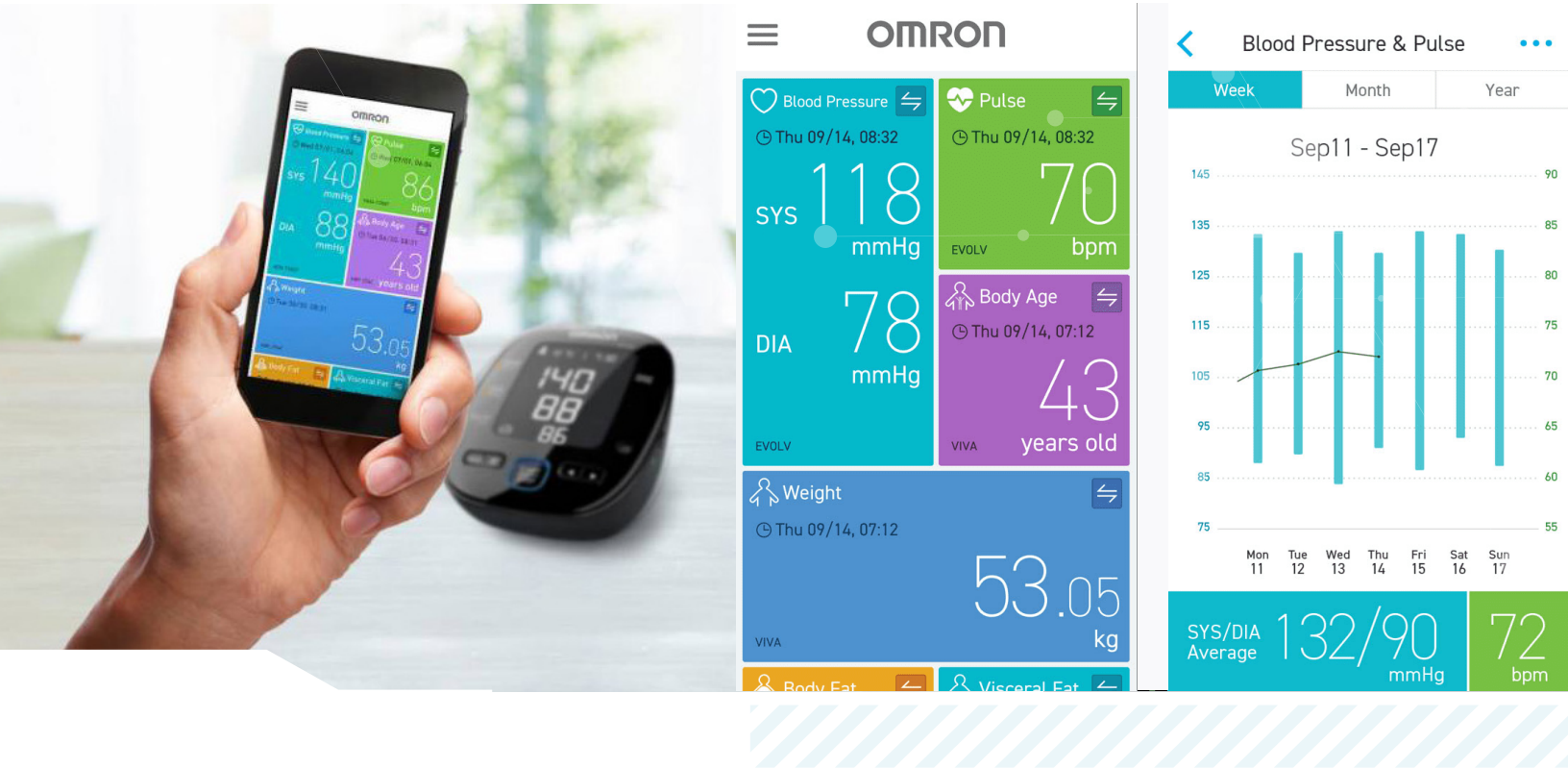# An Omron Healthcare Case Study — Helping People Around the World Become Healthier

Abstract

"Windchill helps Omron drive healthcare innovation."

Omron Healthcare is making huge efforts to create a world of Zero Events; in other words, zero extreme medical incidents, such as heart attacks. For a company like Omron, their efforts often require that they meet government agency compliance requirements while improving their overall product development operations.

Omron Healthcare Co. Ltd. (a division of Omron Corporation), based in Kyoto Japan, is a manufacturer and distributor of personal heart health and wellness products available in more than 110 countries and regions around the world.

Over the past 40 years, they have sold more than 200 million of their market-leading blood pressure monitors.

