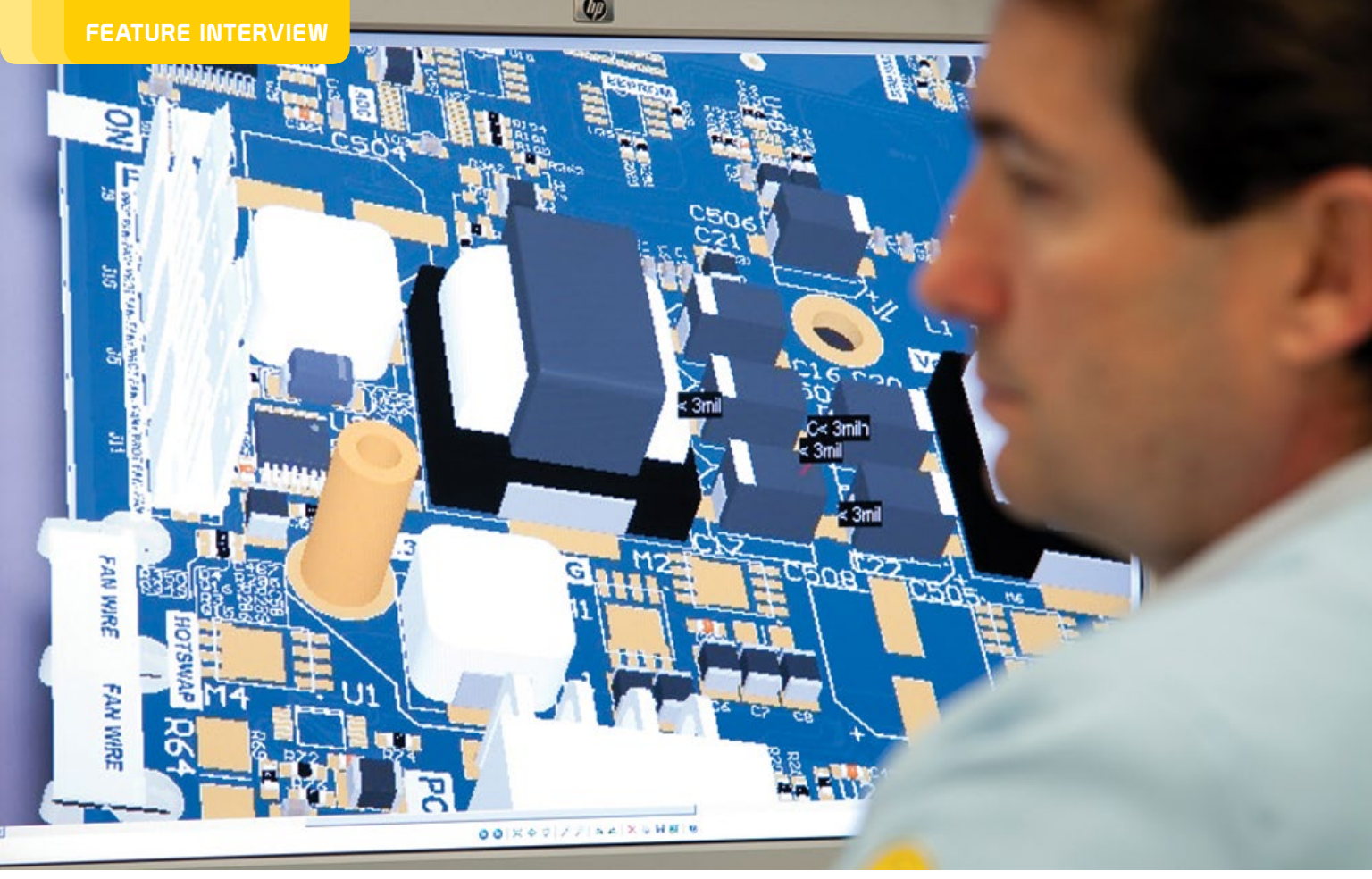


MEDICAL ELECTRONICS:
Risks and Opportunities for Electronics Manufacturers

by Stephen Las Marias
I-CONNECT007

Brian Morrison is the director for Value Engineering & Technology at SMTC Corp. and has direct responsibility for process, test and development focusing on new customer and new product introduction. In an interview with I-Connect007, he discusses the manufacturing challenges facing electronics manufacturing service (EMS) providers when it comes to medical electronics, and the increasing need for risk management, design control and traceability.

