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More Bang, Less Buck

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Medical device manufacturers (MDM) want more of everything—accuracy, quality, speed, throughput, ease of use, predictability, reliability, validation and compliance—and software can make all of these better. Software programs (often coupled with automation) optimize the entire production process and maximize communication. Everything happens in real time and, because all the data is recorded and stored, documentation and analysis have never been easier. This also streamlines regulatory approvals, and makes it easier to provide the data that the FDA and other agencies increasingly seek.

An abundance of manufacturing software is available for operational tasks such as production and process monitoring, quality and document management, workflow review, engineering/design, inventory tracking, bar-code labeling, shipping, customer relations management, estimating, quoting, and accounting—all of which reduce cost and increase speed by maximizing efficiency.

Software outside the manufacturing facility is becoming more important for the function of complex and multifunctional medical devices in the end-user environment. “Smart” data-centric medical devices are driven largely by software advancements—not just traditional embedded controls, but also wireless connectivity, mobile applications, and cloud-based data management and analytics systems. These applications continue to evolve at a rapid rate.

“Developing new systems requires not only the ability to adopt the medical domain—for example, genetic screening—but also the potential interoperability of the system in a connected and changing universe,” said Andrew Dallas, president and founder of Full Spectrum Software, a Southborough, Mass.-based provider of software development and testing services. “Some standards, such as Digital Imaging and Communications in Medicine (DICOM) and Health Level Seven International (HL7), make this especially challenging for medical industry products.”

These sophisticated software needs often go beyond the in-house expertise of MDM companies. For example, in the past, MDMs often built their information systems from disparate pieces of software. Now, however, deeper skill sets are required for more functional and more complex products, which are typically outside their core

competencies. Therefore, OEMs rely on contract manufacturing and component suppliers to provide the necessary software expertise—both for their devices and their manufacturing processes.

"As a result, medical device manufacturers require not just programmers, but also software engineers who take a systems approach to solving problems, while considering different interactions and the results of their algorithms, not only within the device but also on end users or patients," said Ankur Tandon, director of engineering for Logic PD, a Minneapolis, Minn.-based complete product lifecycle management company. "The FDA enforces this thought process through strict guidelines and processes. In general, the engineers with that natural-systems thought pattern tend to be more successful in the medical field."

Jason Spera, CEO for Aegis Software, a Horsham, Pa.-based provider of software solutions that optimize manufacturing operations, agreed. "Medical device manufacturing has significant requirements and challenges, not seen to the same degree in most other manufacturing verticals," he said. "For example, these requirements involve fail-safe and interlocked control of the processes themselves, as well as validation that such control was in fact achieved. Further, in specific applications, the software system itself, and the manner in which it is developed, must be validated to certify that it is capable of supporting the product and manufacturing environment."

Perhaps the greatest challenge for product development is the regulatory climate, which is changing quickly as devices become more complex. Software providers must match the pace of that change so new medical devices can meet and/or exceed the regulatory requirements set forth by bodies like the FDA. That's why, when looking at technology, "it is important to ensure the software not only provides a robust level of functionality for the consumer, but also complies with regulatory standards," said Timothy Lozier, director of product strategy at EtQ, a Farmingdale, N.Y.-based provider of quality and operational risk and compliance management software.

Streamlining Production

Because of market trends and regulatory requirements, "MDMs are migrating from a focus almost exclusively on patient outcomes and recordkeeping for compliance toward best manufacturing and supply chain management practices to ensure quality, minimize risk, and lower product costs," said Steve Bieszczat, chief marketing officer for IQMS Manufacturing ERP, a Paso Robles, Calif.-based provider of manufacturing software and enterprise resource planning (ERP) software systems.

Best manufacturing practices cover a lot of territory. For example, control systems are expected to deliver complete validation of the production/assembly processes, materials consumed, process conditions and location at the time of each assembly action, and often, multi-level redundant verification of activities carried out for the

product. Everything that occurred around the product and its process, as well as the materials used, must be recorded for traceability.

Automation is operating at a higher level of sophistication than it was just a few years ago. Software enables the integration of automated production data with statistical process control tools in real time, sending alerts when processes start to trend out of control, before the variation becomes a breakdown.

“Catching a potential problem ahead of a catastrophic equipment failure also helps avoid making bad parts as the machine performance degrades, and the opportunity cost of lost production for the whole time of diagnosis and replacement parts ordering,” stated Bieszczat.

The more automated the monitoring of process and product parameters, the lower the risk of gaps or mistakes in the critical information in quality controls or even in the products being made. It is now possible for contract manufacturers to ensure traceability for each lot in production history records and have 100 percent accurate inventory tracking. Software is also available for integrated error proofing of the work-order setup; verification of the correct label format, prior to each production run, ensures compliance with product labeling regulations.

Spera is surprised that many prospective customers tend to think their requirements can only be met by highly expensive, customized systems that will require a long rollout and result in a system they cannot evolve over time because it has been crafted so specifically to their environment. “They think this way because they are used to the heavy customization that is required to meet the specifications of the devices they have built,” he said. “Our first step is showing them there is another way.”

