SIEMENS
Ingenuity for life

Siemens Digital Industries Software

What digital transformation means for medical device manufacturers

Smart innovative products require smart integrated systems

Executive summary

This white paper outlines the need for medical device manufacturers to evolve their business practices by transitioning from paper-based processes to digital in three main areas: business, technology and regulatory. To achieve success in today's environment, organizations must commit to adopting innovative approaches to facilitate the development of next-generation medical technology (med-tech) manufacturing.

Contents

Introduction

Question: What does digital transformation mean for medical device manufacturers?

Answer: An opportunity to do the one thing many companies like to talk about, but few do successfully: change!

The convergence of traditional medical devices with high-tech consumer electronics is creating smarter, customizable and connected products that are more complex to design, source, manufacture and maintain. This is happening during the Innovation Age when advanced technology is more prevalent in our personal lives than at work, and more than 50 percent of the world's population has access to information via the cloud. To keep up in the Innovation Age, medical device manufacturers must change.

Innovation and digital transformation in regulated environments presents unique challenges and opportunities for an industry buried under giant mounds of paper. However, new technologies do not change the fact that patient safety, device quality and effectiveness are still top priorities for the United States Food and Drug Administration (FDA).

In fact, regulators have taken note of this trend: "One device manufacturer can meet FDA requirements and still make a poor quality device, whereas a second manufacturer may not comply with all FDA requirements and yet make a high-quality device," comments Dr. Jeffrey Shuren, director of the FDA Center for Devices and Radiological Health (CDRH). The changing business, regulatory and technology landscapes are challenges that medical device executives must address to remain compliant and competitive.

As Juergen Linder, general manager of Microsystem Engineering, Inc. (MSEI), points out, "Digital transformation is an evolution, not a revolution." The problem is that many companies confuse digital transformation with digitizing processes and data.

Simply digitizing an inefficient or cumbersome process is not enough. Taking a paper-based form and process and converting it to a digitized version to make it electronic has limited value. This is known as paper on glass; digital transformation is much more than that. It means using digital data to connect systems and leverage automation and data analytics to create intelligence so better informed decisions are made across the organization. Med-tech companies have to embrace a comprehensive information loop rather than just focusing on information silos such as a products or product attributes. They have to look at innovation in a much broader way. Gaining true intelligence means capturing data from each dimension of the design, engineering and manufacturing process, then combining that data, sometimes with other sources of data (some of which may not be owned), and finally storing and running deep analysis. Thinking about innovation in this way means that companies can focus on quality and outcomes and effectively deal with issues using the relevant contextual data from an entire process.

This white paper addresses three areas that require new thinking and innovative approaches for next-generation med-tech manufacturing to take place: business, technology and regulatory. For this change to be successful, organizations must commit to:

- **Running businesses in a proactive rather than a reactive manner:** Companies must develop manufacturing processes and systems as innovative as the products themselves. This requires moving away from paper, their security blanket, and a commitment from executive management

- **Using advancements in technology and platforms rather than relying solely on point solutions to illuminate data from process automation systems:** This can be achieved by integrating core systems, such as enterprise resource planning (ERP), product lifecycle management (PLM), manufacturing execution systems (MES) and quality management systems (QMS), to achieve visibility throughout the enterprise. This approach ensures stakeholders they are not doing the right thing the wrong way

- **Making the necessary adjustments to operate within a changing regulatory framework:** The FDA has made it clear that compliance and quality are not the same thing, and operating within a global ecosystem requires adherence to more than one regulatory body

An evolving business environment

Key business trends:

• The shift from fee-for-service to fee-for-value with a renewed focus on patient-outcome-based models

• Smart and connected devices/Internet of Medical Things (IoMT)

• Healthcare is becoming more personal

Med-tech organizations are continuing to sharpen their focus on developing high-quality medical devices aimed at improving patient outcomes in support of value-based care models. This approach results in accelerated innovation volume and velocity that in turn drives increased device complexities. Moreover, shortened innovation cycles also result in more product introductions, changes and configurations, and products become obsolete more quickly.

Since many established med-tech companies have grown through mergers and acquisitions, they have inherited a multitude of manufacturing approaches and individual plant models, as well as the accompanying point solutions, systems and processes. In some companies, divisions or manufacturing facilities are treated like autonomous entities, without a corporate information structure, uniform standards or integrated plants. Shifting from point solutions to integrated platforms reduces opportunities for errors across global manufacturing networks, encourages interpretation of data and allows for intelligence-based decision making.

