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Health technology: Better patient care through innovation

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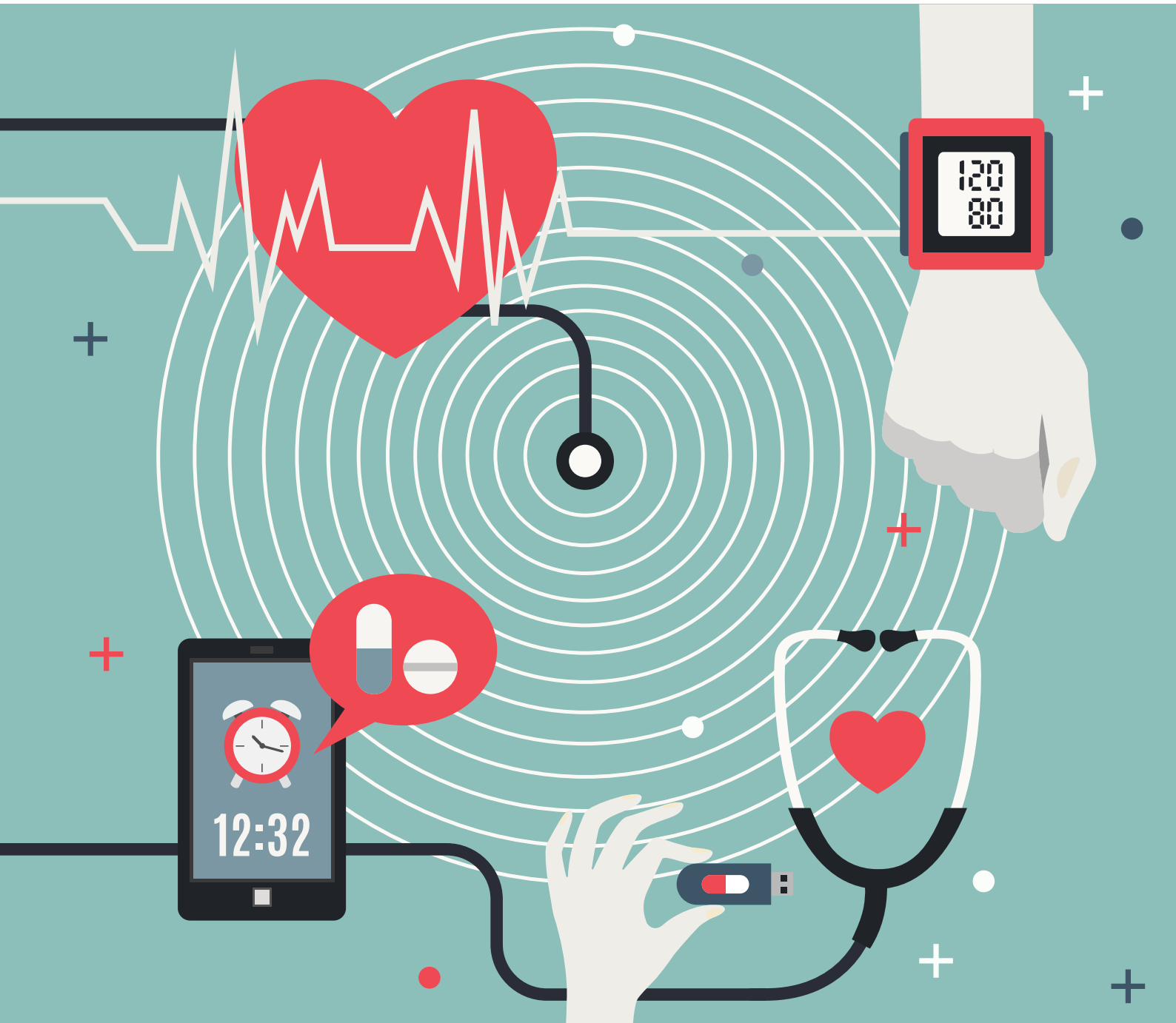

Foreword

Innovation is not just a buzzword – it is part of our DNA. ERNI has been supporting the healthcare technology industry for 20 years and has become one of the most trusted technology partners for the ecosystem.

MedTech companies face serious challenges in the current market environment. Government regulations and restrictions are becoming increasingly complex, and the growing demand for personalised treatments or medication necessitates the development of new services and business models.

We support clients in this space to adopt new technologies that improve the patient journey. We combine expert knowledge, proven best practices and a cultural environment focusing on the needs of our clients and our employees.

ERNI leverages this diverse expertise and knowledge by fostering collaboration among all stakeholders in the MedTech ecosystem. We work with top talent and leverage our in-depth domain knowledge with healthcare providers, MedTech startups and multinational companies to deliver innovative solutions.

While these challenges may be specific to the MedTech industry, our approaches can be applied to many other sectors. I invite you to explore these challenges through our client journeys and the experiences of our industry experts. These insights can play a small part in helping us better address the complex problems of tomorrow.

At ERNI, we are committed to our clients' success. This is our daily motivation and our ultimate goal. We look forward to shaping the digital future with you and are convinced that with the right attitude and approach, anything is possible.

I wish you an inspiring read,
Rafael Botor

Editorial

The Medical Device Industry and other industries have changed significantly over the recent years due to digitalisation and innovation. What originally started as a hardware industry, producing machines to help patients with their health, has transformed into health services.

Nowadays, the device can be seen more as an enabler for the software to provide value to the end consumer. Hence, software has become a leading factor in market success. Moreover, interconnected smart devices are crucial to improving all aspects of patient care and keeping demanding customers satisfied.

The competition has evolved; even though they face other challenges, current market and law regulations offer many opportunities for startups, that move fast and offer outstanding smart solutions which disrupt the existing "traditional" market. Why are startups focusing on software? Time to market can be shortened since the products are brought to market with minimal product requirements. Innovative software updates can also bring new products to market more quickly, and functionalities can be added via these updates. As a result, development costs also decrease, and one gains the advantage of flexibility. Therefore, hardware producers should also concentrate on improving current software and services enabled through the devices. This also includes building redundancies into their interconnectivity.

Another pertinent point is that MedTech has become more accessible without prescription, as many market newcomers develop software that is available over the counter. Furthermore, trends such as eating healthy, being health aware and using fitness apps are also starting to include health measurement gadgets and services. This movement is pushing "traditional" medical device companies to evaluate their strategies and focus on innovation within software development to keep in line with patient demands. In other words, a smartwatch can now measure oxygen levels and give nutrition recommendations, which is further interconnected with a smartphone and a meal planning nutrition app. It also follows that MedTech companies should work on comprehensive services supporting patients with more demanding health issues on their health journeys and through predictive features.

As software engineering and MedTech experts, we would like to concentrate in this magazine publication on the tools and methodologies that promote innovation and allow fast and efficient evolution of the services, as well as adjustments to market needs and competitive position.

Regards,
Reto Ruch and Christian Glück

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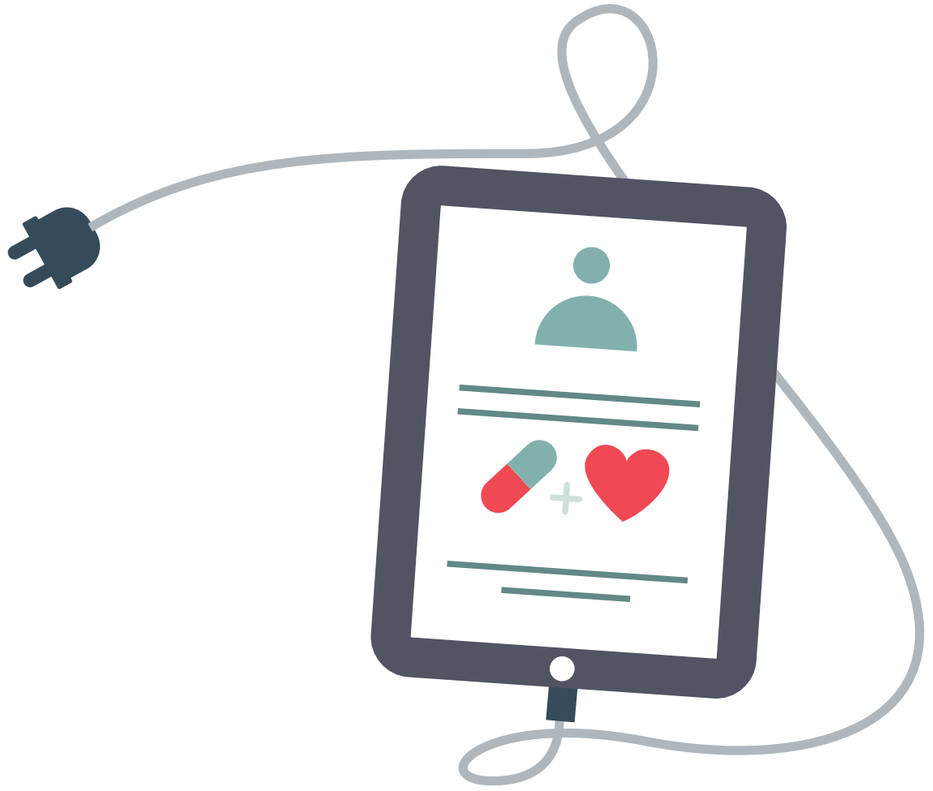
Why do we need digital transformation for medical devices?

For hospitals, it is not up for discussion as to whether they want to digitalise. The increasing age of the population in western countries and the progressive shortage of medical professionals mean that without digitalisation, the healthcare system will not be able to provide the quality that patients want in the future.