VG2020 (i.e. Value Generation 2020) is an Omron initiative that sets goals for Omron becoming a superior value generator (i.e. a leader in innovation) for the people of Earth. This is where a digital thread-powered PLM (Product Lifecycle Management) platform, such as PTC's Windchill, can really facilitate product development in their industry.

VG2020 Initiative — Omron's Path to Innovation

Omron Group has been conducting its business in a wide variety of areas, including control/factory automation systems, electronic components, automotive electronic components, social systems, and medical/health devices and services. In 2011, Omron developed and announced a "Value Generation 2020 (VG2020)" long-term vision for the following 10-year term through 2020. The theme of VG2020 is "*Sensing & Control + Think*, for a Brighter Future for People and the Earth." Omron has been striving for "a value-generator for people and the Earth that is qualitatively and quantitatively superior" to help achieve a sustainable Earth and society through its core technology of "Sensing & Control." The company believes the intensifying global market competition creates business opportunities.

Omron's revenue and profit during the 10-year term grew particularly in its healthcare business. In 2017, the company began its journey based on a "VG2.0" medium-term business plan to a "quantum" growth for 2030.

One of Omron Healthcare's critical missions is achieving "Zero Events." Zero Events according to

the company means "helping people monitor their blood pressures more frequently, identify risky blood pressure fluctuations, predict risk of illness and prevent events from occurring," which means reducing illness (events) to zero. In order to realize this ambitious goal, Omron Healthcare is communicating this goal globally and actively engaging global partners to develop products and services. This "Zero Events" initiative is a driving force behind the VG2020 as well as VG2.0 strategies.

Omron's Other Initiatives

Omron Corporation is currently focused on four business areas: factory automation, healthcare, mobility, and energy management. Omron Healthcare, one of the top earners in the group, is the one that drives Omron's business. Omron Healthcare develops a variety of healthcare devices, such as thermometers, blood pressure monitors, and massagers. They developed a unique blood pressure monitor, HeartGuide, that looks like a smart watch. "HeartGuide" was first launched in the U. S., and is gaining much attention today.

Also, Omron Healthcare has developed "OMRON connect" health management app, providing services that leverage vital human body data, such as blood pressure, body weight & composition, and activity level (step count). The vital body data is gathered and brought onto an OMRON connect cloud server, which can be integrated via API with systems used for local medical services.

Digital Thread for supporting further growth and globalization

Historically, Omron Healthcare's research and development activities are led by two teams in Japan. The Engineering team meets local requirements, while the Production and Distribution team's activities are driven by various overseas demands. The company has accumulated the knowhow of obtaining country-specific permissions and certifications. Today, Omron Healthcare is working to strengthen the product development capabilities of its overseas teams in order to accurately capture local needs and address those in a timely manner.

One of the challenges Product Development organizations were facing was sharing of digital data. Technical information has been centrally managed in Japan. The company has been actively working on digitalizing engineering data and processes, implementing 3D CAD, CAE, PDM and other tools. Engineering data is digital, but there were other types of data stored on individual computers—preventing Omron Healthcare teams from fully leveraging the digital data they created.

Also, technical information and audit-related documents were managed mostly as thick, paper-based documents. As their products and business evolved rapidly in recent years, the number of product variants also grew rapidly; engineering and specification changes were made frequently. Omron Healthcare then realized that continuing to manage data in a traditional way would create a situation where it is harder and harder to quickly and accurately

support increasing number of changes. They actually saw an increasing number of delays and errors updating information, and it was easy for them to realize that the problem would be bigger as they were considering making global releases of their products simultaneously.

Supporting audit processes and maintaining high product quality were some of the challenges they were facing. They implemented a quality management system (QMS), but the team began to see limitations of their QMS in supporting increasing product and process complexities. One of the biggest challenges they were facing in their global business was country-specific permissions and certifications. Obtaining FDA (Food and Drug Administration) certifications is said to be particularly challenging. FDA certification is an absolute requirement for anyone to market food, drugs, and medical devices in the US. The FDA implemented a digital submission process, and as business globalization was being accelerated, Omron Healthcare's paper-based document management began to create challenges during its submission process, such as missed data and documents, and difficulty finding the right data. This inefficient process began to place additional workloads onto their engineers.

"Our employees in Japan, even they face inconveniences, get things done by putting extra time and effort. There are actually some things that we manage to get done in that way," says Mr. Yoshihisa Toki, General Manager, Development Center, Product Development HQ, R&D Management Department, Omron Healthcare Co. Ltd. "However, we were convinced that paper-based information management would not be able to support our processes as our products become more complex and simultaneous global product launches are expected. We believed we would see more quality issues and audit risks without transforming the way we manage information."