As medical device manufacturers consider new business models to foster innovation and remain ahead of the disruption curve, they need to be open to new ideas and aware of emerging technology trends.

Recall counts by fiscal year and class

	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Class I	7	24	26	22	26	14	32	49	50	57
Class II	460	467	422	505	540	710	677	753	1,152	1,043
Class III	137	140	124	132	96	108	67	74	69	90
Totals	604	631	572	659	662	832	776	876	1,271	1,190

Source: Food and Drug Administration – Medical devices recall report

Words like innovative, smart, connected and personalized are already being used to describe medical devices today. In order to bring increasingly complex products to market in a globalized and connected ecosystem, it is necessary to have closed-loop design, manufacturing, service and support strategies to ensure superior product quality and support this new norm.

A closed-loop strategy is a collaborative and concurrent approach that allows medical device manufacturers to leverage information from ERP, MES, PLM and QMS systems. This approach achieves improved control of the manufacturing process, resulting in high-quality devices while simultaneously supporting shorter innovation cycles. The ability to turn vast amounts of available data into actionable intelligence, which in turn has the potential to create business value while supporting compliance with regulatory requirements, needs to be the driver to implement a closed-loop system.

To gauge the business value of closed-loop processes and platforms, it is important to understand the cost of recalls. Although 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. The graphic above shows a 97 percent increase in the annual number of medical device recalls for the 10-year period, increasing from 604 recalls in fiscal year (FY) 2003 to 1,190 recalls in FY 2012.

Axendia, a life sciences and healthcare analyst and strategic advisor firm, has analyzed published recall data shows that a single major recall could pay for the implementation of closed-loop processes and systems for much of the med-tech industry.

For example:

• Recall charges at a major orthopedic company exceeded $1.5 billion net of insurance recoveries[1]

• Another company reportedly spent nearly $1 billion on recalled hip implants[2]

• The same company was reported to have reached a $4 billion settlement on hip implant lawsuits

• A major med-tech company reported a special pretax charge of $400 million to $600 million to cover infusion pump recall costs[3]

Extending productivity
Executives are beginning to focus on strategic, digital transformation initiatives in support of manufacturing operations management (MOM), which will enable them to:

• Lower costs and increase quality by improving production process efficiencies

• Facilitate compliance with regulatory requirements

• Speed innovation and time-to-market

It is possible to lower costs, not by doing more with fewer resources, but doing more with the same. Linder states, "About half of MSEI's employees work in manufacturing. If I compare this to 15 years ago, we have the same number of people and today we are making four times the number of products."