By Sandra Müller



Medical technology companies are expected to support the healthcare system on the path to digital transformation through innovative solutions. This means that more efficient work is made possible not only through pronounced user-friendliness (usability) but also by incorporating upstream and downstream processes in line with the customer journey. Today, tests, measurements and results must not only be visible on the PC in software but also on the medical device itself. It must also be possible to transfer them to a hospital information system (HIS) or medical practice software; interoperability is no longer negotiable. Repetitive processes or work where humans tire quickly, such as analysing MRI images, can be supported by machine learning (ML) or artificial intelligence (AI) to help healthcare professionals better evaluate and diagnose. Swiss hospitals are already analysing MRI images from partner hospitals at a distance, as the latter cannot have qualified personnel on site 24 hours a day. Good care even in rural or structurally weak regions can be ensured thanks to digital transformation – including methods such as remote assessment and computer-aided diagnosis as well as ML/AI. This technological progress also offers emerging and developing countries opportunities to rapidly improve their healthcare systems, as fewer highly qualified professionals need to be available throughout the country for certain processes and treatments.

Educated patients and HealthCare instead of SickCare

There is a clear trend among the population to move from SickCare to HealthCare. With SickCare, one waits until the disease appears and then treats it. With HealthCare, people invest in maintaining their health, i.e. they take preventive measures to avoid getting sick in the first place. With the internet, today's patients are more educated and better informed than ever and often want to see their values or measurement results and understand their diagnosis. Prevention is much more important today than it was twenty years ago, enabling new business models for MedTech companies. Also, after discharge from hospital, the modern patient expects that remote patient monitoring will detect an escalation of the disease at an early stage and preventive intervention will avoid readmission. This also conserves scarce hospital capacities. The electronic patient dossier (EPD) in Switzerland and the electronic health record (ePA) in Germany are important pillars on the way to the healthcare of tomorrow.

Are there also opportunities for MedTech companies?

Of course, price and competitive pressure also mean that today's medical products must constantly be developed further. But do only patients and medical professionals benefit from the digital transformation or do opportunities also open up for MedTech companies? In our opinion, new technologies and increasing people's affinity for technology offer many new opportunities for the MedTech sector. Companies must make good use of these and invest in the development of solutions. Through the IoT (Internet of Things), also called the IoMT (Internet of Medical Things) in medical technology, medical devices, wherever they are used, can send their encrypted data to the cloud, for example. This offers advantages not only for patients and hospitals to retrieve the data from anywhere, in almost real time as well as retrospectively in a web application, but also enables new business models for MedTech companies. For example, Software as a Service (SaaS) can be offered for a web application where the user pays a subscription fee or a payment model per patient or per test/measurement performed. It also makes it possible to make the service business more professional since, thanks to the IoT, it is known which device is in use with which firmware. The manufacturer, local authorised representative, importer or dealer can arrange for on-site maintenance and the required spare parts much more precisely as they know how the device is being used by the customer and what condition it is in. For traceability, as well as the post-market surveillance required by the European Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) as well as the US Food and Drug Administration (FDA), the IoT also offers new opportunities.

If the manufacturer collects data from the devices used, it can, for example, more quickly identify the conditions under which undesired behaviour occurs. This helps in continuously improving the products. Clinically too, new possibilities are opening up through the compilation of anonymised data from countless patients from a wide range of hospitals and countries. It is only through a large amount of good-quality and structured data that physicians and researchers, together with data science specialists, can improve diagnoses and uncover correlations in the coming years that are not yet known today. It also gives us new insights into the prevention, treatment and incidence of diseases. This, in turn, relieves the burden on health personnel.

At ERNI, we also support you on the path of digital transformation through our digital business and technology consultants, be it in the (further) development of innovative solutions and new business models or in the implementation as software partner. Together, we enable you to seize your opportunities!

Digital transformation in MedTech

The medical technology industry is a strong and stable sector that is known for its resilience during economic recessions and global events such as the COVID-19 pandemic and the current energy crisis. Health is one of the primary concerns of people, and this does not change much during difficult times. However, this comfortable business position also has its downsides. Without significant market stress, companies do not feel an urgent need to innovate or increase their operational efficiency.

By Wicher Visser

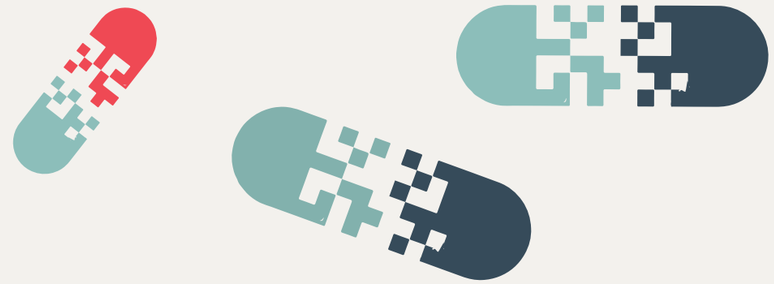
Nonetheless, this situation has been changing in the last several years. A study by Gartner clearly shows that increasing healthcare costs is one of the main business threats. Governments and consumers alike are demanding cheaper solutions. Additionally, rapid technological advancements in Cloud, IoT, AI and other areas are enabling startups and companies outside the traditional medical space to enter and disrupt the market. These advancements are also bringing about new megatrends that the industry will need to capitalise on to maintain their competitive advantage. Regulators such as the FDA and the EU have also increased their expectations – for example about cybersecurity and Software as a Medical Device (SaMD) – which can only really be met when companies digitalise their business processes. Hence, based on the current development of the trends and the market, companies need to undergo digitalisation if they are to survive in the years to come.

Telemedicine as the driving trend

Swiss Medtech's office carried out a study on the MedTech sector in 2020 showing that there are few trends as important as telemedicine. Even though it might seem outdated, we firmly believe that this is still valid. Telemedicine promotes moving healthcare caregiving, in particular, outside of hospitals and clinics. As a result, human stress and financial strain are reduced. For example, medicine injections can be performed in the comfort of a patient's home, live consultation can take place online, appointments can be made on demand, and patient monitoring can be continuous. Furthermore, the communication between doctors, caregivers and patients can be significantly improved.

In order to enable these use cases, devices and applications need to be connected and smart. This necessitates IoT solutions, data processing systems, and service automation such as remote monitoring and back-office processes. New technologies for invasive and non-invasive measurements and treatments, such as continuous glucose monitoring (CGM) and disease treatment through intravenous or intramuscular medication, are both requirements and enablers for trend adoption.

These digital health platforms and their increasing interconnectivity provide an opportunity for big data solutions. Data silos that individual companies may already have are enriched by the integra-



Tech trends enable new use cases for medical technology companies and provide society with compounding benefits.

Tech trend	Use cases	Benefits
Telemedicine	• Remote medication management • Live video consultation	• Real-time monitoring of patients • Improved communication between doctors and patients
Artificial Intelligence	• Medical image analysis • Virtual healthcare assistants • Voice-to-text transcriptions	• Enhanced efficiencies of X-rays and MRIs with accurate image analysis capabilities • Personalised treatment for patients based on their medical history
Big Data Insights	• Electronic health records • Preventing unnecessary emergency room visits • Real-time alerts for patients with complex medical histories	• Lower rate of medication errors • More accurate treatment plans using predictive analytics • Better management of patient emergencies
Internet of Medical Things (IoMT)	• Heart rate sensors • Exercise trackers • Pulse oximeters	• Up-to-date monitoring of high-risk patients • Lower insurance premiums • Possibility for patients to send wearable stats directly to the doctor for consultation

Top challenges to digitalisation in healthcare:

Concerns about cybersecurity and personal data protection

Outdated legacy platforms and a lack of modern equipment in healthcare facilities worldwide

Increased strain on hospitals as a result of high demand for detailed reporting that can only be accomplished through analogue means

Cost and complexities associated with new technologies

Difficult learning curve for technology adoption due to some medical personnel's lack of necessary IT skills

Risk of "digital biases" when using algorithms to create prescription medications or provide a smart diagnosis

tion of these new systems. Business intelligence suites and specialised machine learning algorithms can provide valuable insights. When data is managed and utilised properly, these insights from this wealth of data lead to product improvements, increased efficiency and entirely new business models – further developing a company's competitiveness and securely establishing it as a leader in the modern medical technology market.

Synergy benefits to address the challenges ahead

Gartner's study shows that organisations are by and large not ready to reap the benefits of digitalisation. Medical systems have until recently been developed mostly without taking integrated user journeys into consideration in their product vision. Companies need to make UX, and its practice of user persona modelling, a central aspect of product design.

The medical products out on the market often comprise outdated legacy platforms and equipment. Product life cycles are typically long. As an example: larger systems such as laboratory-scale blood analysers last more than 10 years. These products were not designed with "integrated" use cases in mind, and typically lack the data collection and connectivity functionalities. It is not feasible to retire these products, and the time to market (TTM) for a new system is often up to five years. However, greenfield development may work for new product classes with fast TTMs. This is not an easy decision, and companies need to consider their business strategies and choose between iterative product improvements and greenfield development.

The need for digital health platforms puts companies in a dilemma. Such systems are large and complex, and expensive to build and operate. This is not something companies can create overnight and requires a significant investment of time, money and resources to implement. Consequently, the tendency is for companies to build ecosystems through strategic partnerships. By collaborating with companies from other market niches and bringing various expertise together, partnerships can build such platforms and with them provide meaningful benefits to the end users and their increasing needs.

Companies need to acquire key skills in-house to enable their new use cases and business models. Machine learning and big data particularly stand out as the competencies that make or break their success. However, this reliance on data makes companies vulnerable to cybersecurity threats. As a result, companies need to strengthen their security posture, both digitally and organisationally, something that regulators like the FDA recognise and are starting to demand.

Exciting times

It is an exciting time to work in the medical technology sector. The clear trends and market disruptions require companies to be innovative and collaborative. Some will reinvent themselves, others will improve their products and businesses, while still others won't survive the technology onslaught. Hence, senior leadership needs to be tech savvy in order to make the right calls early on.

Cutting-edge technologies such as multi-clouds, IoT ecosystems and advanced AI are being adopted as companies build centres of excellence to foster these competencies. Complex application integration requires thoughtful systems design.