***Stephen Las Marias:** What can you say about the impact that the medical market has on the electronics manufacturing industry?*

Brian Morrison: The medical market for the electronic manufacturing services (EMS) industry is a branch of electronics that deals with design, implementation and use of electrical devices and equipment for medical purposes such as research, examination, diagnosis, treatment, assistance and care.


Brian Morrison

We are seeing a number of portable and wearable medical electronic devices that are used both in a hospital and home environment. Conventional medical devices have evolved over time with the advent of handheld smart phone-sized systems, which are now becoming available for monitoring patients at home or in the field and can send data to a doctor in a connected environment.

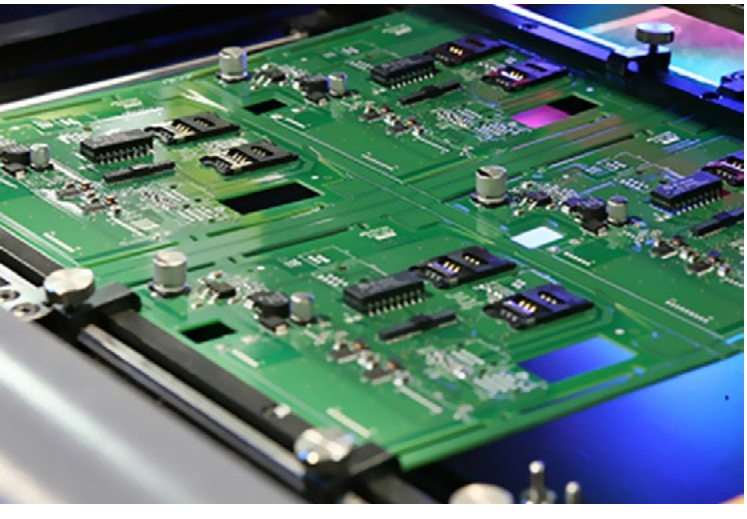
The medical market's drive for smaller, complex and advanced electronics has increased

the overall risk and opportunities for error for electronics manufacturers. As a result, requirements for risk management, design control and traceability has driven manufacturers to evolve from traditional new product introduction (NPI) practices, procedures and manufacturing methodologies typically employed in the electronics industry to meet the challenge.

Medical component level traceability has driven the need for enhancements to both business systems and manufacturing execution systems, including how we communicate and integrate production equipment to facilitate data sharing and collection. Improvements in data exchange standards and adoption from equipment and software providers have helped provide a more seamless traceability system and less reliance on paper driven data collection.

The criticality of risk assessment and controls requires the electronics industry to look at medical products with a more holistic approach to analyzing not just the assembly but also the design, components and processes. As a result, tighter collaboration between the designer and the manufacturer are required for success.

Similarly, control plans for highly complex products and assemblies require more capable and intelligent equipment and test strategies. Manufacturers have been focusing on more real-time feedback through integration and by implementing higher coverage test strategies through advanced test methods to provide a more complete end-to-end validation solution.



We have seen the electronics industry embrace the challenges presented by the medical market through a higher level of design collaboration than previously seen, better and more capable assembly tools and traceability capabilities and tighter closed loop controls. All in all, providing a more complete and robust risk management plan in step with advances in medical technology.

***Las Marias:** How has the medical electronics industry evolved over the past five to 10 years, and what major changes have you witnessed?*

Morrison: Over the past number of years, we have seen a higher focus on wearables, nanotechnologies and an increased use of leading edge technologies which, for reliability reasons, were not commonly found in medical electronics.