Digital transformation in manufacturing requires a cultural metamorphosis

For this transformation to be successful, cultural, behavioral and technical barriers between functional areas must first be eliminated. Achieving this cultural shift requires buy-in and commitment from executive management to allocate resources, encourage collaboration and provide an environment conducive to this evolution, as well as buy-in and commitment from the shop floor. What is needed are new roles for key resources, who would now own the entire product lifecycle, not just the typical individual phases:
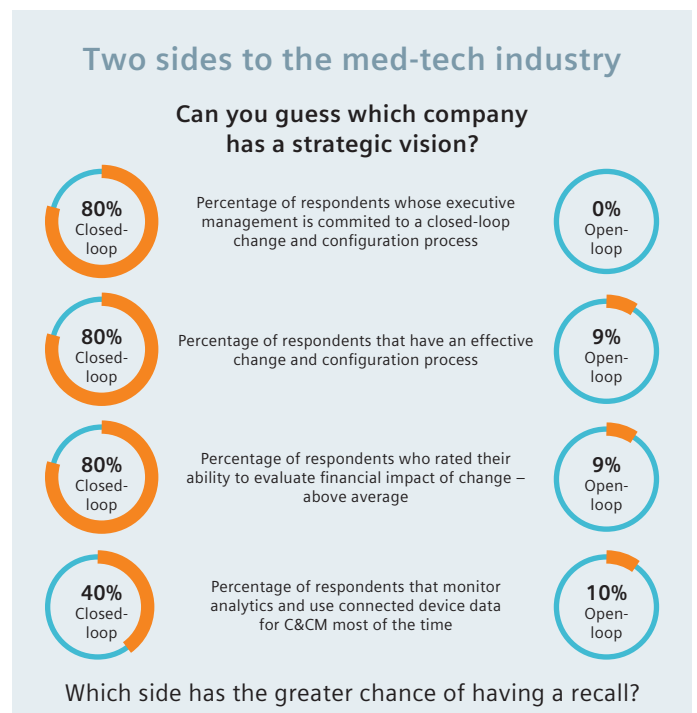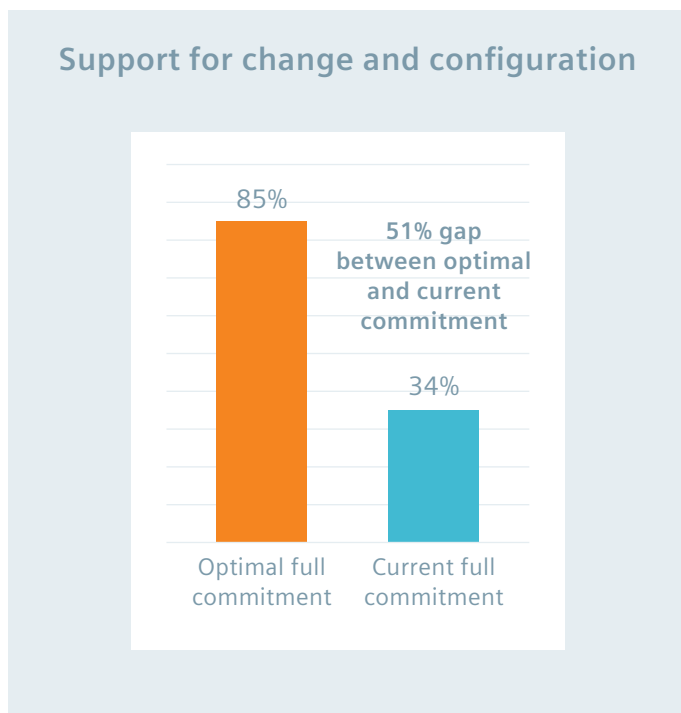
- Research and development (R&D)
- Quality
- Manufacturing
- Supply chain
- Regulatory
- Sales and marketing
- Field use
- Service, support and maintenance

In a survey about the future of change and configuration management (C&CM) in the medical devices

industry (the results of which are collected in a series of five white papers), Axendia shows that most companies are facing a commitment gap. They asked what the current versus optimal commitment level is from executive management in this critical piece of PLM.

Collaboration across functional areas throughout the organization and support from executive management are critical in digital transformation. Today's challenge is not the availability of the right technology, but rather the need for vision and leadership, know-how and discipline to drive digital transformation. Otherwise, companies will end up with paper on glass, for example, digitizing current (inefficient) processes.

Yet companies remain obsessed with paper. In the above referenced closed-loop C&CM survey, a total of 83 percent of respondents revealed they rely on static documentation in some form or another to support their processes. By contrast, only 17 percent responded that processes are mostly or completely data driven. The select few who see the value in closed-loop processes have gained a competitive edge by substantially reducing their risk of having a product recall.

Support for change and configuration

85%

51% gap between optimal and current commitment

34%

Optimal full commitment | Current full commitment

Two sides to the med-tech industry

Can you guess which company has a strategic vision?

80% Closed-loop	Percentage of respondents whose executive management is commited to a closed-loop change and configuration process	**0%** Open-loop
80% Closed-loop	Percentage of respondents that have an effective change and configuration process	**9%** Open-loop
80% Closed-loop	Percentage of respondents who rated their ability to evaluate financial impact of change – above average	**9%** Open-loop
40% Closed-loop	Percentage of respondents that monitor analytics and use connected device data for C&CM most of the time	**10%** Open-loop

Which side has the greater chance of having a recall?