How can we connect laboratories and hospitals in a safe way?

We are all aware of the importance of data in the business context. However, when talking about the data in MedTech, the security and regulations go much further.

By David Soto Dalmau

Despite the complexity of these regulations, data and software specialists do play a crucial role in providing parties with solutions for better treatments, diagnosis and patient care. Therefore, the question remains: how can we safely connect hospitals and laboratories to make the most of the available data?

Developed countries have the advantage of having this kind of connectivity in place – with data travelling from laboratory to the cloud and from the cloud to the hospital and all the way back – and the benefits are amazing: instant results, global information availability between healthcare systems, and at the centre of everything, the patient.

Nevertheless, because of the nature of the information processed by hospitals and laboratories which are part of the health system, a possible security breach that affects the confidentiality or integrity of the data can cause severe issues for the health of the patients, making it an extremely critical scenario.

With the data protection regulations around the world on one hand, with high fines in case of data leakages, and the risk to patient safety of health information on the other, a big fear is present in some people's minds towards the topic of data connectivity. This fear causes countries and hospitals to have a feeling of trepidation towards trying to connect both systems. However, nowadays there are technological solutions to make it possible and safe.

Here is where the importance of secure software design comes into play. Hardware, isolation and locks no longer work as dependably for these scenarios. We need to give the responsibility to the software, and the software has all the necessary tools to make it happen.

If we embrace this make-it-happen mindset, we can think of a viable technical solution putting cybersecurity as a central pillar of the development.

Let's have a look at some of the challenges and the complications that a software solution has to overcome in order to make it feasible:

Infrastructure security

Once the lab or the hospital is connected to the internet, it is exposed to attacks. It is mandatory to protect the internal infrastructure with minimum exposure and the best hardening for the connections.

That means that only the communication service should be present on the internet, and the network access should be secured through hardening best practices, secure virtual private networks and demilitarised zones for the exposed sides. Strong firewall restrictions are necessary for achieving good results, and a strict "Zero trust" policy must be followed.

Software protection

All the software involved in the process must follow the "Secure by design" principle and pass all necessary checks to ensure there are no vulnerabilities that can allow an attacker to gain unauthorised access to the data or the hosting systems.

The user interaction has to be restricted with authentication systems, strong password policies and 2FA in order to ensure the user's privileged access, and these privileges must be managed in a separate way.

A secure software development life cycle must be maintained throughout the development.

Vulnerability assessments and checks should be done often during the development period to address and fix unexpected issues in the early stages.

Runtime Application Self-Protection (RASP) systems would also be a good asset to be included in order to prevent unexpected threats and behaviours.

Data security in travel

In order to protect patients' medical data, ensuring the confidentially of the data while travelling from laboratory to hospital is a must. To do so, strong end-to-end encryption is needed, and a secure communication channel must be guaranteed.

Non-repudiation principle

In order to ensure the identity of the laboratory or hospital, all data communication should be digitally signed.

Data security at rest

It's always said that nobody can guarantee 100% against unauthorised access, so ensuring the data is unreadable once stored is critical. Encryption at rest is needed in order to protect data confidentiality on both sides by using, again, strong encryption and by storing the encryption keys in a secure vault.

As a side note, after talking about confidentiality, integrity and non-repudiation principles, there is another side to consider, namely the availability of the data in the event of a ransomware attack or a service disruption that makes the hospital/laboratory unable to read the results, which can lead to a catastrophic situation. Therefore, the usual measures must be put in place in all the workstations and servers included in the workflows.

In conclusion, I want to remark that connecting hospitals and laboratories in a safe way is a reality. And we at ERNI have been specialising in it for several years. The first steps towards complex ecosystems are the change of mindset and finding the right people with the technical capabilities. We know for a fact that connecting labs and hospitals has a positive impact on the quality of patient care, and we expect to see this trend on the global level in the near future.

Interview with Steve Martin

Steve Martin has been working in systems development for over 40 years. His particular expertise and passion is connectivity between labs and hospitals.

By Ares Cabó Carrera

The starting point was in 1993 when he started as a system manager at one of London's hospitals. In this position, he saw the challenges of both hospitals and labs and implemented various solutions to enhance efficiency in time and resources. Over the years, he rolled out new laboratory management systems which were no longer terminal-based. He also revolutionised test processes by introducing the electronic ordering of tests and connecting labs with primary care (medical infrastructure close to the people, which is necessary to ensure basic medical care), and he still believes in the importance of connectivity in hospitals.

Steve agreed to an interview to share his views on interconnecting labs and hospitals – in particular, the challenges and how the involved parties can benefit.

What are the needs of both hospitals and laboratories in 2023?

There is, if you like, a perfect storm brewing in healthcare. First, healthcare is suffering from the "problems of success". We're keeping people with chronic conditions alive longer, which increases the healthcare system's burden. Second, the success of medical research and technology has resulted in new therapies and treatments, which means that the costs of delivering healthcare are constantly growing. Also, regulators require more oversight over medical procedures, so the regulatory burden on hospitals and laboratories is ever increasing. Additionally, there is a global shortage of healthcare professionals. Lastly, economic pressure is coming from providers (national providers, insurance companies, etc.) who demand better value. They're questioning all the costs associated with healthcare, meaning there's pressure to keep the costs low. Hence, both hospitals and laboratories are pressured to do more with less, through targeted testing or more point-of-care testing done in primary care and non-traditional settings.

Would connecting labs and hospitals address and solve some of the issues you described? What benefits does connectivity bring?

One of the consequences of the pressure on the health service is that more and more care is moving outside of the hospital and into primary care and even people's homes. The single most expensive place to deliver care is a hospital. Hence, healthcare systems are moving delivery of care to less expensive settings such as primary care or the home. That means you need to consolidate the information about that care in one place – which requires connectivity and exchange of information between care settings and wherever the patient needs to be. Being able to connect all of that information is going to become increasingly important in having a view of that patient's history. The second thing is that more and more hospitals and laboratories are becoming digital.

As care moves outside the hospital with these new care settings, paper records become more problematic since it is harder, if not impossible, for them to follow the patient. Hospitals are very used to digital information. For example, radiology and laboratory results are normally digital. So, being able to consolidate the hospital information with information from the remote care settings requires connectivity – seamless connectivity.

Which benefits does it provide not only to hospitals and laboratories but also to patients?

Well, the other thing about connectivity is that it allows you to apply governance over devices and automate documentation of diagnostics and treatments. You've got a record of who did what measurement at what time, and from a medical, legal point of view, you can prove that you made that measurement. Moreover, you can follow up on who made it, and you can prove what the result was, and so on. It's all part of the overall clinical governance regime. When I worked in a hospital,

First, healthcare is suffering from the "problems of success".

there used to be a saying that was often quoted: If it's not written down, it didn't happen. If you're treating a patient and you do something, and it's not recorded somewhere, then you know, from a medical, legal point of view and a governance point of view, it didn't happen. Therefore, the more you can automate the recording of that sort of stuff, the better your records are.

When talking about connectivity, the cloud is a very relevant topic, but what are the challenges of using the cloud instead of on-premise as we did in the past?

Hospitals retain legal responsibility and liability for patient data regardless of where it is stored or who they use as a data processor. This means hospitals are currently cautious and reluctant to commit patient data to cloud systems. There is fear and confusion around this topic since the existing regulations are not well understood. It's so new that countries' legislation is not keeping up with technological advances. However, there are risks associated with keeping patient data on your own network. It is increasingly difficult to get and retain skilled cybersecurity experts who can help to protect it. So, there may come a time when there is a recognition that the cloud is the safest place to store confidential data, but we're not there yet. The second thing is the question about jurisdictions. Many blocks have laws preventing the data from a specific country from being stored in another country (e.g. EU, USA, China).

Another aspect is that you need a completely different mindset when developing systems in a cloud-based system from developing on-premise systems. You need to think about cybersecurity from day one of the design to ensure it from the first line of code you write, because it's not easy to fix afterwards.

What are the technological challenges and how are you solving them?

Bringing together all the information about decentralised care delivery is highly complex. Having the source in the cloud makes data much more accessible from more locations. Another benefit of the cloud is easier change control and ensuring everyone is up to date in terms of software. Its downside is finding cheap and easy ways to connect all the medical devices distributed around. One challenge is to make these things as easy as connecting your iPhone or your Roomba and making them self-service. And in fairness, we're still in a business-to-business environment. Apple can invest a lot of money in making their iPhone updates and connectivity easy because they sell billions. When it comes to medical products, you never sell such large quantities. You sell hundreds or thousands of them, so the investment needed to make them self-service is always daunting. The biggest challenge is to scale the healthcare delivery model and retain the ability to consolidate patient information in one place. Something must emerge within the medical devices landscape to make easy connectivity a prerequisite.

Making things easy is quite tricky.