Omron Healthcare then began its journey of digitalizing technical documents and implementing PLM. In order for the team to gain full benefit from PLM, it was critical for the PLM system to be integrated with 3D CAD and other engineering tools, Engineering Bill of Material and Manufacturing Bill of Material management systems, ERP and other enterprise systems, and with a diverse set of systems and data linked to research & development and engineering. In addition, the new PLM system needed to be integrated with the ERP system and a variety of data that Omron, its parent company, manages.

"Integrating multiple systems with very different historical backgrounds and mechanisms and centrally managing all the data stored in such systems is never an easy task. Digitalizing paper documents, prior to the integration work, was very challenging, particularly the ones related to audits," says Mr. Wataru Date, Senior Engineer, Group Leader, Development Center, Product Development HQ, R&D Management Department.

Some people raised concerns: asking if they would be able to get benefits from the cost and effort they put into, or why they should invest while the current paper-based process is working. However, the senior management's sense of urgency was so strong that they decided to take a top-down approach to the digitalization initiative and jump-start the project.

This journey will not be an easy one, but this is a mountain they needed to climb and conquer in order for them to make great strides in their business. The tool they select in their journey should not be one that could stand in their way.

FDA requirement support was key to selecting Windchill

After going through a process of evaluating a number of PLM systems, Omron Healthcare selected PTC's Windchill.

What was key for the team to select Windchill?

Windchill has more than 20 years of history, and numerous domestic and overseas companies have adopted the solution. Windchill provides templates based on best practices developed by existing users, and new users are able to leverage their knowledge and experience. By selecting and adopting the templates that meet the customer's requirements, the customer can deploy a PLM solution with little customization. Windchill is a solution that provides a wide range of OOTB (Out-of-the-Box) capabilities.

In addition, Windchill has a Multi-CAD data management capability, supporting a variety of mechanical as well as electrical CAD data. Users would appreciate the ability to leverage the 3D CAD and other engineering data they have created in the past. Also, design engineers can access Windchill menus from within their 3D CAD tool, enabling them to easily retrieve data from the PLM system. Windchill provides tools to integrate major CAD tools.

Ability to share data through the cloud is a critical part of accessing the same set of data from anywhere in world. Omron Healthcare also believed that the ability for them to run Windchill on the cloud server that the entire Omron Group relies on is one of the advantages Windchill offers. All the technical information will be consolidated in the cloud, which enables everyone to use Windchill and access the same set of data globally.

It is worth noting that Windchill's solution package designed to support the medical industry, Windchill Medical Package, that Omron Healthcare has selected is equipped with a set of OOTB FDA certification support tools that can be used without customization. Windchill Medical Package provides users with templates based on medical industry best practices. This is a key factor for Omron Healthcare to select Windchill.

This is an area where other PLM tools would require their customers to customize the tool based on specific customer and industry requirements, resulting in additional time and cost for the implementation.

After they decided to implement Windchill, Mr. Toki interviewed domestic and overseas PTC customers. "It was a great opportunity for us to hear not success factors; as well as, the challenges they faced and failures they made along the way, which they don't typically share in public. This opportunity helped us move forward," says Mr. Toki. PTC is actively engaged in providing such networking opportunities.

Windchill in a sense is a system that provides the milestones that others placed along their journey to the top of a steep and rugged mountain of PLM implementation.

Windchill helps engineers innovate themselves and their future products

"We will be able to consolidate once-dispersed data onto Windchill," says Mr. Toki. "We will know how others see your data. This will help us understand the types of data others need; as well as, the types of feedback we should provide to others. This will be a great benefit for us."

"Windchill will help our design engineers think about the types of data they should leverage, and others will leverage. We expect this will also enhance the quality of our design." What Mr. Toki is looking for, is their engineers innovating themselves through Windchill-based initiatives.

"People had limited access to paper-based information, which I think limited the scope of our engineers' thought processes," says Mr. Toki. "With Windchill, everyone will be able to search for and find the data he/she needs and will have a wider point of view. Also, junior engineers, now spending much time trying to gather technical materials they need, will be freed from such hassle. Our junior engineers of the future will then be able to spend more time engineering, working on more creative work, and this I believe will enhance the level and quality of our design."

The current scope of their Windchill implementation project at Omron Healthcare is engineering, however, the company plans to look at other areas of their business, including MES and manufacturing processes, and CAPA (Corrective and Preventive Action) and complaint management processes. They also see other opportunities, such as capturing markets needs for future designs.

Omron Group is actively engaged in research activities to develop next-generation products—envisioning a future of IoT and AI in addition to sensing and control technologies. They say their technology environment based on Windchill might converge with such future initiatives. We all should look forward to a further evolution of their Zero Events initiative and a future where everyone in the world becomes healthy.