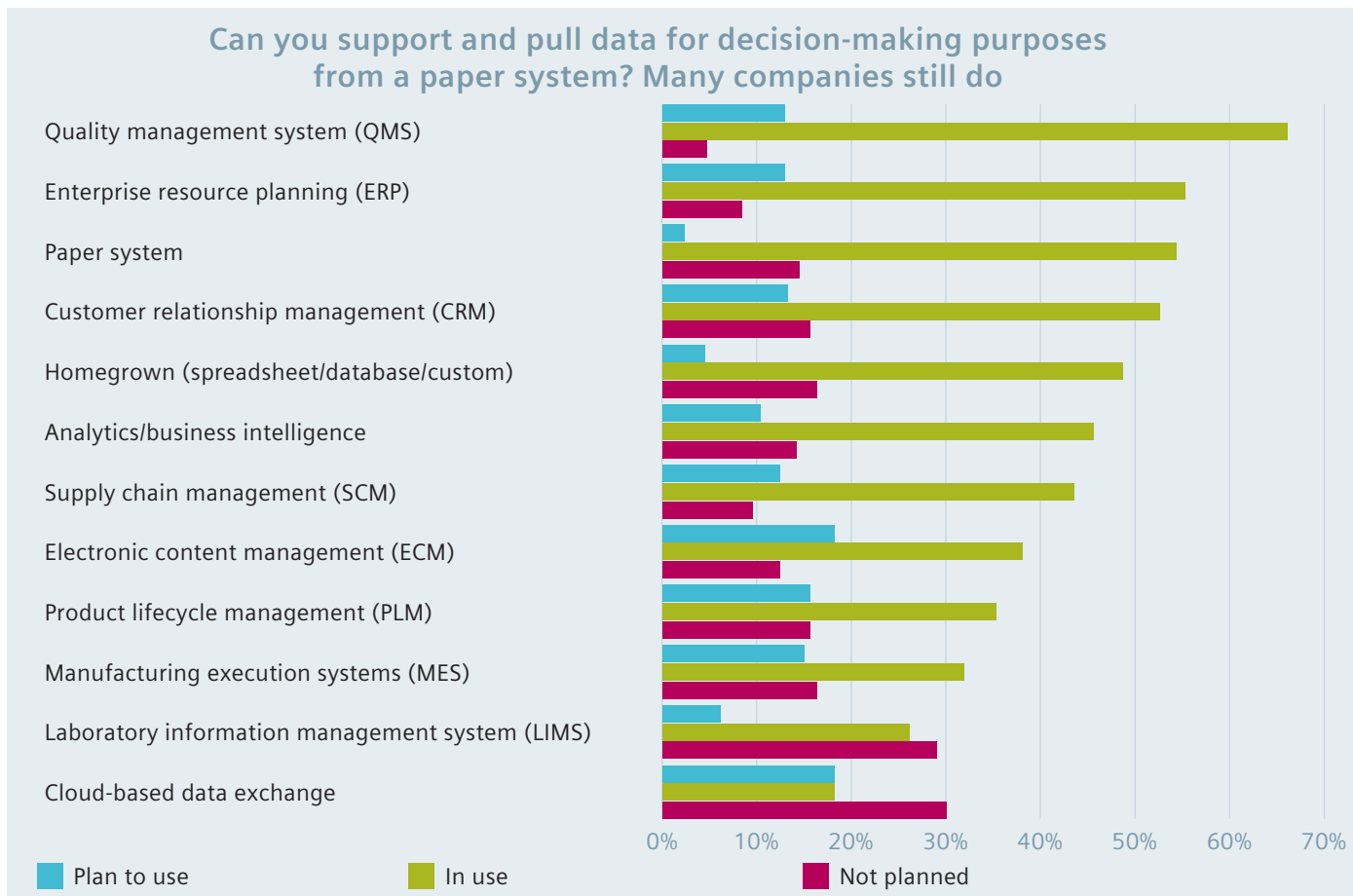Source: Axendia Inc.

Technology

Digital transformation initiatives rely on people, processes, technology and data – actionable, intelligent, reliable data

The FDA defines data as raw measurements of some thing or process. By itself data is meaningless; only when critical context is added about what is being measured and how it is being measured does it become information. That information can then be analyzed and combined to yield evidence, which in turn can be used to guide decision making.

The challenge is that most companies have lots of meaningless data. Generally, the quantity of the data is not the issue, but the value of the data output is. Unfortunately, many medical device companies suffer from DRIP.[4]