Software can even be designed to be flexible enough that the business user can make changes to the system—in other words, configurability instead of customization. “When you think of changing software to meet your needs, you probably think development,” said Lozier. “However, software can be designed to provide drag-and-drop graphical tools and simple settings so that the user can update forms, fields, keywords, the phases—even the look and feel—without programming.”

To make it even easier, EtQ has implemented a series of starter kits for specific life-science processes. “There are many processes that we recognize are specific to the medical device industry and we’ve built a series of configurations and best practices that address these needs,” continued Lozier. “This allows our customers to have a stronger foundation of processes, with considerable breadth and depth, which has already been ‘started’ for them.”

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Internet of Things

The Internet of Things (IoT) is the interconnection of devices, in real time, to facilitate data collection, storage, analysis, and improvement actions. An increasing number of medical devices transmit information wirelessly to a server, where it can be shared and evaluated—for example, a physician can see how a device is performing for a patient and adjust as needed. In fact, one of the greatest benefits of IoT is the large amount of data that can be generated and analyzed. This ability is the core strength of "Industry 4.0," a collective term for the in-depth interaction among manufacturing technology/equipment, automation programs, and data exchange and analysis.

"Industry 4.0 is a major topic of research and discussion in manufacturing at present," said Spera. "It allows for the ability to adapt to infinite configure-to-order requests from the business, and make that happen in the factory—automatically."

Single-piece flow, and being able to adapt to it automatically, is a core aspect of Industry 4.0. Aegis, for example, provides a factory framework for high-speed, real-time data acquisition from myriad machines and data sources. It transforms line operators into data sources and data consumers via its shop floor user interface and has an integrated analytics and closed-loop control architecture. "The gap is actually at the asset level of the factory, and getting the assets, such as assembly machines, to subscribe to the data they need to make their own adaptive decisions," said Spera. "This is something that some machine vendors are beginning to explore so we have great optimism for the future of Industry 4.0."

A major concern, however, with the rapid growth of IoT and interconnectivity, is security of the data that is being generated, transmitted, and analyzed. This is especially true for wireless solutions. For example, an insulin pump, pacemaker, patient monitor, or ventilator is subject to the same kind of cyberattacks as a PC or website. "This safety concern requires not only design considerations up front, but also ongoing monitoring and intrusion detection, said Tim Bosch, vice president and chief architect for Foliage, a Burlington, Mass.-based provider of consulting and engineering services for the development of complex software-intensive products. "A good example is the FDA's reaction to Hospira's infusion pump cybersecurity issues."

Because of cybersecurity concerns, many MDMs are wary of using software of unknown provenance (SOUP) in their products; however, it is nearly impossible to develop software that is not dependent upon software (libraries, operating systems, other components) that was written by a developer not directly involved with your device.

"Many medical device companies try to avoid using SOUP software all together," said Marshall Parker, co-founder and principal software engineer for Gale Force Software Corporation, an Indianapolis, Ind.-based software engineering services company that provides software/firmware engineering services. "Instead, they write their own

software to perform the task that the SOUP component would provide. This can be expensive and time consuming, and doesn't guarantee implementation is any better."

Several design concepts and process actions help utilize SOUP code with confidence. For example, the SOUP code can be placed in its own thread or task so that it remains a self-contained component. Parker recommends keeping it isolated from other threads or tasks in the system. Limit the scope of the SOUP variables and its functions to help protect them from inadvertent or unintentional interference. Protect data storage with cyclic redundancy checks to detect if inadvertent or unintentional interference occurs. A watchdog timer can ensure all threads and tasks are serviced or performed in a timely manner. Also perform a hazard analysis and/or design failure mode and effects analysis to analyze the risks or hazards associated with the software tasks the SOUP code is performing for a system.

"Ideally, the SOUP component will not be performing a safety critical task," added Parker. "However, if it does, understand these interactions and ensure adequate mitigations are put in place to ensure the SOUP code is working as intended. Perform lots of system-level testing that will interact with the SOUP code as a black box. The intent of this type of testing is to exercise the non-happy execution paths the software may perform and to ensure the system can handle it."

Connecting Through the Cloud

The "Cloud" has enjoyed rapid growth in the medical device industry. The combination of increased security, more services, and improved understanding by regulators and auditors has allowed the cloud and SaaS (software as a service) solutions to become accepted business tools for MDMs (the cloud is also essential for strategic use of IoT).

"Platforms such as Amazon Web Services (AWS), Salesforce, and Microsoft Azure are used regularly by medical device and life science companies," said Bruce Kratz, vice president of research and development for Sparta Systems, a Hamilton, N.J.-based provider of enterprise quality management software solutions. "They have closed the gaps around validation, security, and HIPAA, making their platforms a viable option for regulated companies. Sparta operates on both the AWS and Salesforce platforms. For example, cloud technology enables our quality business network called Stratas, which allows distributed organizations to collaborate on solving quality issues across the supply chain."