This shift has placed requirements on manufacturers and designers alike to have a better understanding of the capabilities and limitations of both the design itself and the manufacturing process to ensure both the design and production are capable of achieving a reliable product.

Supplier collaboration has shifted from a best practice to a mandatory requirement and is a key differentiator for new OEMs seeking an EMS partner.

***Las Marias:** From an EMS standpoint, what are the biggest challenges when it comes to medical electronics manufacturing?*

Morrison: The biggest challenge in medical electronics manufacturing is in the development of the risk management plan and the subsequent controls and traceability to support that plan. Commonly, the manufacturer is engaged after the design is complete and the EMS is tasked to develop control plans to address risk as a result of non-optimal component selection, assembly requirements and test strategy coverage gaps which can result in an overly complex and costly plan which may be avoidable.

In cases where critical components or aspects of the design are sub-contracted the EMS

inherits the risk associated with these components which further complicates the risk management plan.

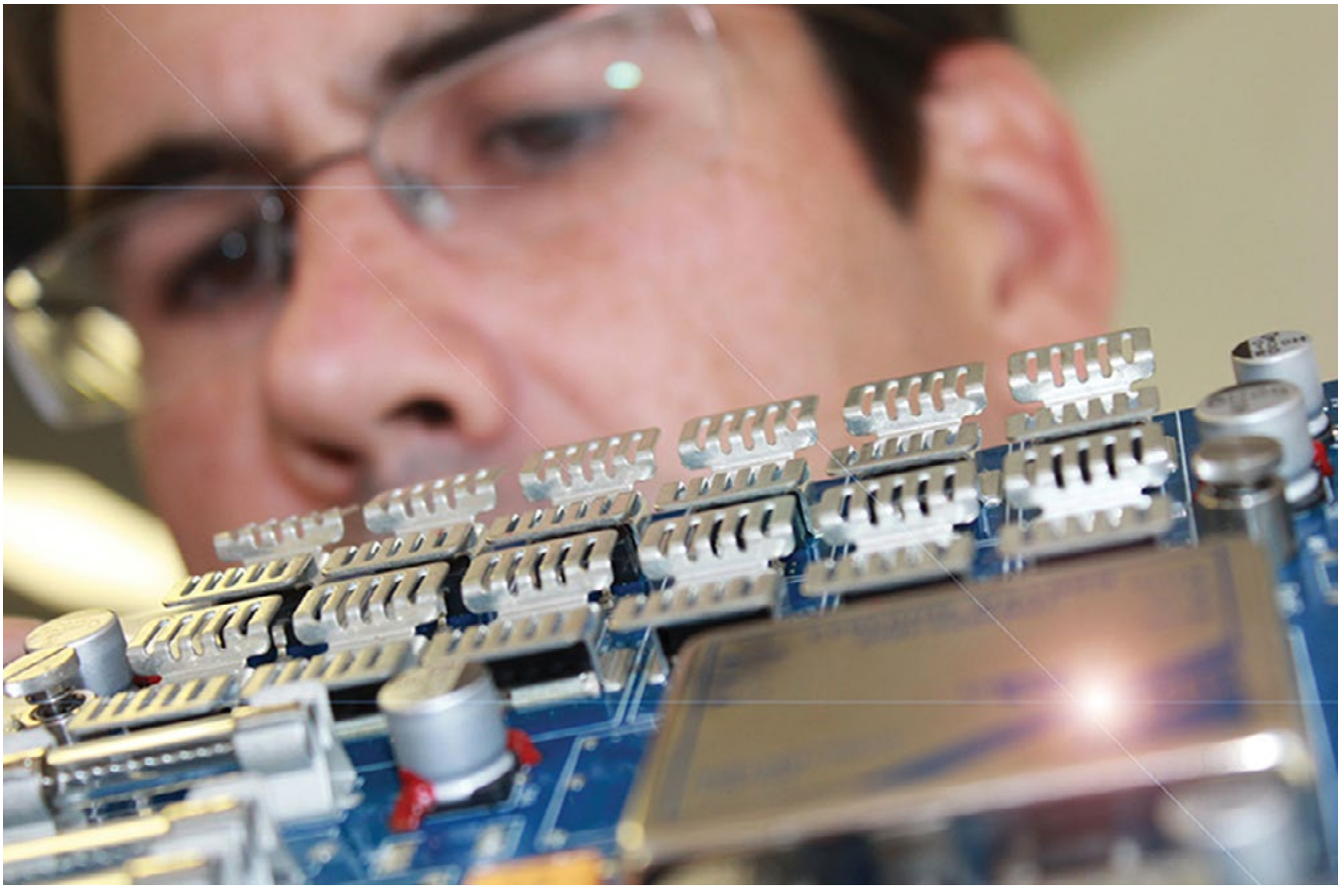
A substantial portion of the risk has already been designed into the product before the EMS has seen the design and as a result the control plan may require additional test/inspection steps, which may have been avoidable if these risks were identified and addressed earlier in the development life cycle.