DATA

RICH

INTELLIGENCE

POOR

Many medical device manufacturing companies collect mounds of data in paper batch records, spreadsheets and PDF reports from point solutions. Unfortunately, most of the data collected is unstructured, rendering it useless as soon as it hits the paper it was printed on, or electronic document (scanned paper) it was saved as.
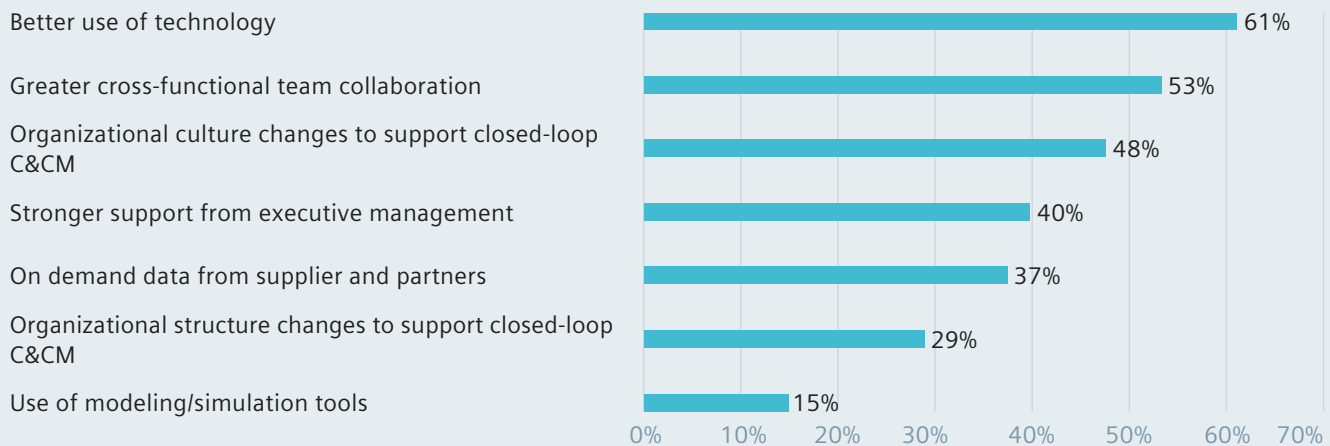
Can you support and pull data for decision-making purposes from a paper system? Many companies still do

Legend: ■ Plan to use   ■ In use   ■ Not planned

Categories (top to bottom): Quality management system (QMS), Enterprise resource planning (ERP), Paper system, Customer relationship management (CRM), Homegrown (spreadsheet/database/custom), Analytics/business intelligence, Supply chain management (SCM), Electronic content management (ECM), Product lifecycle management (PLM), Manufacturing execution systems (MES), Laboratory information management system (LIMS), Cloud-based data exchange

Axis: 0% 10% 20% 30% 40% 50% 60% 70%

Smart products require smart manufacturing systems

A platform approach to MOM is critical to support the next generation of smart med-tech innovations. Harnessing manufacturing intelligence to improve efficiency and product quality, enhance process yields, avoid recalls and address regulatory inquiries by assimilating functionality from multiple standalone systems could deliver continuous feedback to provide issue resolution to both products and processes in minutes versus days. The intelligence gleaned allows decisions to be made that will have the highest probability of success and in a timely manner.

What can help you improve C&CM?

Better use of technology	61%
Greater cross-functional team collaboration	53%
Organizational culture changes to support closed-loop C&CM	48%
Stronger support from executive management	40%
On demand data from supplier and partners	37%
Organizational structure changes to support closed-loop C&CM	29%
Use of modeling/simulation tools	15%

0% 10% 20% 30% 40% 50% 60% 70%

Source: Axendia Inc.

Is better use of technology the answer? According to 61 percent of respondents in a recent Axendia survey, it is. Learn more about that in: "Drowning in Meaningless Data, Time to Fix the Drip!"

The Digital thread

Smart manufacturing is defined as systems that integrate manufacturing intelligence in real-time across an entire production operation. Weaving a digital thread through data sources and throughout the product lifecycle encourages continuous collaboration, innovation and improvements. In order to make this shift to manufacturing intelligence:

• Data must be traced and analyzed seamlessly across global manufacturing networks

• Product and process changes must be managed and traced through the integration of ERP, MES, PLM and QMS

• Information must be traded between suppliers, resources and regulatory

This provides the opportunity to develop predictive and prescriptive models of products and processes to support intelligence-based decision-making.

Medical device companies have vast amounts of data amassed by a multitude of disparate systems, including ERP, system control and data acquisition (SCADA), MES, PLM, QMS, laboratory information management system (LIMS) and clinical trial management system (CTMS), etc. Soon additional data will be amassed by the devices themselves. So the issue isn't collecting data, but collecting usable data. If a company does not have the right structure to collect data and rework it into valuable information, it will be a meaningless exercise.