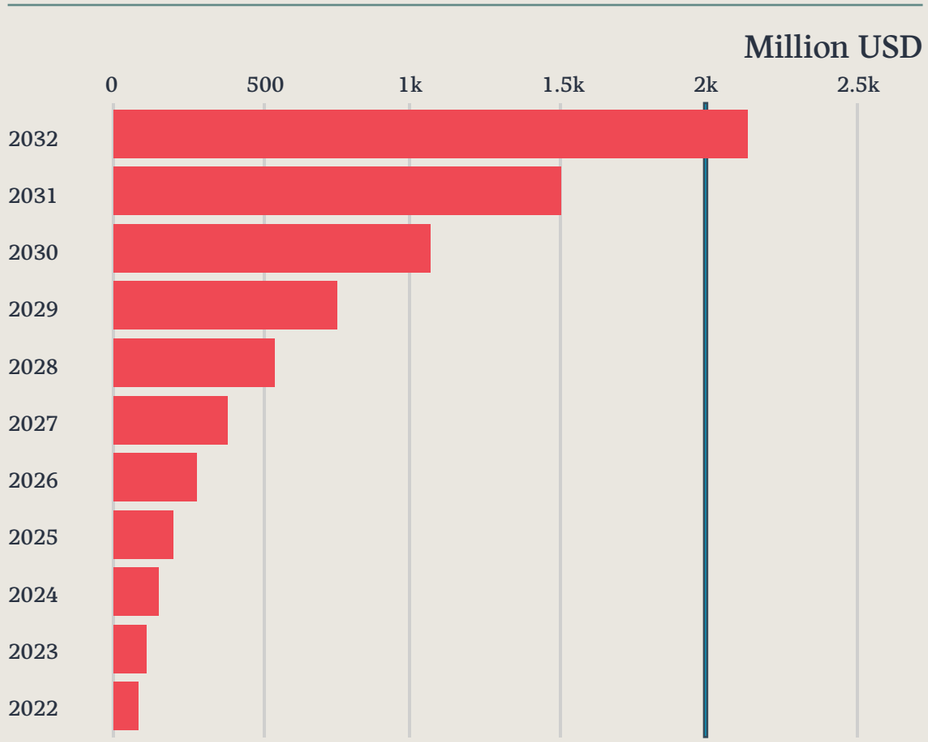
Making things easy is quite tricky. At the moment, in medical devices, the landscape is still very fragmented, and it's not all big companies doing it. Innovations generally come from small companies.

Case study: From Cobot to medical device

The use of robotics in sample preparation for clinical diagnostics is one of the fastest-growing trends in laboratory automation – primarily due to manual sample preparation being such a time-consuming task. According to Statzon (2022), the market value of Cobots in Pharma is to grow to USD 210 billion in 2032, mainly used in quality testing.

By Rubén Rodríguez Roldán

Laboratory automation systems have improved the velocity, quality and performance of sample preparation by a factor of 2 or 3. These systems not only minimise human exposure to hazardous chemicals but also provide consistency in sample preparation. In addition, laboratory automation systems improve the precision of the obtained data while reducing waste and improving the velocity by delegating repetitive tasks to the robots.



Global Collaborative Robots Market Value in Pharma, 2022–2032, USD millions
https://app.statzon.com/datasets/ogWY5

The customer

One of our customers, who is among the world's top 5 robot manufacturers, wanted to adapt their general-purpose collaborative robots (Cobots) into the MedTech domain and transform them into pre-analytical and post-analytical laboratory instruments, handling samples.

The challenge

We were asked to develop a regulatory-compliant solution to transform an all-purpose robot into a fully LIMS-integrated medical device, including the solution's definition, design, development and deployment. Moreover, this project was strategic for our customer as it would let them validate and start their first collaborative robotic solution for laboratory automation, allowing them to sell their products in the MedTech industry, fully certified and compliant. However, to do so, the first prototype had to be deployed in less than six months.

The solution

We took the best from our expertise in MedTech, robotics, highly regulated environments and cybersecurity to interpret the business and technical needs and constraints. From the beginning, we provided recommendations regarding the minimum viable product (MVP) to be delivered for meeting the business, certification and technical goals.

Our team was involved in all the stages of the project's development. From the beginning, we helped the customer to better understand the diagnostics laboratory environment in terms of regulation and interaction with other software agents. We created a solution based on .NET Core which, using laboratory communications standards, enabled the Cobot to be directly managed by any Laboratory Information System (LIS) on the market. In addition, we embedded a responsive Human-Machine Interface (HMI) to visualise the information in a friendly and intuitive way based on Angular standards.

Reasons

Reasons why MedTech companies (especially the ones focused on diagnostics instruments) should also consider investing in Cobots:

Increasing the throughput in your lab

Integrated lab automation increases your lab's productivity and efficiency, enabling you to obtain results more quickly and advance the science rapidly.

Avoiding possible human mistakes

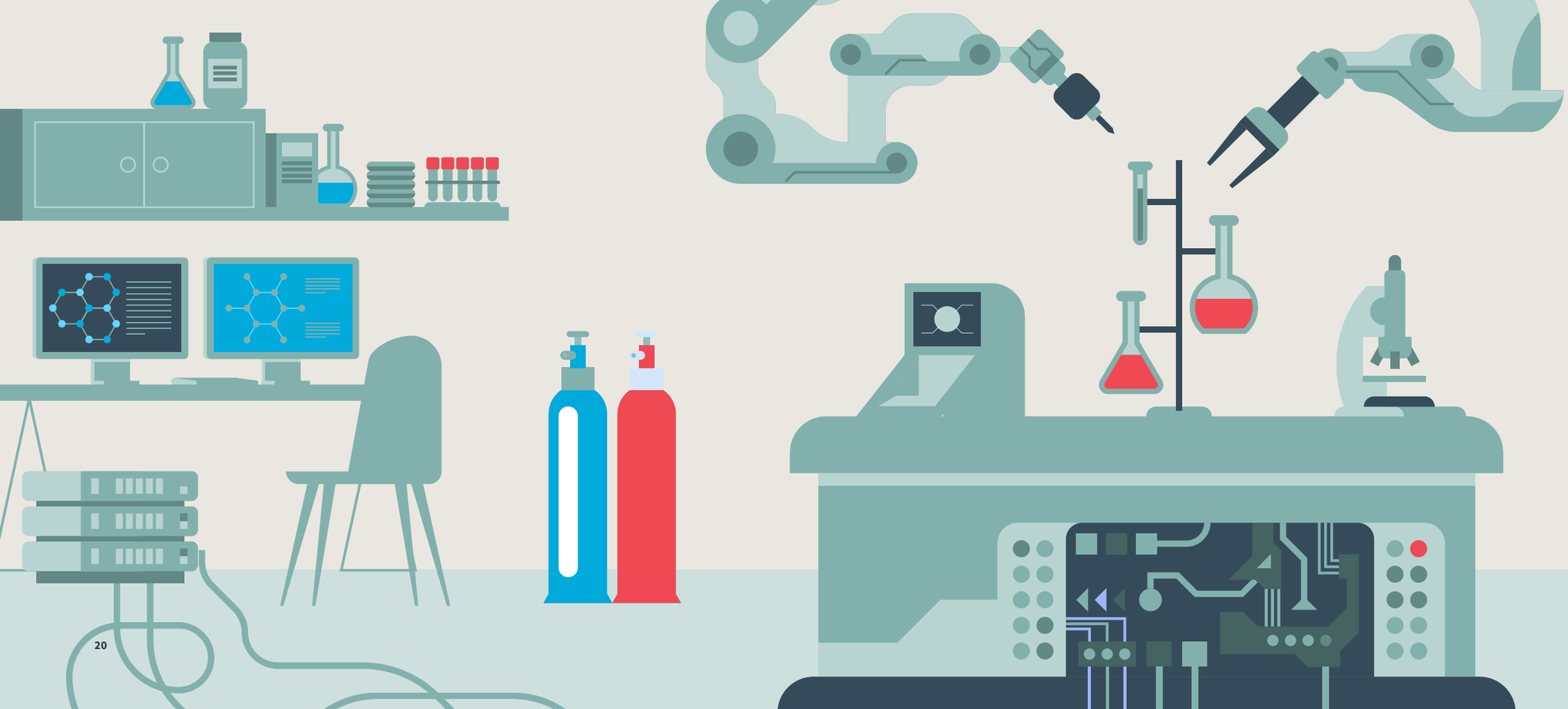
Getting rid of the human factor for non-critical processes can improve test accuracy and expedite data flow.

Empowering you to focus on the future

Walkaway time is lengthened by integrated lab automation. This opportunity allows lab scientists to work more creatively, reengage in cutting-edge research and continue their development instead of being constrained by manual tasks.

The value provided to the customer

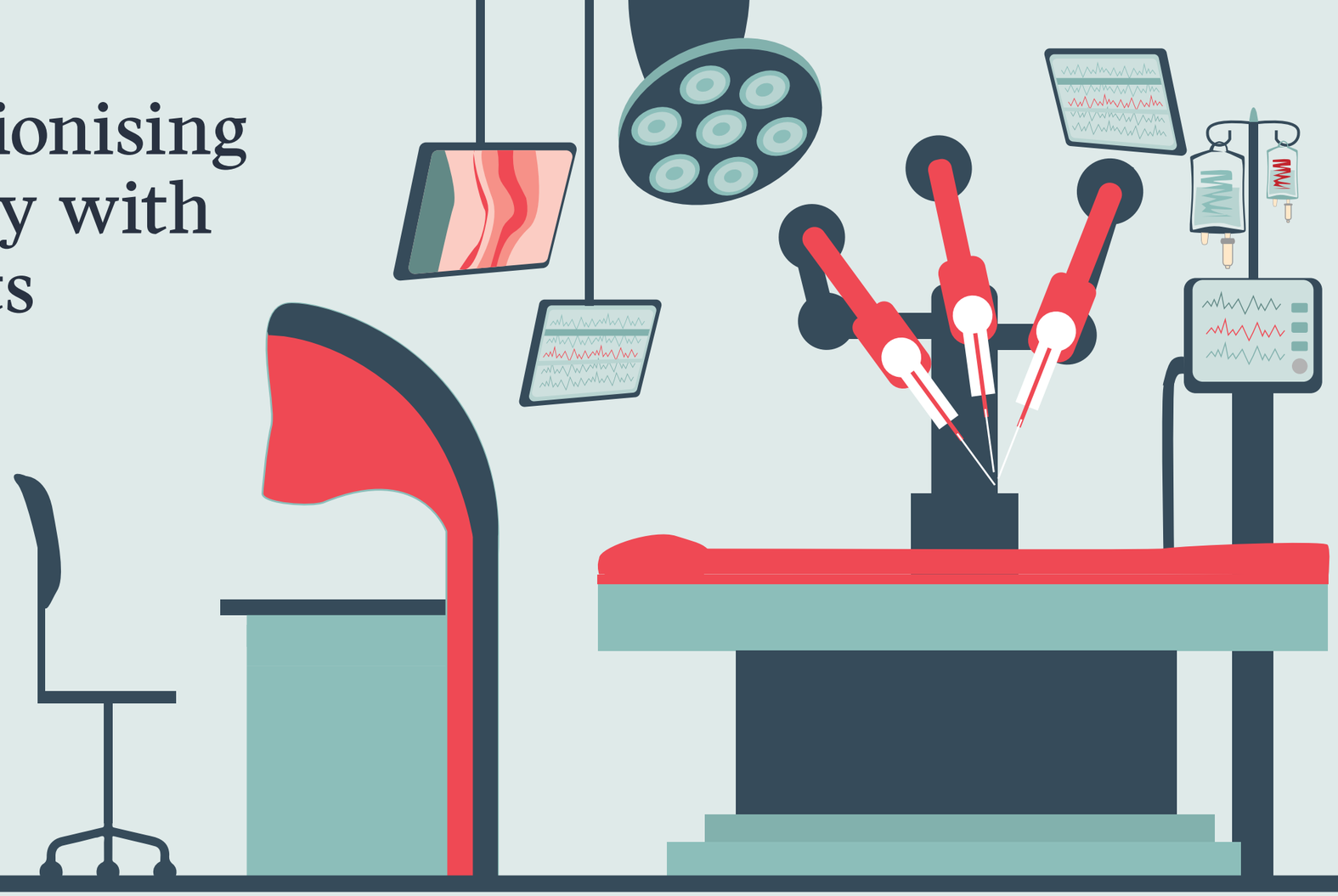
1. Shortened Time to Market.
2. Guidance for regulatory requirements and Quality Management System (QMS).
3. Fully LIS-integrated medical device.
4. Agile development.
5. Improved UX, with the same look and feel as existing lab devices.
6. Reusable and scalable solution.



