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Successfully managing change through integrated manufacturing operations management

How Med-Tech companies manage ongoing change will be the key to success

Executive summary

To support the increased rate of innovation, Med-Tech companies must stop chasing defects and instead manage product changes as a set of data instead of documents. To succeed in this changing environment, medical device manufacturers must focus on improved product outcomes while simultaneously supporting shorter innovation cycles driven by closed-loop integrated systems that allow for real-time decision-making based on real intelligence.

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Introduction

This white paper is derived from and based upon primary research on the "Future of Change and Configuration Management in the Med-Tech Industry" conducted by Axendia. Industry executives and professionals in product design and manufacturing know all too well that the only constant is change. Today, as the rate of change for medical device manufacturers is continuously increasing, Med-Tech organizations cannot afford to aim for average.

Simply "throwing medical products over the wall" from engineering and R&D into manufacturing puts time-to-market and product quality at risk. Next-generation medical devices are smart, connected and personalized, with some components being produced using 3D printing technology. This white paper discusses additional challenges affecting the Med-Tech industry, including chasing defects, the cost of recalls and the potential to avoid them by relying on data, not documents.

The traditional medical device market must be prepared for a new kind of competitor[1] that will require companies to innovate faster and more efficiently through the use of closed-loop processes. To support this increased rate of innovation, manufacturers must stop chasing defects and instead manage product changes as a set of data instead of documents. To succeed in this changing environment, Med-Tech organizations must focus on improved product outcomes while simultaneously supporting shorter innovation cycles driven by closed-loop integrated systems that allow for real-time decision making, based on real intelligence.

For the purpose of this white paper, a closed-loop process is a system in which the desired output depends on input and feedback elements. For the Med-Tech Industry, closed-loop processes must start with R&D/ ideation, support manufacturing operations and include post-market surveillance/obsolescence.

The terms "innovators" and "laggards" are also used throughout. Respondents to Axendia's survey who strongly agreed that they have a closed-loop configuration and change management (C&CM) process were categorized as innovators; those who strongly disagreed were categorized as laggards.

See the Definitions section for additional details.

Major changes are ongoing

Current medical device change and configuration management activities are not often managed as global processes. Instead, they are typically implemented to:

- Address a subset of change issues
- Respond to a particular functional area of an organization

This stage-gate process results in a lack of complete visibility throughout the product lifecycle. To be effective, information must be communicated in a collaborative way that will support improved outcomes internally and outside of a company's own walls.

Change management and design controls are not only the foundation of regulatory requirements around the globe; they are paramount to avoiding the often unintended consequence of a change. Axendia's industry research confirms the rate of change is increasing: 59 percent of global survey respondents indicated that their companies will make major product and configuration changes within the next two years. To be successful, a major change towards digitalization of processes is essential, and will enable companies to take advantage of future opportunities for scaling innovation and growth.

Competitive advantages can be achieved across the enterprise and into new geographies that would otherwise be almost impossible to do while relying on paper processes in a data-driven world.

To support the increased rate of change, manufacturers must manage product changes as a set of data. Managing documents is old-fashioned.

Manufacturing operations management (MOM) is a strategic initiative for overseeing, designing and controlling production processes to drive operational excellence, product quality and improved patient outcomes. Considering the increased rate of change, manufacturing execution systems (MES) play a critical role in consistently supporting closed-loop manufacturing processes throughout the product lifecycle, including C&CM. Implementing integrated product lifecycle management (PLM) and MOM solutions that support this approach is a strategic action that is critical to success.

Major changes are ongoing

59% of respondents report that their companies will make MAJOR changes to the product/configuration within two-year timeframe.

65% of respondents report that their companies will make MAJOR changes to the manufacturing process within a two-year timeframe.

Source: Axendia Inc.

Avoiding the cost of a recall

Unfortunately, the great incentive for strategic action is often a warning letter or a recall. However, when faced with a recall companies can't throw enough money at the problem.

Many Med-Tech companies have yet to implement MES because of the difficulty of justifying the return on investment (ROI) and the perceived disruption to the business. These are real concerns that every company struggles to balance when considering an investment in technology. Modern MES systems that are built on industry best practices out-of-the-box can be implemented in a timely manner and scaled across the manufacturing network. Although widely adopted in other regulated industries such as electronics and semiconductor, MES remains a new concept in Med-Tech, an industry plagued by regulatory inertia and one that remains heavily reliant on paper-driven processes.