Axendia's survey on the future of MES revealed what most medical device companies want from next-generation

systems. Using MES as an example, what companies desire and consider priorities at times does not align with how some vendors are communicating their offerings. When Axendia asked brand owners to pick the top three requirements for a next-generation MES, they were:

• Support for predictive maintenance
• Global visibility into supplier networks
• Manufacturing optimization

Software vendors answered this same question and chose:

• Support for the Internet of Things (IoT)
• Cloud platforms, mobile/connectivity
• Serialization

However, priorities are more aligned than they first appear. Medical device companies indicated what they want and need can be achieved through the IoT, cloud platforms, mobility and connectivity in support of smart manufacturing. The requirements and needs of both groups intersect within the digital enterprise and are byproducts of a data-driven, smart and connected digital enterprise.
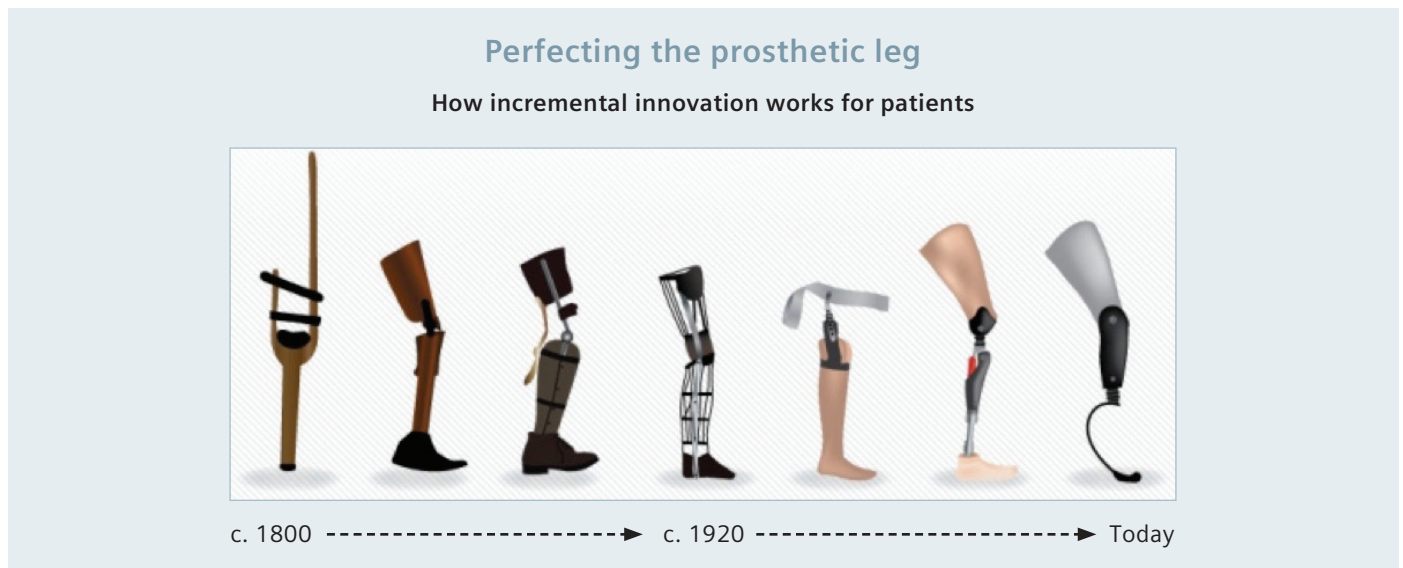
Getting personal
The automotive industry would not attempt to manufacture and assemble an electric car in a 1985 automotive plant. Yet many medical device manufacturers are relying on aging facilities, systems and paper-based processes to source and produce current-day, innovative products.

Supporting personalized products
Devices that were previously mass produced are becoming personalized. The challenge to industry is that personalized products cannot be manufactured using existing/current mass production processes.

Example: Perfecting the prosthetic leg.

Perfecting the prosthetic leg
How incremental innovation works for patients

c. 1800 - - - - - - - - - - - - - - - - - - - ▶ c. 1920 - ▶ Today

Linder points out, "Deploying systems in an affordable way requires doing it the right way the first time. It requires work upfront but organizations can reap the rewards in the end." Read the case study entitled, "Micro Systems Engineering: Medical device manufacturer uses Camstar Medical Device Suite to enable agile business processes and continuous growth."