Case study: Revolutionising the future of surgery with high-precision robots

The healthcare industry is continuously evolving, and with technological advancements, robots are becoming increasingly prevalent in our daily lives, including in the healthcare sector. One such area where robots are making a significant impact is in the field of surgery, particularly in minimally invasive laparoscopic procedures.

By Alejandro González



Within this field, ERNI is collaborating with a company that specialises in developing robots for minimally invasive surgery, aiming to universalise high-precision surgeries to enhance patient care. Our customer has built a state-of-the-art robot designed to support surgeons in performing more accurate and efficient surgeries. ERNI is contributing to making the software to control the robot.

The robot comprises two subsystems – the Console Unit, where the surgeon controls the robot, and the Robotic Unit, where the arm movement is executed according to the surgeon's control movement. The robot is designed specifically for laparoscopic surgeries, and the surgeon can view the laparoscope image on a 3D display located on the Console Unit. The robot is versatile and can be used in various medical fields, including urology, gynaecology and gastrointestinal interventions, which are the most common and crucial surgeries that can be performed using the laparoscopic technique. The precision and accuracy of the robot are unparalleled, as the robotic arms replicate the surgeon's movements with an error lower than 1mm in translation and lower than 1° in orientation.

As a medical device, obtaining the necessary certifications guarantees the product's quality and ensures its hospital usage. The product is classified as a Class III Medical Device, the highest and most complex classification possible, as its use can lead to severe injuries or even death of the patient. Hence, everything must be analysed and studied following stringent regulations. One of the challenges encountered in this effort is that a group of about 25 experts from multiple companies work together in a single location to design and develop all the mechanics, electronics and software for the client. Hence, effective coordination between all the team members and other involved teams is essential in achieving the project's goals on time. Developing such a complex product requires strong leadership, smart communication, and cooperation to succeed as a team.

ERNI experts are an integral part of the team and make up a crucial part of the robot's success. Our experts are involved in all areas of the development lifecycle from the management of the software team, including software requirements elicitation, risk analysis, software architecture and software development to software testing and software state reporting.

As of now, the robot has entered the preclinical assay phase and is on track to be ready for the medical market by next year. The aim is to obtain the CE mark in mid-2024, guaranteeing safe surgeries for patients in the near future. Coming up next, the customer plans to integrate artificial intelligence, computer vision and data analysis into the robot to further enhance its capabilities.

In conclusion, the successful collaboration between ERNI and our customer will help revolutionise invasive surgery. With the use of high-precision robots, surgeries are set to become more accurate, efficient and safe for patients, ultimately improving patient care. The product is a testament to the power of technology in the healthcare industry, and we can only expect more exciting advancements in the future.

Beyond testing:

ERNI Labs – pioneering the future of MedTech with predictive maintenance

By Ares Cabó Carrera

The environment

From point-of-care to laboratory medical devices, the market is constantly growing, and with it comes the need to test them – not only during their on-market period but also until their end of life, especially with the entry into force of the regulation for in-vitro diagnostic medical devices (IVDR). In addition to the instrument's performance in terms of the measurement, any additional functionality, as well as its hardware, shall be extensively tested, as decades can pass between the first software release to retiring the product.

What we offer

As part of our partnership-based technology services, we have our ERNI Laboratory in Sant Cugat del Vallès (Barcelona), which complies with the Biosafety Level 1 (BSL-1) requirements, the lowest security level for handling biological material. This means the material handled in the laboratory does not pose any risk to healthy adult humans and presents a minimal potential hazard to laboratory personnel and the environment. With our laboratory, we can support you from the software development analysis and feasibility phases until the release, including the verification of medical devices. Our laboratory is unique because we are ready for a quicker ramp-up to working with hardware. We are also ready to maintain and test specific machines such as medical devices. The whole package is then completed with software developers and testers experienced in MedTech projects, along with lab technicians and lab managers.

Case study: The customer and their challenge

One of our customers, a world-leading research-focused healthcare group in the fields of pharmaceuticals and diagnostics, was looking for a provider who could support them in the software development, verification process and maintenance phase of some of their key analytical and pre-analytical devices. It was critical to maintain the existing processes to keep compliance and ensure quality. The customer also needed time to focus on core competencies and new technologies to remain competitive.

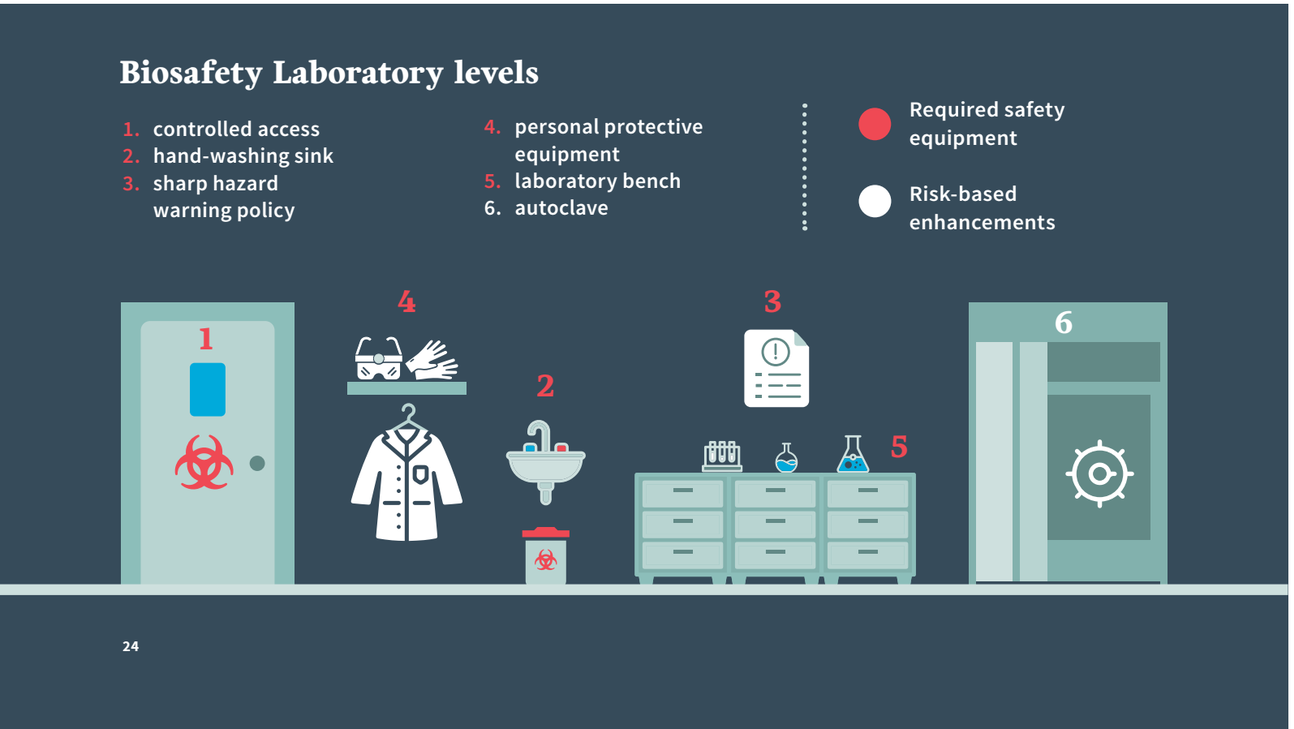
The solutions

For one of those medical devices, a system used in virology and blood screening, we started performing the Software Product Care in 2016, and it continues today. By having a laboratory with two instrument lines and subject matter experts, we were able to conduct investigations of field cases and internal customer cases as well as assisted support requests for software and hardware as if they were performed in house.

Our expertise in MedTech, highly regulated environments and testing was crucial in our customer's decision to choose ERNI. Together with our BSL-1 laboratory, we also started a "Digital Twin" initiative to gather data and use it for scheduling predictive maintenance – which reduced service costs and downtime of systems at the end customer's laboratories, among other benefits. Any downtime in a laboratory is critical; it means that patient measurements cannot be performed in a timely manner, and therefore it has direct consequences on patients' health. Additionally, any malfunction of a medical device could impact the accuracy of the patient's measurements, directly affecting the patient's health.

