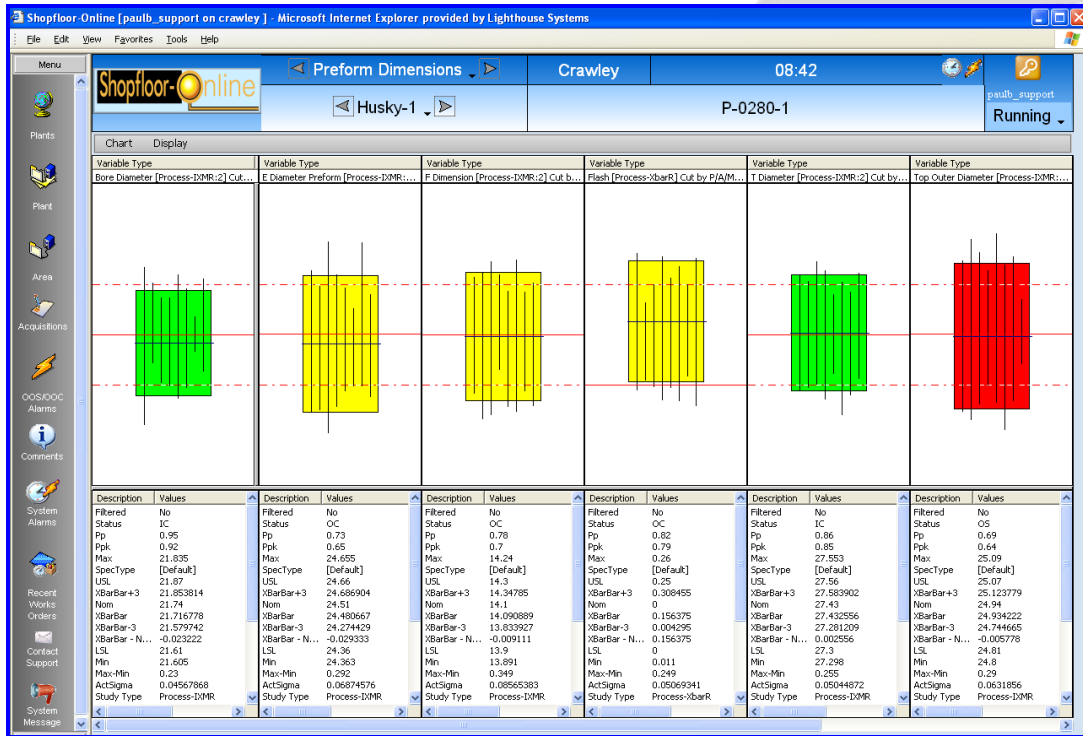
- Raw material consumed. All batches of raw material consumed throughout the production run had to be recorded along with the date and time of batch change over. The date and time was vital in order to trace any pallets of production that may have been produced with a defective batch of raw material
- Traceability by tool and tool cavity. Not only is the identity of the mould tool a key factor in the traceability requirement but also the identity of the cavity insert. This is particularly complicated by the fact that from time to time worn cavities are replaced with new cavities mid way through the production run. The three digit cavity name (e.g. A01, A02) previously recorded on paper, was virtually impossible to trace prior to the introduction of Shopfloor-Online. Now Shopfloor-Online identifies the production batches, produced pallets, customer orders, date/time of produced parts, operator, measurement tool used and even the specific measurement values of individual components produced from a specific cavity.



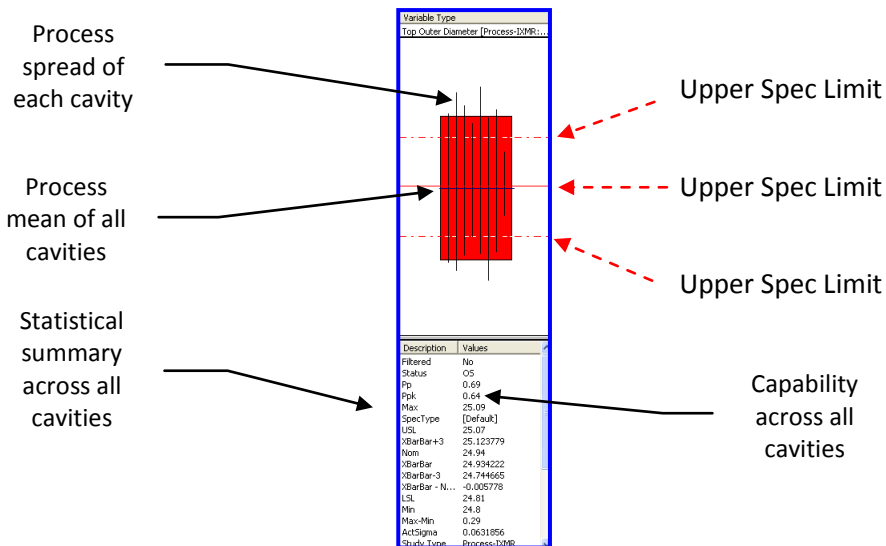
### Capability and Certificates of Analysis

Another major requirement was to prove process capability for each production run and to generate Certificates Of Analysis automatically. Both requirements were very time consuming prior to the introduction of Shopfloor-Online.