Regulatory

Compliance doesn't equal quality
Medical device companies should be driving quality and innovation with less of an emphasis on merely achieving regulatory compliance. Quality and compliance are not the same yet they are often used interchangeably. Consider the sports analogy below:

- Following the rules (compliance) does not guarantee improved team performance (quality)

- Teams cannot make the proper adjustments without looking at all of the performance data

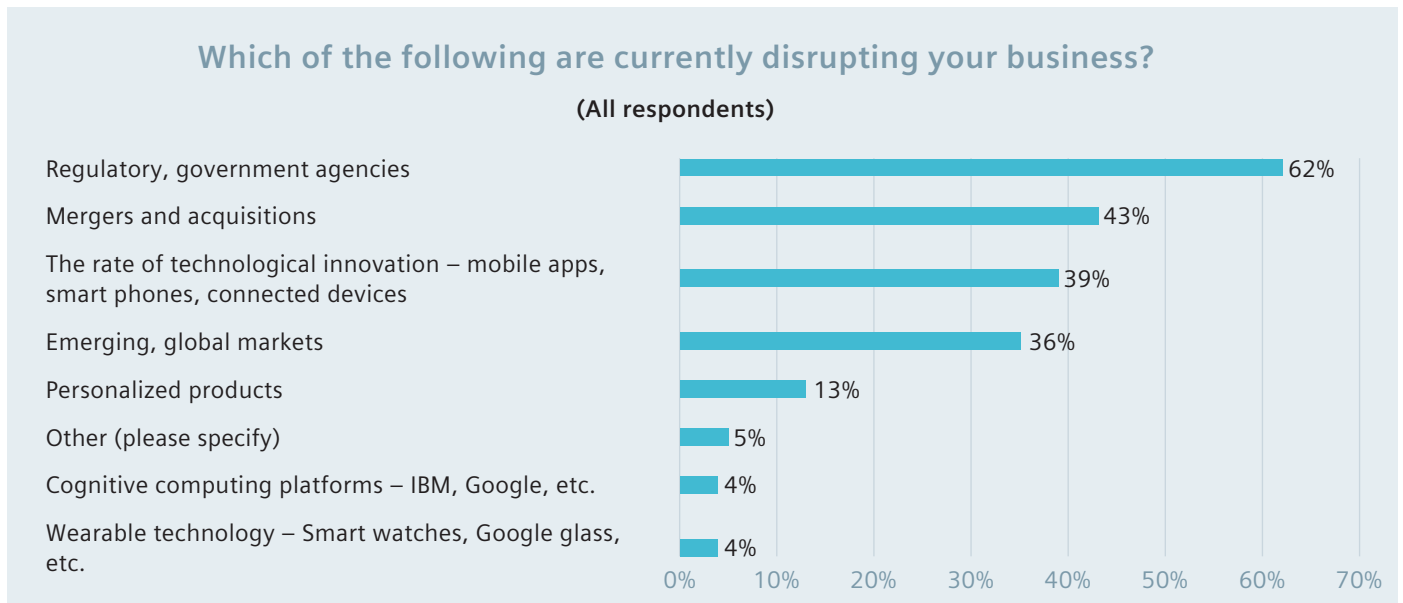- It is extremely difficult to achieve a win by only avoiding penalties

According to a recent Axendia survey on the future of C&CM in med-tech, a majority consider regulatory audits and inspections to be disruptive and burdensome to a manufacturing facility. The FDA is hoping to change that experience by incentivizing companies to show their commitment to quality and avoid being audited as often.

" We want to encourage firms to prioritize quality and to encourage their boardrooms and their pocketbooks because quality costs money."

Howard Sklamberg
Commissioner, Global Regulatory Operations and Policy
United States Food and Drug Administration

" One device manufacturer can meet FDA requirements and still make a poor quality device; whereas a second manufacturer may not comply with all FDA requirements and yet make a high-quality device."

Dr. Jeffrey Shuren
Director, Center for Devices and Radiological Health
United States Food and Drug Administration

Which of the following are currently disrupting your business?

(All respondents)

Regulatory, government agencies	62%
Mergers and acquisitions	43%
The rate of technological innovation – mobile apps, smart phones, connected devices	39%
Emerging, global markets	36%
Personalized products	13%
Other (please specify)	5%
Cognitive computing platforms – IBM, Google, etc.	4%
Wearable technology – Smart watches, Google glass, etc.	4%

0%   10%   20%   30%   40%   50%   60%   70%

Source: "Future of change and configuration management survey," Axendia Inc., December 2015.