To gauge the business value of closed-loop processes, it is important to understand the cost of recalls. While medical device manufacturers are focused on bringing innovative high-quality products to market, many organizations are in recall denial, believing that recalls affect other companies, not them.

Unfortunately, the number of recalls is on the rise. Analysis[2] shows a 97% increase in the annual number of medical device recalls for the 10-year period, increasing from 604 recalls in FY 2003 to 1,190 recalls in FY 2012.

Axendia's analysis of published recall data shows that a single major recall could pay for the implementation of closed loop processes and systems.

For example:

- Recall charges at a major orthopedic company exceeded $1.5 billion net of insurance recoveries[3].
- Another company reportedly spent nearly $1 billion on recalled hip implants[4].
- The same company was reported to have reached a $4 billion settlement on hip implant lawsuits[5].
- A major Med-Tech company reported a special pre-tax charge of $400 million to $600 million to cover infusion pump recall costs[6].

Axendia's research shows that the cost of implementing closed-loop C&CM processes and the underlying technologies to support visibility and product quality would be:

- Five to 10 percent of the cost of a recall
- One to two percent of the total litigation costs resulting from a recall

Closing the loop for a competitive advantage.

The implementation of MOM technologies that support closed-loop approaches can be a competitive advantage, with the end goal to continue to improve product quality. As an example, following a consent decree Terumo Cardiovascular invested in a MES solution to error-proof manufacturing and focus the operators on building higher-quality product (as opposed to filling out paper). When the company multiplied work orders per year times pages per work order times data collection points per page, it had close to five million opportunities for error. Even if Terumo's device history record (DHR) accuracy was 99.5 percent, it would still have 24,000 potential errors per year. This translated into 96 opportunities for error, every day.

The new system provided:

- Early detection and prevention of issues with "hard stops"
- Visibility to quickly find and correct root causes
- Real-time data and key performance indicator metrics to drive continuous improvement and consistency across all plants

Terumo's quality system implementation realized business value from its investment:

- Six to 10 percent increase in productivity
- 41 percent reduction in production nonconformance reports (NCRs)
- 58 percent reduction in overall complaints
- 65 percent reduction in workmanship complaints
- 100 percent reduction in documentation errors[7].

The only constant is change

The only constant in organizational life is change. Yet many Med-Tech companies still struggle to manage and more importantly improve upon their C&CM processes. This topic is becoming critical since recalls are on the rise and medical devices are becoming increasingly complex as are supply chains and business and regulatory ecosystems.

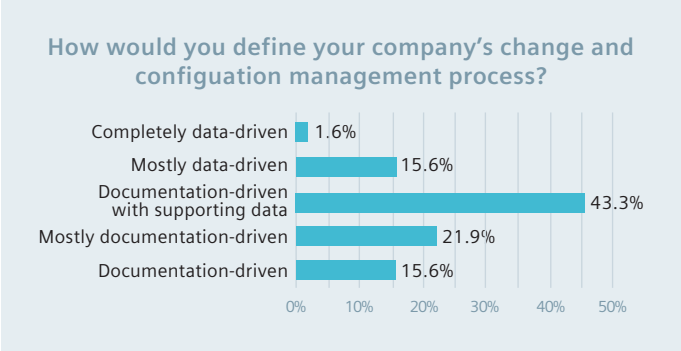
Med-Tech organizations that have implemented closed-loop change, configuration and business process management systems are able to support the acceleration of these complex new product introductions consistently and in a timely, cost-effective and regulatory-compliant manner.

On the other end of the spectrum are organizations who admittedly have no closed-loop process and are most concerned with regulatory compliance over product quality. These organizations operate in a reactive manner by fixing defects as they occur throughout the product lifecycle and are ultimately unable to evaluate the financial impacts.

The inability of companies to effectively manage product and process changes is especially puzzling since they are so fundamental to the success of the business and carry tremendous risk. A total of 63 percent of respondents in a research study conducted by Axendia reported that their change and configuration management process was only somewhat effective or useless. The same study examined the C&CM process across many dimensions including technology, regulatory, organizational and global implications.