EtQ has operated in the cloud for nearly a decade. "We are seeing a trend now where companies want to interact more with their supply chains," said Lozier. "They want to be able to push information to suppliers and external stakeholders, but at the same time limit access to their sensitive data." EtQ's Reliance Cloud Portal allows companies to interact more securely with external parties in the cloud to maximize workflow process, without providing direct access to their internal network and data storage.

"This is a huge benefit of enabling supply chain visibility, while mitigating the typical risk associated with supplier involvement," added Lozier.

Ease of Use

Smartphones and tablets are now being used as medical devices themselves. The Android platform is becoming more prevalent as the core component for many medical devices. "The main advantage to using an Android platform [hardware and software framework], as opposed to a traditional embedded processor, is that so much comes for free—Wi-Fi connectivity, Bluetooth, display, audio, multi-language support, and more," said Laura Combs, principal software engineer for Gale Force Software Corporation.

Smartphones have also established the standard among consumers for graphic interfaces and ease of use. They like the look, response, and easy handling of a smartphone. As a result, there is greater focus on user interface aesthetics and human factors in medical device design, compared to just two or three years ago.

"This has clearly been a positive influence on product design, and is driving companies to reconsider mature products that are showing their age," said Dallas. "Rather than upgrading an existing application, the more cost-effective approach is to build a new interface with newer tools, adding more value through additional capabilities for the user."

Many of the recent advancements in software are related to the user interface, Spera pointed out. "Aegis is leveraging the latest user interface technologies for touch compatibility and operator ease on the factory floor and will continue to advance what we have created in terms of human-machine interface to an entirely new level," he said.

With the proliferation of smart devices and end-user demands, and to support their evolving business models, MDMs must enhance ease of use as part of their product solutions. In the past, traditional medical devices relied on field programmable gate arrays or basic embedded control software to manage the computational and operational needs of the device. "This has now expanded to include the connectivity stack, more consumer electronics-like user interfaces like the iPhone, and the exchange of data with other systems, such as electronic medical records, smartphone apps, or cloud-based systems," said Bosch.

Regulatory Complexities

International Standard IEC62304 (software lifecycle processes for medical devices) has become the standard the FDA expects to be followed when developing a medical device. "The standard outlines the type of development processes that should be used when developing software for the different classes of medical devices," said Combs. "It outlines planning, development, testing, and ongoing maintenance for the lifecycle of software development."

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However, the FDA continues to work on new guidance—for example, what constitutes a mobile medical device and how to use the cloud. Mobile technologies are also rapidly pushing the boundaries of agency guidelines; in response, regulators are asking for more data.

"A large pharma customer recently told me how auditors that used to find violations on paper rather easily are having an increasingly difficult time doing the same on electronic systems with massive amounts of data," said Kratz. "This has caused auditors to become data experts and direct their investigations at a lower level, where the raw data is stored in the application's database."

Data privacy, especially across the world, is a complex and shifting landscape. With the EU rejecting safe harbor as a suitable mechanism for protecting data, companies are scrambling to find other legal and procedural methods to protect and govern data. The FDA has released updated guidance on interoperability, human factors, and cybersecurity. These all represent new challenges for software development and verification. "For example, there is increased need for and expansion of risk identification and risk management for medical devices that include cyber threats," said Bosch. "These experiences and skills are unlikely to be part of the core competencies of most medical device makers."

Moving Forward

Comprehensive manufacturing software is not as complicated, or expensive, as MDMs might think. It does not have to be customized; it can be largely off the shelf. It can use simpler systems or tap into the SaaS smorgasbord in the cloud. In addition, there doesn't have to be any mystery about development costs.

"It is entirely possible to design, prototype, develop, test, and completely verify and validate software products within 15 to 20 percent of estimate," said Dallas. "I often hear how projects go over by two or three times, with minimal scope change requests. Good planning, prompt decision making, reliable design patterns, disciplined development, and good communication are the keys to success."

While software can seem expensive up front, gains can be impressive, with dramatic cost reductions. For the typical project, if recommended solutions are fully implemented, Bieszczat estimated that operational improvements can be a 15-50 percent reduction in held inventory, 25-50 percent reduction in scrap, 20-40 percent drop in customer returns, and 10-30 percent increase in inventory turns. "Depending on the size of the manufacturer, savings can range from $50,000 to $500,000 per year," he added. "Also, a well-implemented system will pay back its cost of software and implementation in the first year of operation. Those savings recur annually, so the ROI is very large—which is why companies invest in enterprise resource planning."

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The software landscape is always changing, from automation to ERP to mobile to the cloud. Every MDM seeks to have unique, differentiating capabilities in order to maintain or advance market share. This “first-of-its-kind” aspect could be an improved algorithm, better user interface, or smartphone capability with attached sensors. Whatever it is, chances are it won’t be developed without having the software development team involved from product conception through product release.

“The team provides software solutions/products in conjunction with the product lifecycle management strategy,” said Tandon. “Software is developed from user needs, translated into use scenarios and software specifications, documented in detailed designs, implemented in code, unit tested, integration tested, and supported through product release and beyond. It is our job to help customers identify opportunities, reduce risk, and maintain value throughout the product lifecycle.”