In a world where the tendency is to provide more with fewer resources (in the health ecosystem) and with longer life expectancies, we need to optimise all the resources invested. Having predictive maintenance contributes to this.

At ERNI, we know our way around medical devices in and out, and we have the environment and tools to carry out development verification and product care.



Ares Cabó and Germán Marín in an ISO 13485 certified ERNI laboratory

How can high-quality software be developed in MedTech?

Software development is still a young field in the MedTech sector; however, it is of growing importance. In Switzerland alone, the annual increase in sales (before COVID) was 6% per year. New decision-making processes and workflows must be established and aligned with existing products and processes to keep up with the high pace of innovation. High-quality, secure products and a stable development process are of utmost importance. With this article, we will be looking at the following two questions:

By Nadine Broghammer

How can this be done? And how can the Agile way be of help?

It is widely agreed that using the benefits of software for improvements in medical and health areas – for example, blood analysis – is the thing to drive towards. Various fields have emerged over the last several years; they range from software-in-product appliances for customers such as hearing aid devices or new software for laser eye surgery equipment to new video game technologies helping children in cognitive behavioural therapy.

All those advancements have the well-being of the patient or user of the technology product as a common focus: To this end, principles and guardrails for technology development must be implemented. In 2019, the German parliament approved the new Digital Healthcare Act, driving the digital transformation of the healthcare system forward for the benefit of patients.

Especially in the medical and MedTech environment, it is crucial to put the patient at the centre of attention. High quality standards have to be reached, especially since the devices are used in medical care, and any imperfections might have an impact on human life. To ensure certain levels of quality, security, standardisation and alignment, regulators such as the FDA, EMA and PMDA Swissmedic help us to find assurance. When it comes to software within a medical device or software as a medical device, and thus to the development process of software, a few clarifying concepts have to be taken into account. Furthermore, fundamental certificates such as ISO 13485, ISO/IEC 27001, ISO 14971 and IEC 62304 have to be considered when developing software products. Complexification is not the goal!

What role does agility play in software development?

Modern software development (including software development in MedTech) follows an evolutionary strategy, acknowledging that the user needs are not fully understood at the beginning. Moreover, these needs may change, and requirements may not be defined upfront. A DevOps mindset brings clarity; this culture and set of technical practices is part of Agile product delivery and enables continuous flow where quality and security are built in at every step and where solutions are architected for change.

The pioneer David Farley describes this effective software development process with two core principles: first, learning and exploration, and second, managing complexity. Contemporary frameworks, methodology and concepts highlighting the above are often referred to by the term agility.

The evolutionary life cycle approach of modern software not only puts the patient in the centre but it also satisfies the previously mentioned regulatory requirements of medical and MedTech environments for qualitative and secure products. The Technical Information Report 45 (AAMI TIR45) bridges the gap and provides written guidance on what has so far been implicitly applied. The TIR was developed to align Agile software development practices and their associated beliefs with the regulated medical world and to foster the focus on human safety, risk management and quality. Even without being directive or referencing beyond the FDA, this pioneering document earns a lot of respect and application.

Through alignment in goals and values between contemporary Agile software development and regulatory perspectives, high-quality software can be developed in medical and MedTech environments.

Also, in the business field of MedTech, we feel the pressure to innovate and speed up in the context of Agile software development. True to the oath of protecting and improving the lives of patients, medical and MedTech companies must choose their life cycle model wisely. The process model described by Agile ways of working can bring the benefits of enhanced delivery and patient focus.

Furthermore, integration activities on various work levels bring much-needed visibility and transparency. Integrating small parts (or stories) into an increment, and releasing dedicated parts on demand provides feedback to the stakeholder and the various people working within the system.

Generally, we aim for an agreed product or outcome of our software development process. In the fields of medical and MedTech, those agreements and characteristics are compiled in a Design Input (DI) Document and a Design Output (DO) Document. Activities have to be mutually defined and understood to have an agreed DO. The valuable insights from the DI Document and DO Document combined with the Definition of Ready and Definition of Done of work (or stories) align with agility and the regulations of medical and MedTech environments. This is also true for releases of document versions; this can be done incrementally with every increment delivered (aligned with the definition used in AAMI TIR45) or per Release Version. Therefore, defining the release cycle is a crucial element for MedTech companies.

Hence, medical and MedTech companies have to define those review and control processes, irrespective of whether they follow Agile methodologies and frameworks. Complexification is not the goal; evolutionary design of products and Agile thinking are.

MedTech is in the lead. How can other industries learn from them?

This transformation process of medical and MedTech companies towards an evolutionary design within given regulatory boundaries brings excellent insights into the regulated business world. Other business areas such as FinTech, energy and telecommunication have already started their transformations into more tech-related aspects and digitalisation. Of particular interest could be the product aspect of the transformation; transformations are complex per se, but the production aspect, based on the evolutionary design of physical products, brings yet another layer of complexity. Therefore, it can be concluded that MedTech is leading the way.

What role does ERNI play?

We are pioneers of Software Engineering. We have great respect for performing a transformation within regulatory boundaries and help you embrace the challenge. We are convinced that alignment in all we do, and a shared mindset on why we do it, are vital. As your trusted advisor, we help your business to achieve precisely that.

Interview with Dr Daniel Heller

Dr Heller has been Chairman of the Board of Directors of Kantonsspital Baden (KSB), Switzerland, for more than 8 years and has played a major role in the hospital's digitalisation.

By Roy Müller

What does a hospital need today to be a leader in digital transformation?

Technological innovations – often described with the buzzword digitalisation – are also changing the healthcare industry rapidly and sustainably. We are probably at the beginning rather than the end of a rapid development.

What is important here?

We need proximity on all levels; first and foremost in hospital management:

Proximity means focusing on the hotspots where change is taking place.

We need to be ready to anticipate and not shy away from constant change.

Being close also means investing in projects internally and externally in cooperation with others: Internally, in interdisciplinarity – this is the only way to come up with the best solutions. Externally, by building expertise and treatment chains and developing optimal patient pathways.

Being close also means that we want to be there where new diagnoses and therapies are being considered and developed. I'm thinking of universities, the Paul Scherrer Institute (PSI) and the thriving culture of innovative startups.

What is the best thing that has happened at KSB in terms of innovation in recent years?

In early summer 2018, we established our Health Innovation Hub at KSB. We cooperate there with leading research and educational institutions such as the PSI, universities, including the Swiss Federal Institute of Technology Zurich (ETH) and the University of Zurich or the University Hospital Zurich (USZ). The Hub is our platform for contact with numerous technology partners and exciting startups that help the hospital innovate. In this way, we pave the way for an even better healthcare.

To what extent is artificial intelligence (AI) used in these innovations?

Artificial intelligence is used in modern imaging procedures, where it supports the specialist's findings by means of initial diagnosis. For example, KSB has started a project to develop an AI tool for the automated detection and reconstruction of uterine axes from 3D MRI data sets – an approach that does not yet exist in this form.

You say that the innovative power of a hospital is thus dependent on technology companies and startups that develop solutions and products and make them marketable. What are the expectations as a hospital of partnerships with technology companies?

Hospitals like KSB depend on comprehensive technological partnerships because medical technology equipment is the central nervous system of future-proof healthcare. A partnership includes, for example, the procurement and maintenance of imaging systems (imaging procedures) through to training programmes and support for research activities, for example in the field of mammography. KSB will receive state-of-the-art medical equipment over the next few years which will enable it to further improve patient care in the region.

What are the obstacles preventing medical specialists from working even more efficiently?

First, the excesses of government regulations, requirements and interventions. Second, a lack of cost-covering tariffs that would allow the hospital to afford innovation.

Apart from government regulations, where do you see the greatest need for action on the part of medical technology manufacturers?

If a hospital wants to expand its leading position in the transformation of the hospital landscape through technological innovation, infrastructure and process efficiency, it needs technology partners. The partnership must take place at eye level, i.e. manufacturers must know and take into account the individual needs of hospitals as well as patients. This is often neglected today. Only this way, however, can the implementation of new technologies be optimally process-oriented and take place in patient-centred structures. Through continuous training of the staff, the partnership must also ensure that the technology is applied optimally.

If you were a patient, what would you expect from your hospital in terms of digitalisation and innovation?

A functional and functioning electronic patient dossier with all my relevant health data and files.

What will your hospital look like in 20 years in terms of technologies, innovation and processes?

Twenty years is infinitely far away – I simply cannot say. Because in a time when medical knowledge doubles every 70 days, the bon mot applies: "Forecasts/visions are difficult, especially if they concern the future."

Agile working in medical technology

Revolutionary ideas have a way of spreading in all directions, and Agile is no exception. What started in software development in the late 1990s can now be found in the business world everywhere. Even highly regulated industries like medical technology can no longer escape this trend – and that's a good thing.

By Javier Hernández Braña and Cristian Sances Ibáñez

A highly regulated environment

Medical technology industries are even more sensitive to their final product than other industries because the final result is people's health. For this reason, all kinds of different regulations are in place to ensure safety and quality in all the processes involved, and any medical technology industry needs to follow them.

Traditionally, in order to ensure compliance with regulations, companies have approached this challenge by using highly strict control frameworks, commonly based on old waterfall models, where a few people try to control every aspect of product development and compliance.

This comes with a price: first a false sense of security; medical devices are highly complex products, and a small group of people cannot control everything. In addition, if all the decisions come from this group, companies are not flexible enough to find solutions to the challenges that arise. As a result, it also becomes challenging for them to innovate. In a world where customer requirements and their environment change constantly, companies need to be able to adapt virtually every day.