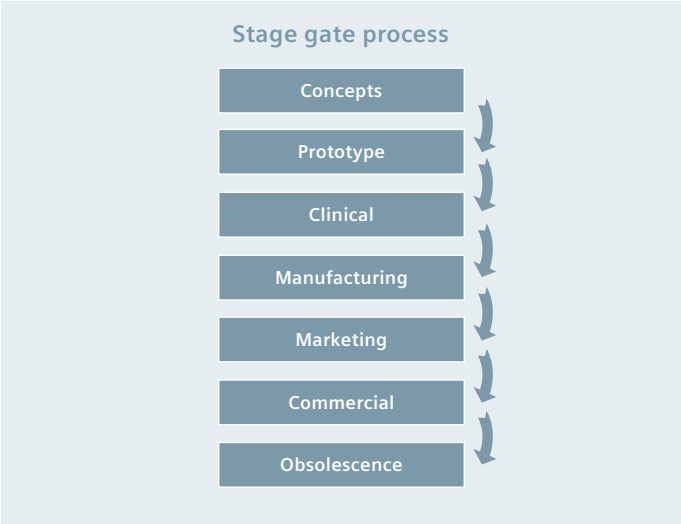
Data rich, intelligence poor (DRIP)

Effective closed-loop processes require cross-functional team collaboration, enterprise-wide visibility and a shift in siloed functional areas, culture and technology. Integrated PLM and MOM infrastructures support all of the above and enable intelligence to be gleaned from data. Yet, the Med-Tech industry is obsessed with collecting vast amounts of data, retaining and hoarding it to meet statutory and regulatory requirements. Unfortunately, most companies do not harness this data to produce better quality products. As a result, companies suffer from DRIP (data rich but intelligence poor).



Source: Axendia Inc.

The industry often collects vast amounts of data using a stage-gate process throughout the product's lifecycle.



Giant mounds of paper (GMPs) are the direct results of documentation-driven processes/systems that are neither connected nor dynamic. Yet, based on Axendia's research, they remain the industry's safety blanket and are still heavily relied upon.

Perhaps industry's obsession with paper is its own worst enemy. Even when organizations want to (or more accurately, are forced to) look at patterns in data to support nonconformances, corrective and preventive actions (CAPAs) or field actions, it is like looking for the proverbial needle in the haystack (or to use a medical device analogy, a contact lens in a swimming pool). Medical technology products can produce very large haystacks, making it even more difficult to find the needle.

For data to have value, the underlying structure must be actively managed. Data must be visible and supported across the entire product lifecycle, from R&D to manufacturing to patient (post market), and back, with a closed feedback loop. Connecting the data drives actionable intelligence and supports closed-loop processes that support continuous improvement.

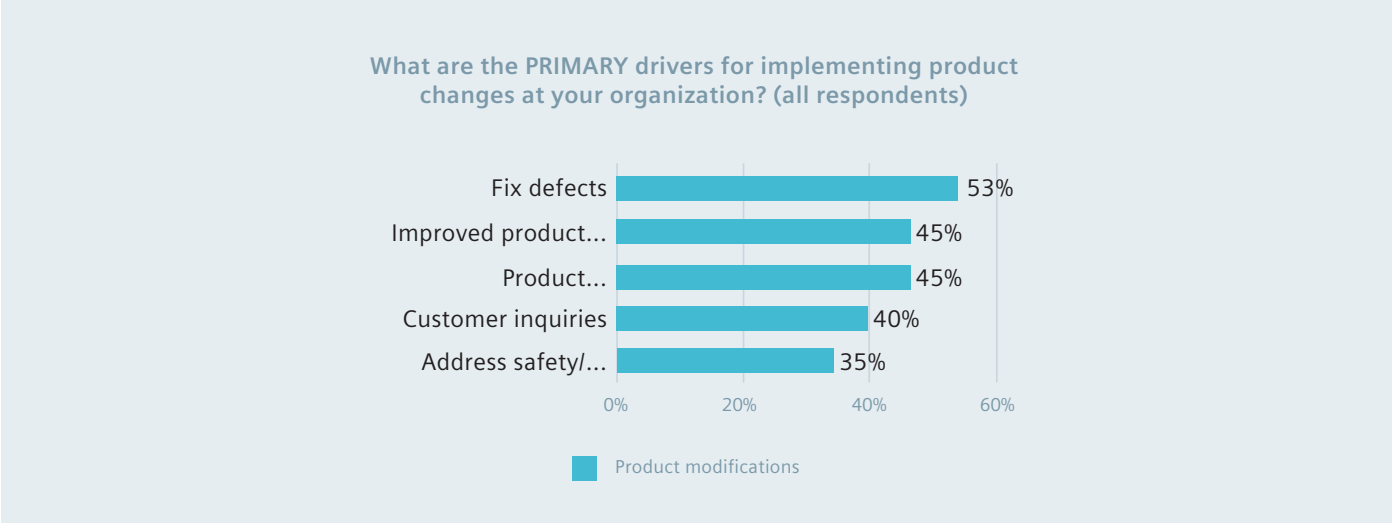
By investing in closed-loop systems and processes, companies will immediately benefit from:

- Shortened product development cycles
- Reduced device lifecycle costs
- Proactively identifying problems before they occur
- Enhanced and consistent product performance
- Real-time decision making based on intelligence

Stop chasing defects

Firefighting is a strong indicator that a company is focused on compliance over quality. This purely reactive approach has had the unintended consequence of creating disincentives for medical device manufacturers to innovate on device quality and has resulted in the industry's "if it isn't broke, don't fix it" attitude to addressing issues. This is supported by the fact that the majority of respondents (53 percent) reported "Fix defects" as the primary driver for implementing product changes.

Without a MOM strategy and technologies to support visibility across the enterprise and continuous improvement initiatives, companies risk not knowing what they don't know, and will continue to firefight and chase defects.



Source: Axendia Inc.

MES supports the total product lifecycle

In addition to avoiding quality and regulatory issues, the shifting business and regulatory landscapes call for closed-loop product management strategies across the connected enterprise. These strategies enable Med-Tech companies to keep up with the increasing innovation tempo and the complexity of medical devices while at the same time:

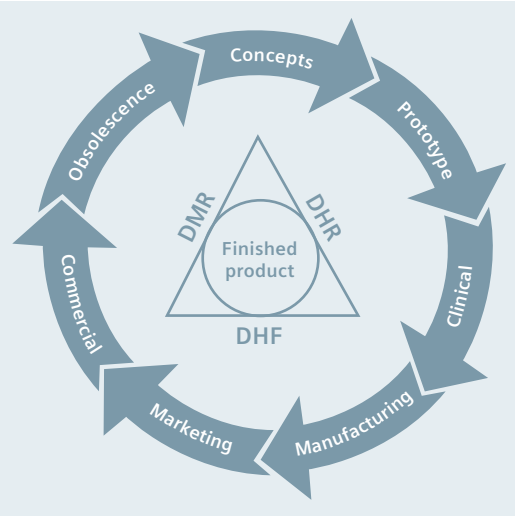
- Lowering cost
- Increasing quality
- Supporting compliance with global regulatory requirements

Closed-loop processes also align well with regulatory frameworks including the total product lifecycle (TPLC) and can drive accelerated innovation. It is important to keep in mind that this process is a collaborative and concurrent approach that enables medical device manufacturers to leverage product information for better decision-making, thus yielding more effective, higher-quality, and safer medical devices.

A closed-loop process supported by an integrated PLM and MES infrastructure pulls data across the product lifecycle including the design history file, design master record (DMR) and the device history record (DHR). The approach achieves improved product outcomes while simultaneously supporting shorter innovation cycles that are driven by closed-loop integrated systems.

Analyzing the responses by innovators and laggards to questions in Axendia's survey provides valuable insight concerning how effective and helpful closed-loop C&CM processes are to their businesses compared to open-loop systems.

When questioned about their company's approach to design transfer, nearly 63 percent of laggards who admittedly did not have a closed system, say they use a "throw-it-over-the-wall" approach to design transfer most of the time, compared to innovators, who indicated they have a closed-loop system and only use a "throw-it-over-the-wall" approach 20 percent or some of the time.