***Las Marias:** How do you get to become an approved or qualified supplier or manufacturer for medical electronics?*

Morrison: Compliance with ISO 13485 is often seen as the first step to becoming an approved or qualified supplier or manufacturer for medical electronics. ISO 9001 is generally harmonized with ISO 13485, but the primary differences are as follows:

- Regulatory requirements are promoted as a management responsibility
- Demonstrated controls in the work environment must be in place to ensure product safety through employee training, manufacturing area policies and procedures, records including handling of material, product and tooling
- Specific processes and procedures with a focus on risk management activities and design control activities during product process development, including risk management and control plans
- Specific requirements for inspection and traceability of components with an emphasis on critical components or aspects of the device including product serialization, label control and material lot control
- Specific requirements for documentation and validation of processes including equipment/tool qualification, operating qualification of process operating procedures and methodology and performance qualification demonstrating capability and expected result
- Specific requirements for verification of the effectiveness of corrective and preventive actions

Quality management systems were audited by third-party certification bodies with demonstrated medical product risk management activities and control plans including documented validation plans to support compliance with our processes and procedures. To support traceability, supplier procurement practices were updated to require lot codes from our suppliers, including full lot control from incoming through to shipment utilizing 21 CFR Part 820 certified serialization and manufacturing execution systems supporting integrated traceability records.



All employees were trained on the requirements and procedures, and internal audits performed to ensure organization compliance.

***Las Marias:** Are there regulatory standards/compliance issues you have to comply with?*

Morrison: ISO 13485, Food and Drug Administration (FDA) 21 CFR Part 820 Quality System Regulation and Medical Device Directive 93/42/EEC (European Union) are the primary standards we comply with.

***Las Marias:** Among the many challenges today when it comes to electronics products are reliability, complexity and sophistication, more so with the medical electronics market, while meeting the many regulatory requirements in the sector. Please give your comments here. What strategies do you have in place to address these challenges?*

Morrison: Medical electronic product is becoming increasingly complex due to the increasing complexity of electronic circuits; power requirements; introduction of new component and material technologies; and the introduction of less robust components.

To meet these challenges, as an EMS partner to our customers, we collaboratively work with our customers to perform design reviews at key stages throughout the design cycle. This early supplier engagement provides critical feedback to address potential issues to ensure a successful new product introduction and high-quality, high-yielding, reliable and manufacturable product.

About 80% of the design cost and risk decisions are made during the first 20% of the development cycle. Strategies including DFX (Design for Excellence) and leveraging our technical services group to develop solutions and alternates have mutually benefited both our customers—by providing a higher quality product—and SMTC, in producing a more robust and repeatable manufacturing process.

***Las Marias:** What are the biggest requirements for your medical electronics customers?*

Morrison: Regulatory standard compliance, traceability, controls and established risk management and quality management processes are paramount for our customers. To support this, we provide our customers with complete end-to-end risk management plans that are demonstrated through computer integrated manufacturing control from incoming through to shipment.