Does it mean we should stop working with a "waterfall" approach? No, it does not; it means that we need to adapt our way of working by adding new techniques and approaches. For example, we always need a final validation. Why? Not only because, as we said, our final product is people's health, but also because when validating these products, we need resources such as laboratories and operating rooms. And those are finite and not always available.

While both approaches require a final validation, using an Agile approach, any medical technology project will get more frequent feedback about the verification processes. Moreover, in shorter iterations (3–4 weeks), we can ensure that we deliver value along with the needed quality because verification is part of the iterations themselves.

Even though working in MedTech means working under strict regulations, an Agile framework enables rapid changes and fast development while complying with these regulations and policies. As a result, teams are capable of inspecting and adapting every day, iteration over iteration.

Working in an Agile environment

This transition may be a challenge, but it is worth it, especially in a "VUCA world" (volatility, uncertainty, complexity and ambiguity) where the context may change at any time.

When working Agile, we are able to produce small functional parts of a product after each iteration – so-called increments. We are also capable of generating MVPs (Minimal Value Products), and with each new iteration, needs and requirements can be introduced flexibly. This procedure makes it possible to complete a product more flexibly and to obtain feedback faster, which in the end leads to significant savings and top-design products.

As we said before, another highly relevant advantage is that it is easier to ensure that every increment of functionality has the expected quality, and that it does exactly what is needed. On the other hand, if we waited until the final product as old waterfall models do, we would have to check all the functionality, small piece after small piece built months before, in an endless and overwhelming effort – an almost impossible and very expensive task.

Verifying each increment on its own brings yet another advantage: additional security. Instead of just checking the new parts, we are incidentally rechecking all the previous ones – which is an essential part of the Agile way of working. This additional safety aspect combined with the higher flexibility is one reason why more and more companies are adapting their current way of working, especially in medical technology, where new scientific findings need to be easily integrated.

"When working Agile, we are able to produce small functional parts of the product after each iteration."

Customers and their expectations

Having more frequent and verified product increments and the possibility of building MVPs helps companies to reduce the time to market for new updates and products from years to months – a huge step in such a regulated environment. We also become capable of detecting bugs earlier, being able to fix them much faster and to have new updates 100% verified and ready for the validation phase.

This strategy has been tested and proved in several other areas, most conspicuously with our smartphones, where apps are constantly updated week after week, and nowadays, medical technology companies are able to benefit themselves as well, having only a single constraint on the availability of their resources, such as laboratories, as we mentioned previously.

Imagine this in the near future: instead of releasing a major update of your software every year, releasing smaller updates with bug fixes, closed security gaps and smaller new features on a quasi-weekly basis. And normally, bug fixes for the features implemented last time come with the next one. No one wants to wait a year for new features, and certainly not for bug fixes or closing security gaps.

With this strategy, for example, medical technology companies could release five big new features over a year instead of all at once. This way, each feature will be validated separately – reducing risks and ensuring product stability – and if one of them needs any adaptation/correction, we are able to plan and deliver on the next date available, not needing to wait for a whole year.

Whether it's new findings, bugs or simply changing product requirements, things change all the time, and you can react better to all of them in smaller iterations and adjust the plan accordingly. This is important in all industries, but in medical technology, it ensures companies' survival and patients' welfare.

Testing automation in MedTech

Software testing should be anchored in every project in order to develop a high-quality and reliable software product. A professional software testing process is a commitment by the company to take quality aspects seriously and to work by defined guidelines and principles to deliver a functional, stable and secure software system.

By Florian Gumhold and Ashwini Bhat

Medical employees are obligated to complete a medical degree to obtain professional skills in the field of healthcare. These experts need to rely on software systems to apply their expertise in medical facilities and to support the best treatment of patients. A lack of quality assurance can lead to the danger of death, and therefore, quality criteria are not only set by vendors but also by regulating authorities. As there are many guidelines to be followed to achieve approval of a medical device, the usage of test automation is beneficial to guarantee comprehensive, consistent and documented software testing. With test automation, we can combine functional knowledge with technical expertise, which allows us to run more frequent test runs faster to improve test coverage. Having a framework to automate is not enough here; we need to understand the functional process to have a good set of automation tests.

Regulations in healthcare

Due to the high level of risk in the healthcare industry, the software development and testing process is regulated by authorities. Any software developed or tested needs to comply with ISO 13485 and IEC 62304. Medical devices are used for different purposes in the whole patient care process. Software systems are responsible for creating and collecting relevant data, consolidating and displaying information or even keeping patients alive. The risk of malfunction and unreliability is mitigated by complying with regulations. The FDA (Food and Drug Administration) is one of the biggest regulating authorities in the world and is responsible for the approval of medical devices in the USA. The verification and validation of software is essential when it comes to fulfilling high-level quality criteria. Verification and validation basically describes a documented process which aims to prove that a software system has been built and can be installed correctly and conforms with the expectations of the end user and the requirements defined upfront. The FDA does not dictate how the verification and validation process needs to be performed in detail, but the organisation provides a general guidance document with principles of software validation to fulfil the rules of approval.

The EMA (European Medicines Agency) is responsible for approving medical devices in Europe. Since the FDA is the most restrictive authority, it is common to approve new medical devices in the USA first and then in other countries. This approach subsequently leads to a higher certainty for companies to have their medical devices allowed on other markets too.

The FDA defines two requirements which need to be fulfilled to achieve approval:

1. The developed product and processes used need to fulfil the standards of the FDA.
2. Every step in the validation and verification process needs to be documented.

Challenges and types of testing processes

Based on almost 30 years of experience in the MedTech industry, at ERNI we have faced the following challenges in Medical Device Testing:

- **Device compatibility**
  With the need to have data available on the move in our everyday life, we need medical devices and apps to be compatible with the web and mobile devices. It is critical that these applications are accessible and safe with all necessary updates.

- **Security breaches**
  Security is one of the most critical aspects of medical devices. To avoid any security breaches, it is necessary to incorporate security tests in every stage of development.

- **Cloud adoption**
  For business development, migrating data to the cloud is very important, which raises concerns about network and data security. To overcome this, we need to adopt cloud application testing and security testing practices during data migration to ensure a more secure network and the safety of cloud data.

To overcome these challenges, especially in healthcare, a professional software testing process is required to fulfil regulations and high-level quality criteria. The software testing process used needs to be traceable and documented. Besides the functional testing of requirements, the following test types need to be performed:

Usability and user experience testing

This testing verifies that the user interface is intuitive and easy to understand and that each element on the screen does what it is intended to do. Problems and complexity in the user interface can lead to confusion and wrong inputs, which could have fatal consequences.

Performance testing

Performance tests guarantee that the medical device can work properly under stress and in high-load scenarios. The software system is not allowed to decrease performance or fail in specific high-load situations. Otherwise, this would lead to the danger of death.

Conformity testing

Regulating authorities have defined production criteria that must be fulfilled to assure that medical devices are fully secure and reliable. Tests against these regulations ensure that approval is granted and maximum reliability is achieved.

Interoperability testing

Medical devices are intended to work in embedded environments and to exchange data and information with other systems. Interoperability tests ensure that medical devices can communicate and interact with these software systems.

Reliability testing

Reliability defines the ability to work on a high level over a long period of time. These tests are intended to prove that the medical device works reliably in every situation, even after a long run time.

Data-driven testing

Manual testing for a huge data set is time consuming. Hence, with test automation, we can create large sets of data and test them in multiple executions.

Authenticated validation

Test automation allows setting a large set of valid and invalid test data to ensure that the device application's user authentication features are functional.

Test automation

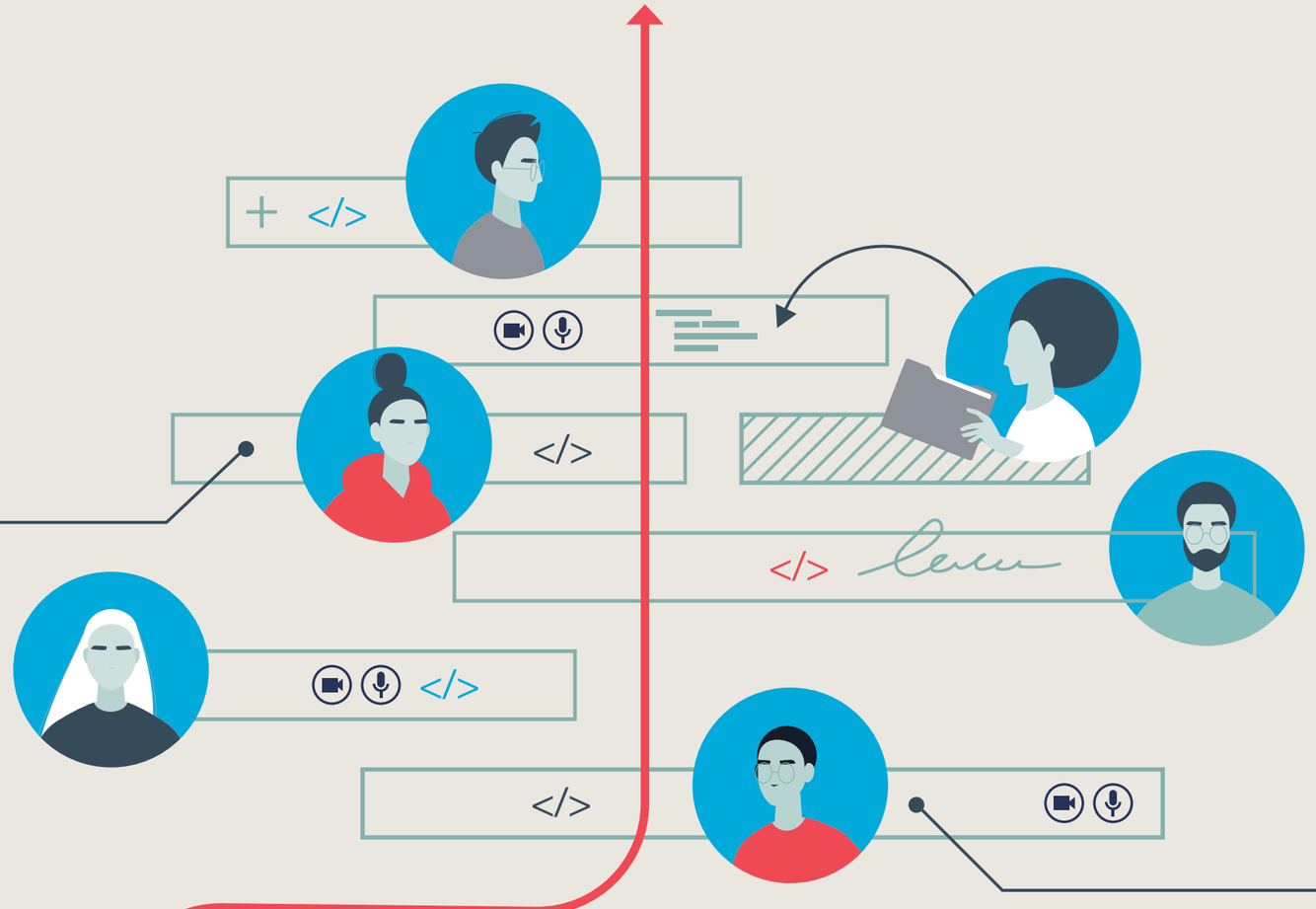
Testing medical devices is a responsible task which requires more attentiveness than in other industries. There is no excuse for malfunction, outage or performance issues. To develop a compliant software system, the testing process should be supported by test automation. Automating tests supports faster test execution and higher test coverage while eliminating human error. In addition, automated tests are documented by generated execution reports, reducing costs. This increase in efficiency results in more time for manual testers to find errors based on their experience and intuition by performing exploratory testing and other meaningful tasks. However, setting up a test automation framework requires expertise and technical know-how. A test automation strategy must be established to define the scope, architecture and test environment. Medical device testing can take advantage of the full capacity of test automation. Not only can functional testing be automated, but performance and reliability testing can also be conducted to prove the conformance of non-functional requirements.

