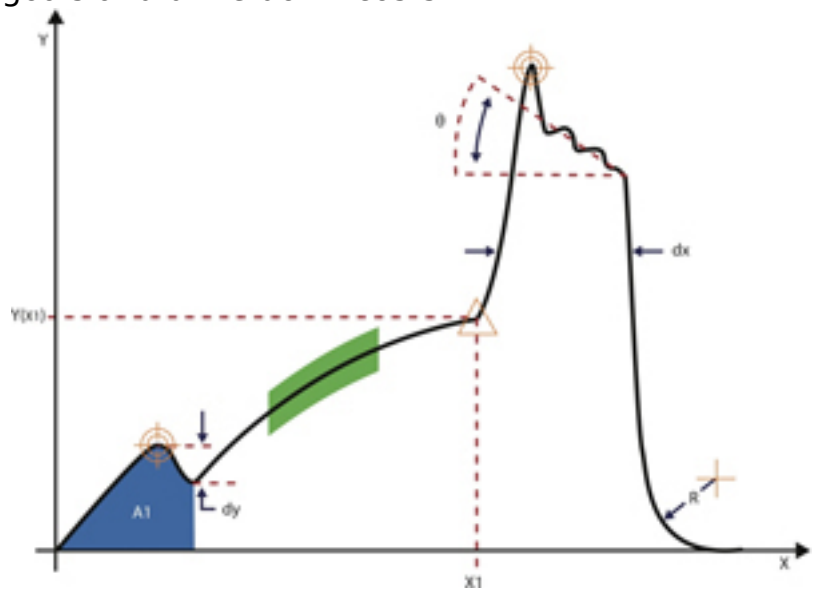
Embrace Process Signature Technology

Quality issues cost companies billions of dollars each year, negatively impact brand reputations and damage customer loyalty. Competitive pressures in a global marketplace are making it both more urgent and more difficult to deal with these very real threats to core business success. In automotive manufacturing, and in highly regulated industries such as medical manufacturing, lives are at stake. Therefore, quality must be a key consideration in order to protect consumers.

How manufacturers are choosing to address these crucial quality concerns seems to depend largely on one key factor: cost. There’s a misperception that improved quality will drive up costs. In fact, there are a range of technology approaches that not only deliver a swift return on investment, but also drive process improvement and optimize manufacturing efficiency, ultimately providing an effective mechanism for cost control.

This article expands on the topic of technology approaches to quality improvement, and introduces readers to another methodology: process signature technology and how it can be used to gather real-time, actionable data about critical manufacturing processes. Adoption of this methodology provides manufacturers with an effective way to eliminate defects, manage recalls, improve processes, prove compliance with both internal standards and external regulations, support lean manufacturing goals and drive down costs.



Pictured here is a process signature showing examples of different feature types that can be extracted and monitored in real-time.

The landscape

The advent of lean manufacturing and cost-cutting related to the ongoing recession

have eliminated many positions once responsible for quality control, or has left just one individual to monitor an entire manufacturing line or plant. At the same time, maximizing yield, getting the most high-quality product off a line, is critical. In an era where price-conscious consumers can choose from an array of global manufacturers, dependable quality can be a potent competitive differentiator.

Fortunately, over the past decade, significant technological developments and innovations have been introduced that make it possible for manufacturers today to minimize defects, thereby achieving optimum quality, maximizing yield, and vastly reducing the need for product recalls.

One proven methodology that is specified into the manufacturing practice at many blue-chip automotive, industrial and medical companies is process signature verification.

An overview of process signature verification

Process signature verification is the capturing of the distinct signature or waveform of critical manufacturing processes as they happen and comparing this with a pre-determined standard. Deviations from the acceptable standard are readily identified and root causes easily determined. This approach recognizes irregularities in the process that may not be easily identified by post-assembly test approaches, audits, or destructive testing methods, since any variation from the ideal waveform is instantly apparent and its impact on quality readily assessed.

It is possible a part met standards at the start of manufacturing and reached the desired endpoint yet experienced an issue that wasn’t previously known or monitored that will impact quality after the product has gone to market. By that point, without extensive, detailed records of critical manufacturing processes, selective recalls are difficult to manage and sweeping, expensive recalls of what may be mostly “good” product become the only way to contain the defects.

By capturing process signatures in real time on the production floor, manufacturers gain complete visibility into their manufacturing processes. Instead of ineffective and expensive testing modalities that decrease yield and highlight problems only after it’s too late to implement process changes, in-process testing using process signatures reduces the need for costly recalls. Furthermore, it gets lines moving again more quickly if a problem is discovered and facilitates perpetual process improvement that eliminates future defects and saves manufacturers money. Using process signature analysis, detailed records exist that cover a range of factors that could have influenced quality.

Signature analysis an effective approach to quality improvement say analysts, regulators

Industry experts and federal regulators agree: process signature analysis contributes to an effective quality strategy.

IDC Manufacturing Insights said in its August 2010 Theory & Practice newsletter about signature analysis: “Continuous signature analysis is the foundation for early warning signals, containment of scope of rework and recalls. Signature analysis can

serve as an important quality management tool during manufacturing planning, ramp-up, and volume production. It can accelerate the detection and the root-cause analysis of manufacturing and supplier quality concerns, as well as provide an early warning signal, drawing attention to an impending quality problem. Manufacturers should consider adding signature analysis to their existing [Failure Mode &Effects Analysis] process to enrich the understanding of failure modes and effects, and accelerate root cause analysis and corrective actions. An equally important side-effect might be the ability to see long term changes in the frequency of failure modes and modify their prioritization."

Through its title 21 CFR part 820 QSR, or Quality System Regulation, the U.S. Food and Drug Administration (FDA) has instituted multi-faceted manufacturing-process-measurement regulations. The mandate of the QSR is to ensure that variation in the medical device manufacturing process is understood and minimized in order to produce low-risk, quality products. The stringency of the FDA's regulatory framework requires that systems be put in place to protect the consumer.

In its report, "Guidance for Industry PAT – A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance," the FDA further supports process signatures as an effective approach for quality. "For certain applications, sensor-based measurements can provide a useful *process signature* that may be related to the underlying process steps or transformations. Based on the level of process understanding, these signatures may also be useful for process monitoring, control, and end point determination when these patterns or signatures relate to product and process quality."

The ideal solution

The implementation of quality-management systems should not disrupt or negatively impact core business. Rather, any hardware that needs to be deployed on the production floor should fit seamlessly into your existing processes.

Process signature verification technology provides the most accurate determination of process health and part quality while collecting all data. Data collection is just one part of the equation. Analytics is the other part.

Manufacturing managers must have access to analytic tools to transform the collected data into actionable information. These tools must be able to analyze all the data, including the process signatures, ranging from individual parts to populations of parts. It's this analysis that ultimately enables manufacturers to reduce costs, manage quality, and maximize yield while providing proof of process compliance and complete line-wide traceability.

Conclusion

Lack of awareness and lack of understanding about the real costs and benefits of implementing quality-improvement technology like process signature analysis is costing manufacturers money, brand equity and business opportunities. With a thorough understanding of their core manufacturing needs and the internal and

market conditions within which they operate, manufacturers are able to adopt quality improvement systems that will help them achieve their goals and pass cost savings on to their customers.

Since 1981, Sciemetric Instruments' process-monitoring and quality-management systems and software have enabled some of the world's largest automotive, medical and industrial manufacturers to gain visibility into, and control over, their manufacturing processes. For more information, visit www.sciemetric.com [1].

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