# Signature Analysis

## Applying R&D Science to the Manufacturing Plant

***Laura Dierker** explains the science that gives insight to the successful manufacture of medical devices.*

**Signature Analysis is a science that allows medical device manufacturers to understand, in great detail, the physics underlying the successful manufacturing and assembly of their devices. One method, Process Signature Verification, applies signature analysis during a manufacturing or assembly process.**

With a process signature and rigorous, real-time signature analysis, medical device manufacturers can:

- Develop an objective specification for a manufacturing process that yields a perfect or near perfect result
- Monitor during the process for specific failure modes and identify those modes as such when they are found
- Re-evaluate the quality of even already-shipped product if an unknown failure develops downstream or in the field.

### What is a Process Signature?

The closest analogy to a process signature is an ECG. Doctors are concerned with the output of the heart, a volume of blood flow to the body. However, to determine whether the output is correct, doctors measure instead a critical parameter of the pumping process, the electrical signals of the heart. The ECG becomes a process signature of the beating heart.

In manufacturing exactly the same technique can be applied. The Process Signature is the digitised trace of chosen parameters that are critical to ensuring an output, in this case the manufactured or assembled product.

Like the ECG, the Process Signature details the changes in physical characteristics that occur during a manufacturing process. Each unique process operating on a particular type of part will generate a unique Process Signature.

The signature is formed from digitising, at high speed and high resolution, the data supplied by sensors monitoring the physical parameters deemed to be critical to the success of a process. For welding this can be energy applied, resultant heat, or even opacity. For a crimping operation this will include force and distance, but also potentially pressure and temperature depending on the article and nature of the operation. For liquid, dispense pressure across the dispensing nozzle can be used to indicate the presence of bubbles and the consistency of flow.

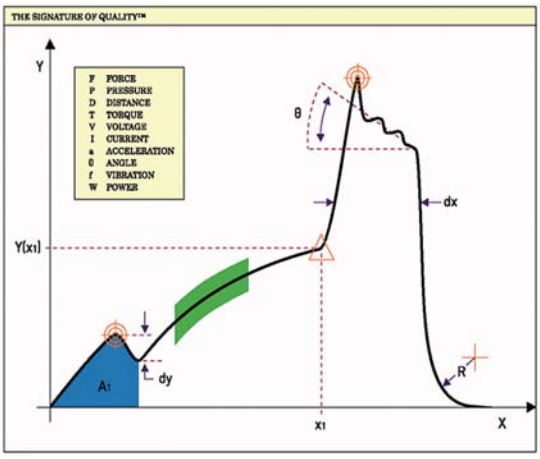
Process Signature Verification applies advance mathematics to the signature to individually identify known failure modes, and/or check for compliance with a 'gold standard' signature. Frequently, combinations of individual parameter signatures lead to the best answers. For instance, on the press-fitting curve above the distance and force signatures combined will show friction or debris between fitted parts.

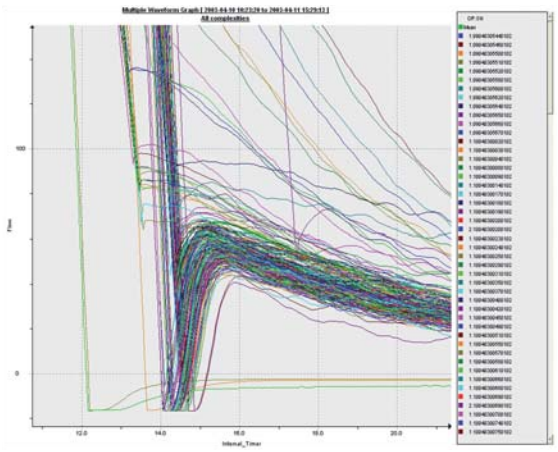
### The relationship between process monitoring and product quality

Manufacturing procedures are carefully designed to generate a product without defects; a perfect product.

If those procedures are carried out exactly, with zero variation in operator action, positioning and placement, applied force, applied energy, ambient temperature, material composition, material cleanliness, rotation, fluid density, and no tool wear, then you will have a perfect product.

In the example above top, notice the varying behaviour in the set of fluid flow curves through a valve system. The flow is curtailed early or late, partially curtailed, or cut off but not increased again to reduce blockage.



If there is a variation in one of the above it may affect quality. Detailed parametric monitoring allows the physics of these changes to be identified, and non-compliant parts to be rejected. Only parts with acceptable manufacturing processes, that is, good parts, get through.


***the authors***

*Laura Dierker and Steve McMahon from Sciemetric Instruments Inc.*


### Even simple processes benefit

In the image above, several signatures have been captured from a very simple process that stretches a plastic under the effect of heat. During the trials the heat effect on the stretch of the plastic was clearly visible. You can see it in the two grey curves at the

top. However two very unexpected effects became visible as well.