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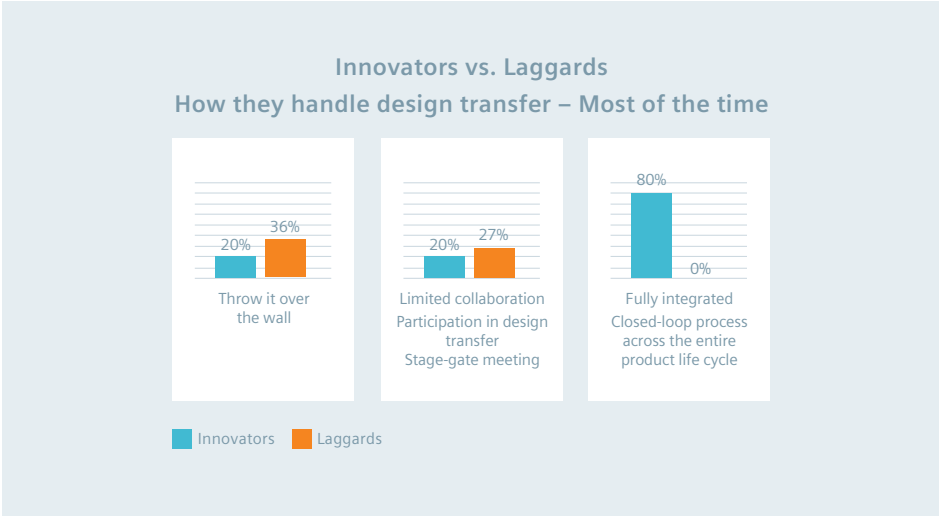


Source: Axendia Inc.

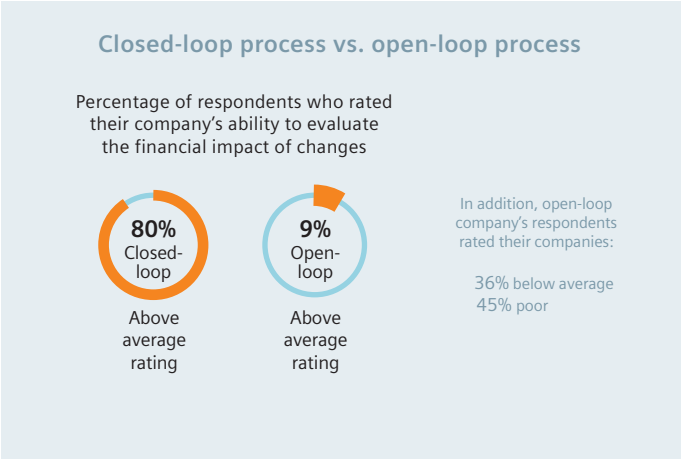
Can you afford to aim for average?

A primary concern of any business is to understand the financial impact of C&CM decisions. This is especially critical when evaluating the financial implications of product changes. Although necessary, it is surprisingly difficult for the companies surveyed to evaluate the financial impact of changes.

Only two percent of the respondents rated their ability to evaluate the financial impact of changes as excellent, compared to 10 percent assessing it as poor, with the majority of companies rating their ability to evaluate financial impact as average.

Evaluating the financial impact of changes becomes critical as healthcare models shift from fee-for-service to outcome-based models. In this new model, providers are rewarded for keeping patients healthy and out of the hospital, as well as improving overall quality of care and patient outcomes, instead being paid for episodes of care.

As a result, understanding the financial implication of implementing changes and improvements to medical devices becomes a core competitive advantage. Data gleaned from integrated MOM and PLM infrastructures is critical in evaluating the impact of changes and supporting outcome-based models



Source: Axendia Inc.

Effective C&CM strategies

Effectiveness is defined as the power to produce a desired result. For businesses to be successful, all processes supporting the product lifecycle must be effective at producing desired results.

To become more effective at producing the desired results, Med-Tech companies must gain the ability to connect decision loops across the total product lifecycle internally and from outside of their own walls. To this end they must implement strategies, processes and technology that support a harmonized, integrated and closed-loop approach. This will facilitate response to product, supplier and process changes as well as customer inquiries, adverse events and regulatory findings.