Our ability to produce a compliant medical product of high quality and reliability at the end of the day is why medical customers outsource, and this is where we exceed.

***Las Marias:** What are the top opportunities in the medical electronics EMS sectors? What markets are growing the fastest?*

Morrison: We are seeing increased growth in home or remote diagnosis as well a health vital reporting and collection, and the ability for health professionals to effectively read, diagnose, and in some cases treat remotely, has introduced more wearable device and portable electronic device product introductions. With the increased need for connectivity including leveraging the Internet of Things (IoT), location has been less of a barrier for patient access including older technology advances such as wireless pacemakers.

We are also seeing electronics and advanced technologies increasingly being used to support DNA sequencing and new ways of disease detection/treatment, which is driving increasingly smaller electronics and denser devices and requires very small form factors to support this growing area.

Along with these areas, the use of new manufacturing techniques such as 3D printing (additive manufacturing), inclusive of metal printing and other nano-materials, has been a growing area especially for implants and related markets.

As an EMS provider, these areas are driving the need for more advanced and connected electronics and new opportunities to continue to grow our medical manufacturing sector.

***Las Marias:** What do you see as the biggest driver of medical electronics innovation?*

Morrison: Advances in connectivity (IoT), manufacturing techniques (3D printing) and nanotechnology (materials and technology) are the biggest drivers in medical electronics innovation. These advances have opened new ways to communicate, interact and treat patients, which has been embraced by the medical industry, and as a result, we are seeing more and more electronic devices taking advantages of these innovations.

***Las Marias:** Please highlight some of the best practices that help medical electronics customers select the appropriate contract manufacturer for their applications/products.*

Morrison: When selecting an EMS partner for their manufacturing needs, it is important to select a partner that complements the medical customer's core competences, market space, regional requirements and manufacturing needs. Picking a partner that is matched to the product characteristics and requirements should be taken into consideration, a higher complexity system with low volumes may be a different partner than a smaller, high volume runner.

Other considerations may include manufacturing and industrialization expertise; end-to-end service solutions that complement their product requirements; a collaborative partner that can provide value to the organization through value add services; and quality and regulatory expertise.

***Las Marias:** How do you ensure the reliability of the components in your supply chain? Do you have traceability systems in place?*

Morrison: For reliability, we focus on critical components by narrowing the selection assessment to those of highest risk to the product:

- Sensitivity of the circuit to component performance
- Number of components within the circuit
- Output from the FMEA/FTA

- Past experiences/industry-wide experiences
- Complexity of the component

Critical components such as optoelectronics, low-volume or custom parts, memory devices, parts with mechanical movements (switches, relays, potentiostats, fans), surface-mount ceramic capacitors, electronic modules, power components, fuses, and electrolytic capacitors are considered high risk and involve increased scrutiny and audits to ensure supplier quality, reliability and performance.

All component selections and approvals are managed centrally through our product life cycle management (PLM) system to ensure only approved manufacturer lists (AML) can be procured and is fully integrated into MRP and traceable back to the originating PO. Procurement requirements include lot code issuances at the component level.

To support material traceability, we utilize lot control on all incoming parts and associate manufacturer lot codes to the lot control ID. As material progresses through production, ID are scanned at point of use and associated to product consumption points to complete the product hierarchy. Complete product level traceability is maintained for a minimum of seven years from the date of product manufacture.

***Las Marias:** Where do you see the medical electronics market headed in the next five years?*

Morrison: We believe the development of smarter wearable and portable medical devices will significantly increase over the next five years. Due to the advancement of smaller, faster and more intelligent microprocessors these devices are more portable, compact, lighter in weight and have reduced power consumption. Also the mobilization of medical devices will be a major driving factor for the healthcare industry as the use of medical devices has and will continue to boost the growth of this market and expand beyond hospitals to homecare environments.

***Las Marias:** Thank you, Brian.*

Morrison: Thank you. **SMT**