Capability by Cavity - New or repaired tools undergo thorough examinations before they can be released to production. Parts from multiple shots are dimensionally checked with the data being tagged with the cavity name from which they originated. Shopfloor-Online automatically processes this data and determines capability across all cavities and for each specific cavity. A procedure that previously took more than 24 hours using Excel Worksheets now takes less than an hour.

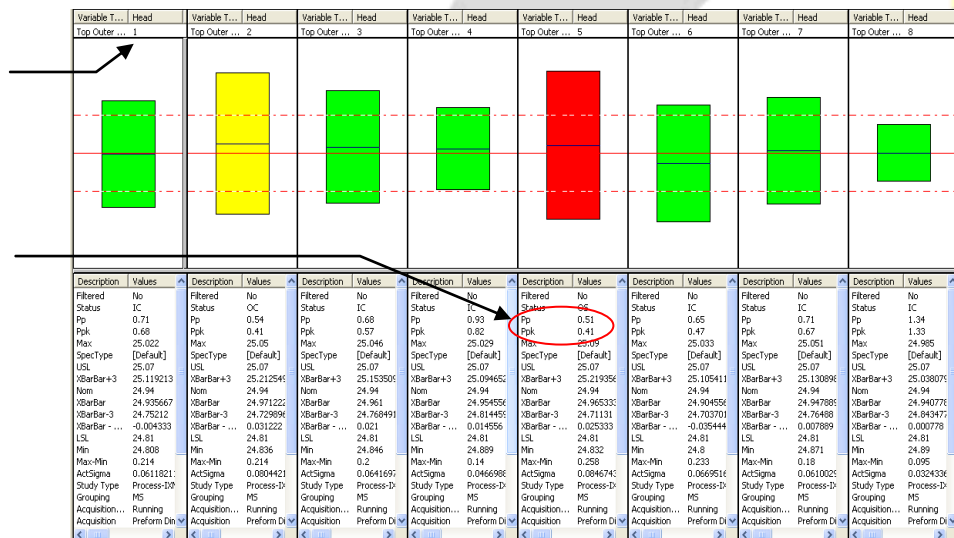


The example screen above shows six critical variables and eight cavities in the mould tool, in real terms this amounts to forty-eight variables. The Process Capability Overview above shows a summary across all of the 48 variables in a single screen.



Drilling in on a single variable shows the performance by cavity

Capability for each cavity is shown



The report above shows the capability for the same variable across each cavity. Cavity 5 is reporting Out Of Specification (Red), Cavity 2 is reporting Out Of Control (Yellow) the remaining cavities are In Control (Green). Despite being in control the capabilities of each cavity can require attention.

Certificates Of Analysis Production batches supplied to customers require a Certificates Of Analysis. Each certificate demonstrating the number of samples checked, average, range and standard deviation across selected key characteristics. Yet again, the administrative burden of generating this documentation was high, particularly given the fact that many of the measured characteristics are inspected by specialised equipment with the results being stored in different formats and in different locations. The implementation of Shopfloor-Online resulted in the automation of the data collection and the automatic creation of the Certificates Of Analysis. On this aspect alone, 4 people were released from the administration burden and able to perform more value added tasks. Since the introduction of Shopfloor-Online this manufacturer is now rolling out the system across their assembly and packaging lines. Other production plants across Europe and North America are also expected to follow suit over the next 12-18 months.

*Lighthouse Systems is one of the world's leading developers of Manufacturing Execution Systems (MES) with offices in London, Singapore, Australia and Rochester, NY. Lighthouse Systems Shopfloor-Online is web based modular software that provides real time visibility of the entire manufacturing*

operations environment. Applications include Maintenance Management, Concern Management, Quality, SPC, Downtime, OEE, Spoilage and Inventory Traceability. Shopfloor-Online is being used in a wide range of industries with some of the biggest manufacturing companies; it is deployed in 15 languages in 28 countries.

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