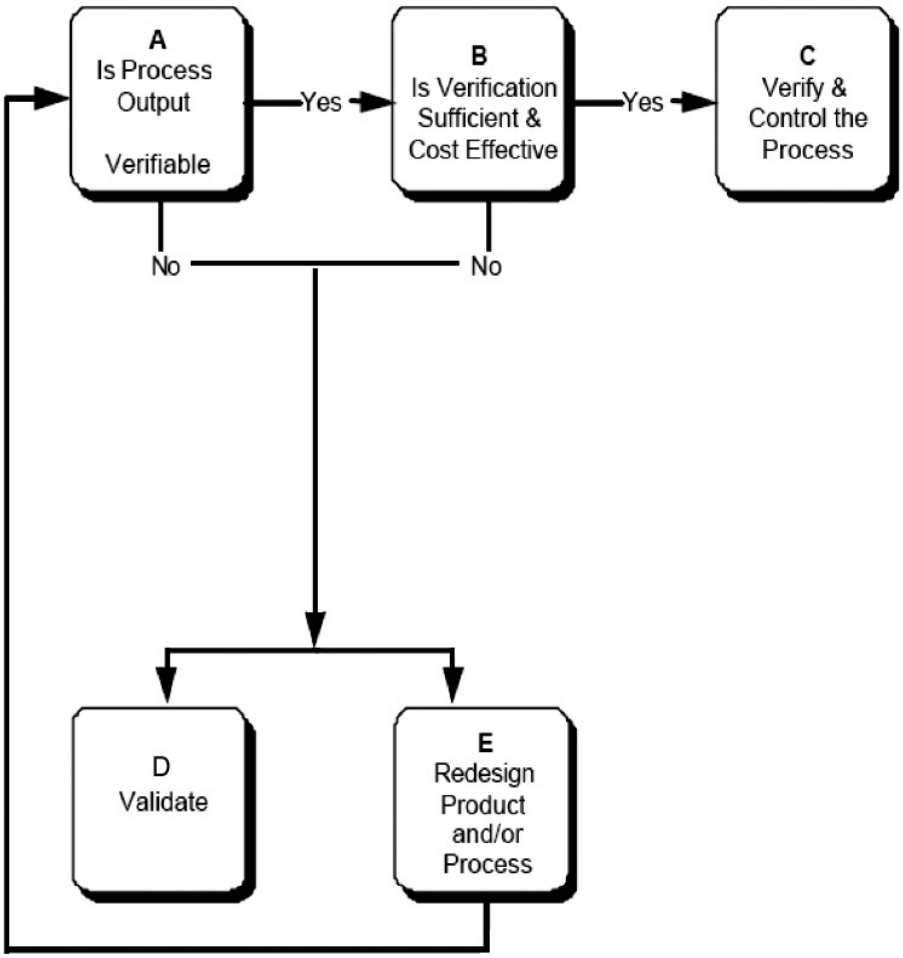
The first is evidence of slippage from the fastening mechanism, in this case, caused by an operator insertion error. The slippage was not visible to the naked eye, but clearly visible as the green curve in the diagram. The second unexpected information comes from the 'furry lines'. These are not poor data collection but in fact very sensitive indications of the friction of the servo motor used to stretch the tubing.

**The relationship to regulation**

The Global Harmonized Task Force; Quality Management Systems – Process Validation Guidance defines process validation as: establishing by objective evidence that a process consistently produces a result or product meeting its predetermined requirements, and process verification as: confirmation by examination and procision of objective evidence that the specified requirements have been fulfilled.

The relevance of signature analysis should be clear. Firstly, with a data-derived specification an automated objective proof of compliance to specification is available, for each part off the line. Secondly, if the physics of an operation is understood well enough, verification may be sufficient. As an example, a dunk-test is often used to verify that pacemaker cans have been sealed adequately and do not leak. Because this is a statistical destructive test, the process needs to be validated. If however, the sealing process is monitored and the manufacturer can prove objectively that an adequate seal is achieved at every point then one could make the argument this process is effectively verified.

In fact, 100% verification based on critical parameters should give a better measure of quality than process validation. Instead of trusting, objective evidence on each part is available.




Each process should have a specification describing both the process parameters and the output desired. The manufacturer should consider whether the output can be verified by subsequent monitoring or measurement (**A**). If the answer is positive, then the consideration should be made as to whether or not verification alone is sufficient to eliminate unacceptable risk and is a cost effective solution (**B**). If yes, the output should be verified and the process should be appropriately controlled (**C**).

If the output of the process is not verifiable then the decision should be to validate the process (**D**); alternatively, it may become apparent that the product or process should be redesigned to reduce variation and improve the product or process (**E**). Also, a change in a manufacturing process may result in the need for process validation even though the process formerly only required verification and control.

*From Quality Management Systems – Process Validation Guidance; Edition 2 January 2004; Authoring Group SG3, Taisuke Hojo GHTF Chair.*

**Moving manufacturing towards 100% product verification**

In summary the tools exist to take verification well beyond the traditional SPC monitoring that manufacturers are used to. While SPC monitoring has been a very useful tool for many years, the competitive and regulatory environments are demanding a move forward. That move forward could include a detailed understanding of manufacturing process success and the physical response of materials to those processes. Detailed understanding could help both reduce variability through root cause determination, and quickly provide the capability to discern a good part from one which contains failure indications.