A key Food and Drug Administration Safety and Innovation Act (FDASIA) provision is the ability to conduct electronic inspections and target onsite inspection based on metrics. By shifting to a metrics-based approach, the agency seeks to encourage industry to implement state-of-the-art, innovative systems that drive industry to focus on improving product quality through actionable intelligence, rather than simply ensuring compliance to regulatory requirements. While paper systems are still prevalent in our industry, the requirement to submit metrics annually in electronic format, per FDA's draft guidance, makes the use of paper systems unmanageable.

To support electronic inspections, most life-science companies will be forced to discontinue the use of paper batch records in favor of electronic batch record systems and MES. Integration with complementary systems like ERP, PLM and QMS will play a key role in achieving a single source of truth to support quality metrics reporting.

Case for quality

The FDA's case for quality (CfQ) initiative goals are to provide stakeholders with understandable and objective information about medical device quality; facilitate medical device innovation and quality through data and analysis on device performance; and foster strategies that focus stakeholder interactions on device quality.

In today's complex manufacturing processes, med-tech executives must balance a multitude of divergent interests and concerns. At the end of the day, the safety, quality, efficacy and/or effectiveness of each product must take precedence.

More information on CfQ is available on the FDA website.

Conclusion

"When you can measure what you are speaking about, and express it in numbers, you know something about it; but when you cannot measure it, when you cannot express it in numbers, your knowledge is of a meager and unsatisfactory kind; it may be the beginning of knowledge, but you have scarcely, in your thoughts, advanced to the stage of science, whatever the matter may be," said William Thompson, mathematical physicist, 133 years ago.

Today this quest is about harnessing these numbers and data into knowledge through digital transformation.

So what does digital transformation, or digitalization mean for medical device manufacturers?

This evolution is a huge opportunity to transform MOM to support the convergence of traditional medical devices with high-tech consumer electronics, providing the ability to manufacture smarter, customizable and connected products that are more complex to design, source, manufacture and maintain.

To this end, medical device manufacturers must overcome regulatory inertia and leapfrog manufacturing to the 21st Century by transitioning from paper systems to smart MOM systems and using digital transformation to get there. This will minimize opportunities for error, improve quality and reduce costs, while enabling firms to comply with new regulatory requirements.

Compliance and quality are paramount to ensuring the safety and effectiveness of medical devices. Quality must be the driving principle within all medical technology organizations. This drives continuous improvement to enhance the quality of life and health of every patient touched by medical devices.

Definitions

Throughout this white paper the following definitions were used:

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

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

Innovators and laggards: According to *Diffusion of Innovations*[6], innovators are those who are willing to take risks, have the highest social status, have financial liquidity, are social and have the closest contact with 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 as innovators and those that strongly disagreed as laggards.

Axendia defines 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.

References
1. Stryker Corporation, Stryker fact sheet, 2015
2. Feeley, J. and Voreacos, D., "J&J Said to reach $4 billion deal to settle hip lawsuits," Bloomberg Business, 2013
3. Japsen B., "FDA orders recall of Baxter's Colleague infusion pump," Chicago Tribune, 2010
4. McMullin, E., "Unlocking Big Data to Achieve Business Value," Axendia, 2015
5. Thompson, W., Lecture on "Electrical Units of Measurements," 1883
6. Everett, R., "Diffusion of Innovations," fifth edition, Simon and Schuster, 2003, ISBN 978-0-7432-5823-4

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

About Siemens Digital Industries Software
Siemens Digital Industries Software is driving transformation to enable a digital enterprise where engineering, manufacturing and electronics design meet tomorrow. Our solutions help companies of all sizes create and leverage digital twins that provide organizations with new insights, opportunities and levels of automation to drive innovation. For more information on Siemens Digital Industries Software products and services, visit siemens.com/software or follow us on LinkedIn, Twitter, Facebook and Instagram. Siemens Digital Industries Software – Where today meets tomorrow.

About Axendia
Axendia, Inc. is a leading trusted advisor to the life science and healthcare industries, providing counsel to industry stakeholders on business, regulatory and technology issues.
For more information, visit www.axendia.com or contact at info@axendia.com

Acknowledgement:
This whitepaper was co-authored by Sandra K. Rodriguez, Market Analyst at Axendia.

siemens.com/software