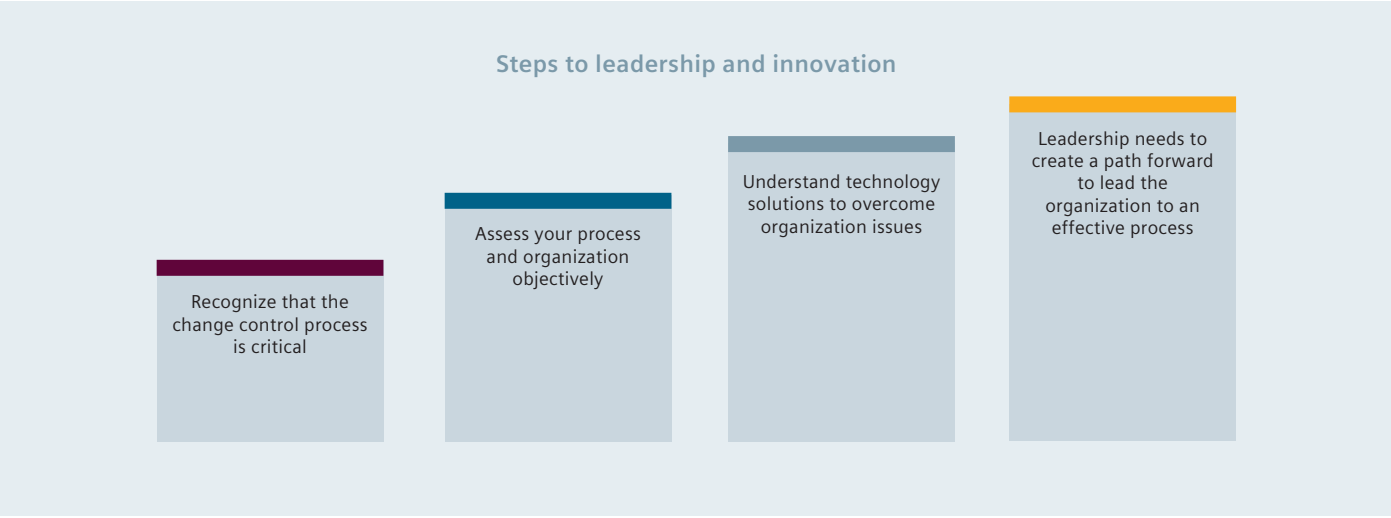
Conclusion

Do not wait for the "great incentive" such as a recall or warning letter to take strategic action. While many Med-Tech companies have difficulty justifying the return on investment (ROI) in closed-loop systems and technology, when they are hit with a recall they cannot spend enough money and resources to remediate the situation.

With total visibility throughout the product lifecycle, companies can prevent recalls and reap the benefits that come from a managed, disciplined approach to C&CM. A closed-loop C&CM strategy is a collaborative and concurrent approach that allows medical device manufacturers to leverage information for better decision-making, thus yielding more effective, higher-quality, and safer medical devices.

Improved patient outcomes can be achieved while simultaneously supporting shorter innovation cycles that are driven by closed-loop integrated systems that allow for real-time decision making, based on real intelligence. Implementing integrated PLM and MOM solutions that support this approach is critical to success.

To support this increased rate of innovation, manufacturers must stop chasing defects and instead manage product changes as a set of data instead of documents. Managing documents is archaic. Leadership must create a path forward to lead the organization to an effective, closed-loop and efficient process through the use of technology.



Source: Axendia Inc.

Definitions

Throughout this study and resulting white papers the following definitions were used:

Open-loop system: a system in which the desired output only depends on the input signal.

Closed-loop system: a system in which the desired output depends on the input and the feedback element.

Innovators and laggards: *According to Diffusion of Innovations*[9] innovators are those willing to take risks, have the highest social status, have financial liquidity, are social and have closest contact to scientific sources and interaction with other innovators. By contrast, laggards are the last to adopt an innovation. Laggards show little to no opinion leadership and typically have an aversion to change. Laggards generally tend to be focused on traditions.

To evaluate the impact of closed-loop change and configuration management processes Axendia explored the difference between those survey respondents that "strongly agreed" with the assertion that "we have a closed-loop system for change and configuration" from those who "strongly disagreed" with that assertion. In this distribution, Axendia labeled respondents that strongly agreed they had a closed loop system as innovators and those that strongly disagreed as laggards.

Axendia defines **closed-loop change and configuration management (C&CM)** as a collaborative and concurrent approach that allows medical device manufacturers to leverage information for better decision-making, thus yielding more effective, higher-quality, and safer medical devices.

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Siemens Digital Industries Software

Headquarters
Granite Park One
5800 Granite Parkway
Suite 600
Plano, TX 75024
USA
+1 972 987 3000

Americas
Granite Park One
5800 Granite Parkway
Suite 600
Plano, TX 75024
USA
+1 314 264 8499

Europe
Stephenson House
Sir William Siemens Square
Frimley, Camberley
Surrey, GU16 8QD
+44 (0) 1276 413200

Asia-Pacific
Unit 901-902, 9/F
Tower B, Manulife Financial Centre
223-231 Wai Yip Street, Kwun Tong
Kowloon, Hong Kong
+852 2230 3333

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