Conclusion

Conducting software tests in healthcare is even more important than in other industries as it is necessary to ensure optimal device performance without major risks. Software systems need to be tested extensively according to guidelines and regulations. A standardised and professional software testing process is the basis for fulfilling given regulations. Due to the comprehensive testing scope and different types of risks, test automation is essential to support test activities. The approval of medical devices does not depend solely on developing software but even more on testing it appropriately. Test automation improves accuracy and test coverage, which in turn helps companies to ensure the dependability, safety and effectiveness of the device in use.

Case study: Building a Managed Capacity team for digital transformation

By Anastasiia Shelukhina



Challenge

In today's times, when IT is indispensable and almost everyone has heard of the term "digital transformation", many companies are asking themselves how can they enter this IT world. Since these companies have little to no experience with IT and software development, they need qualified professionals who have the necessary know-how and can support them in the transformation and development. One of the possible solutions to this challenge is the concept of Managed Capacity.

ERNI offers clients the opportunity to have a team built and managed for them. The team is assembled to fit the tasks and challenges of the client. The client benefits from all the knowledge and experience that the team members bring to the table.

Solution approach

One of our clients from the MedTech sector decided to set up a team, and we were able to accompany them on this exciting journey.

It was decided that a Managed Capacity team would be set up in Barcelona. The preceding value-for-money analysis showed that the Barcelona location met the client's requirements best of all those evaluated. Barcelona is considered a MedTech hub, can be reached quickly from Switzerland and, with its universities, offers a large supply of well-educated talent. Barcelona is very popular with local employees as a place to live and work, as well as with those who travel there.

The reasons for building a team were very diverse, but not necessarily sector-specific. Many companies have similar challenges and all clients can benefit from the following advantages:

- **Global accessibility and acquisition:** The demand for experts is increasing. To meet the demand, the Managed Capacity solution enables access to global talent pools. Different geographical locations offer a variety of universities, fostering diversity and development of talent. As a result, the combination of such candidates enhances team performance, market know-how is directly acquired and the company is thus strengthened.
- **IT talent:** In our fast-evolving world, know-how determines the success of companies. Therefore, the search for talent and the development of know-how go hand in hand in measuring the development potential of a company. A Managed Capacity project not only provides access to talent but also promotes the development of know-how through the exchange and diversity of experts.
- **Short time to market:** Each team is assembled for the client-specific requirements and tasks. Thus, the perfect size of the team and speed of development can be achieved with shorter development cycles. In addition, the customer benefits from the entirety of ERNI's know-how, established processes and existing infrastructure.
- **Digital transformation:** Our teams support the customer on their path to digital transformation and the implementation of the Agile mindset. We help them define suitable processes and structures and build an efficient infrastructure.

The Managed Capacity project process

The project starts with the ramp-up phase, which forms the foundation for the entire project. In this phase of the project, the initial getting to know each other and the kick-off take place. The project and the necessary infrastructure are set up and the team is built. For example, the collaboration model, project manual and contract are defined and all the necessary tools are set up. Already in this phase, the most important architectural decisions are made and the first requirements and design proposals for the product to be developed are collected.

After the ramp-up phase comes the operational phase. The team and the first backlog are ready and the development of the product can begin. ERNI takes responsibility for further recruitment (if necessary), introduction and management of the team. The phase continues until the desired result is achieved and the project stakeholders can start with the acceptance. The goal of the project does not necessarily have to be a finished product; it can be an MVP or other partial result. For example, the result of the project described in the article was a delivery centre in Barcelona that develops various software products especially for this customer.

Summary

Finding the right experts for short- or long-term MedTech projects has been shown to be fraught with many challenges. Therefore, Managed Capacity solutions have often proven to be the best options, offering many advantages. For example, our clients have benefited from the expertise and fast delivery cycles. In addition, they now have their own delivery centre, which allows them to make further product developments and thus enjoy a strong market position.

Case study: Breaking data silos and implementing big data & AI for drug development

The customer is one of the world's largest pharmaceutical companies, dedicated to researching ways to improve health through high tech and innovation.

by Enric Domingo Domènech and Aitor Mars Pérez

The challenge

Researching and developing a new drug is a long journey that can take up to 15 years from discovery to an approved medication. Moreover, it requires significant investment, and only a few will succeed. In addition, manufacturing these medicines involves a complex and highly controlled set of processes where machines and pharma operators work together through different interfaces and software. While coming up with a novel drug and getting it approved is challenging, scaling up its production to meet the needs of the global health market (while ensuring its high level of quality) is not a trivial step.

The customer previously had their data distributed across multiple data silos. Each data silo was controlled by one department or business unit, isolated from the rest of the organisation. So, accessing the data or collaborating between departments was an arduous journey.

Moreover, more than one department could use the same data source, so each team had to develop and maintain its own pipeline. This meant spending more resources.

The solution

First, the company needed to collect, manipulate and analyse massive amounts of data, including, among other things, R&D processes and patient data. Using big data technologies, ERNI broke the data silos and created a data platform where scientists have clean, reliable, consistent and linked data to speed up new drug R&D. Moreover, thanks to having a centralised data platform, the departments can now collaborate among themselves. Therefore, the R&D time has been reduced.

Second, the proper integration of artificial intelligence models into their data pipelines has increased their research outcomes and at the same time improved manufacturing efficiency and scalability.

ERNI has provided development services and support across different company branches, from research to production, leveraging their previous procedures and systems to a new data-centric model where decisions can be made based on accurate data insights. Furthermore, ERNI has contributed to the customer's cloud adoption for data storage and computing resources while ensuring security and compliance with pharma regulations.

Insights and takeaways

In this issue of .experience, we have learned that the challenges in MedTech are similar to those in almost all industries. In addition to the economic challenges such as price pressure, inflation and the maintenance of supply chains, most are concerned with staff shortages, technical challenges with digitalisation and data security, as well as the business challenges of digital strategy and service design of the future. Along with this, many decisions are delayed because of the fear of doing the wrong thing.

By Christian Glück and Reto Ruch

In our experience, successful companies are those that have a clear digitalisation strategy on the one hand, and on the other hand move forward in small, incremental steps where they can learn. They rely on combined teams, where product management and development form one unit as a team and are also in the same organisational unit.

It is important to set a clear focus and to combine and complement existing elements in a meaningful way, so as not to start from scratch. Business hypotheses should be formulated and continuously reviewed in order to learn from them, draw the right conclusions and use them to change the chosen path. Successful companies know how to adapt the course during the journey, but never lose sight of their fixed star.

It is always important to keep the end consumer in mind – in MedTech it's ultimately the patient – and to align the solution with them. It is also important to combine the global influence of this solution in a meaningful way. In the case of medical software solutions, it can increase efficiency or even save lives.

Digitalisation is currently taking place and new technologies are constantly opening up new opportunities. Therefore, it is important to continuously assess one's own potential, to start with digitalisation and to gain experience. In MedTech, it has proven useful to start with services outside the regulations or at most with Class I services, learn from this and then move into the regulated area. Reliable partners can also help to prevent avoidable mistakes, so that the first successes can be celebrated quickly.

About ERNI

ERNI stands for Swiss Software Engineering. What are we really interested in? How we can support you and your employees better than any other company in developing and marketing software-based products and services. Our global platform for software development in combination with a sound understanding of the market forms the framework for our customers' success. Our team also implements complex projects, empowers people and delivers outstanding customer solutions in the shortest time. We apply the Swiss mentality with behaviours such as consensus building, pragmatism, integration, reliability and transparency on a global scale – and have done so since our foundation in 1994 together with our great team, which is the basis for successful software projects. Today, the ERNI Group employs more than 800 people worldwide.

About .experience

In this magazine, which is published couple of times per year by ERNI, we provide information about important learning experiences that we have had in our daily work in the areas of collaboration, processes and technology.

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