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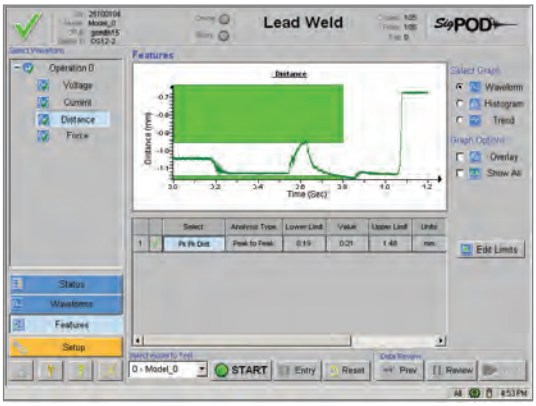
Process Signature technology helps manufacturers apply risk management in a tough regulatory environment.

SCIEMETRIC MEDICAL SOLUTIONS

Medical device companies in both the United States and Europe are facing pressure from regulatory bodies to place a greater emphasis on improving manufacturing quality and risk management.

This pressure follows steps already taken by pharmaceutical bodies to promote the adoption of PAT (Process Analytical Technology), an in-process approach that builds quality into manufacturing. While PAT has not yet been integrated into existing devices legislation, regulators have taken notice of its benefits and its principle of continuous improvement.



Improving manufacturing to reduce risk involves understanding the critical parameters that affect the quality of a product and measuring these parameters to ensure compliance. While many manufacturers have placed controls over the design of critical manufacturing processes they have neglected to put controls over the process once released to production. This lack of in-process control forces many manufacturers to rely on final acceptance batch testing which tends to be costly and adds risk that no defective parts are contained within a released batch.

Reducing a manufacturer's reliance on batch testing and furthering risk management goals can be achieve through the application of Process Signature technology. Process Signature is a means of analyzing all the critical process parameters at the point where product defects are introduced, and collecting electronic records to provide a traceable quality history across the many processes that go into making the product. Using sensor instrumentation to measure these parameters and plotting a 'signature' of the parameter over the duration of the process, analysis can be made to determine if the parameters were within design specification. This allows every manufactured product to be released or quarantined immediately, right at the critical process station reducing the costs of downstream batch release testing.

BENEFITS

- **Improve Quality System Regulation compliance**
- **100% monitoring of critical processes**
- **Detect defects at the source**
- **Reduce destructive testing**
- **Actionable information for CAPA campaigns**
- **Full process traceability and communication with MES architecture**

the science of quality

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Corrective and Preventative Action (CAPA) campaigns can also benefit from in-depth analysis and understanding of critical process parameters. Batch test methods of product release tend to identify defects late in the manufacturing process, often too late to easily identify what the cause of the product failure might have been; in many cases the contributing parameters are not even available. Implementing in-process test with Process Signature technology shortens the interval between failure and detection while providing full traceability of all possible contributing factors. Process Signature allows timely intervention and root-cause analysis.

Process Signature technology is applied using Sciemetric's Medical PSV, a flexible solution for in-line analysis of critical processes across the device manufacturing enterprise. Using a common hardware platform and software interface, Medical PSV offers a standard tool for managing risk across a wide array of medical device processes, such as:

- Welding – ultrasonic, resistance, laser
- Crimping
- Leak testing
- Profiling
- Adhesive dispense
- Materials joining
- Functional test
- Swaging

Process Signature data gathered from critical manufacturing processes is stored as a permanent record of device compliance using Sciemetric's QualityWorX™ database system. QualityWorX tools can be used to perform complex analysis of critical process station data such as comparing parameters across similar process stations, identifying machine changes that can affect quality and determining root-cause failure analysis. Data stored in the QualityWorX database can also be integrated to Manufacturing Execution Systems (MES) and used to enhance the product's Device History Record (DHR).

While regulators continue to increase pressure on the devices industry to improve risk management, manufacturers will be looking for technologies that fulfill their obligations without burdening costs. Process Signature provides a solution to meet these stringent obligations while also realizing important cost reductions and efficiencies. Remaining competitive when regulation evolves will challenge many device companies; Process Signature technology offers an opportunity to stay ahead of the curve.

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