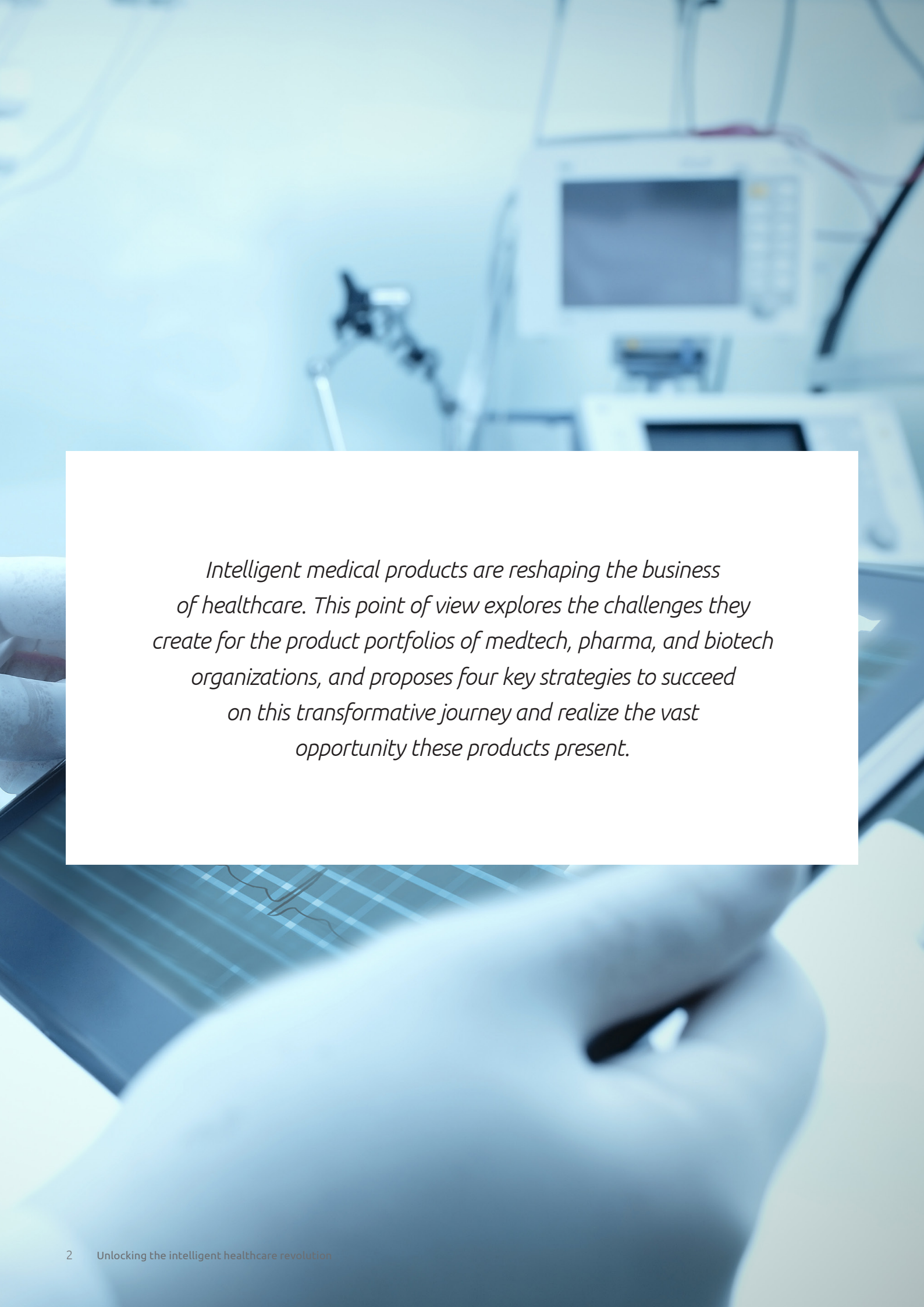Capgemini engineering

UNLOCKING THE INTELLIGENT HEALTHCARE REVOLUTION:

FOUR STRATEGIES TO SUCCEED WITH CONNECTED MEDICAL PRODUCTS

Intelligent medical products are reshaping the business of healthcare. This point of view explores the challenges they create for the product portfolios of medtech, pharma, and biotech organizations, and proposes four key strategies to succeed on this transformative journey and realize the vast opportunity these products present.

THE FUTURE OF HEALTHCARE IS INTELLIGENT

In the last decade, pharma, biotech, and medtech companies have all been investing in and acquiring intelligent medical products, with many more in the pipeline.

These solutions form an increasingly broad suite of software-based products that acquire patient data, analyze it, and use it to provide medical insights upon which diagnoses, or healthcare interventions, are made.

These fall into two camps. One involves adding software and connectivity to physical medical products, such as heart-rate monitors. The other involves creating entirely software-based medical products (Software-as-a-Medical Device, or SaMD), such as AI tools, to gather insights from medical sensor data or apps that incentivize drug adherence.

These new software activities promise to move medicine out of the hospitals and into daily life. They open the door to communication channels to patients and the collection of real-world data on people's health. This can result in earlier diagnoses and personalized treatments, as well as provide remote services with less need for expensive hospital care. The data generated also provides a source of real-world evidence, which can

show regulators and buyers that products are safe and effective and enable reimbursement by demonstrating improved outcomes.

Perhaps most significantly, they offer the promise to transform business models – enabling companies to move from selling products to selling health insights or outcomes. Where once healthcare companies sold heart-rate monitors that would be used by a doctor to inform a diagnosis, they can now deploy software into patient-held devices and sell data-driven insights into heart health. That is a much more valuable offer.

This shift to value-based healthcare offers huge benefits to patients and efficiencies to healthcare systems. But it also transforms the way medical devices, and even drug regimens, are developed, sold, regulated, and managed over their lifetime.

In this paper, we explore the challenges and propose solutions for how to develop intelligent medical products in a way that is rigorous and secure, but that enables rapid innovation that is cost effective, minimizes time to market, ensures smooth compliance, and efficiently supports post-launch maintenance processes.

THE CHALLENGE OF DEVELOPING INTELLIGENT, CONNECTED MEDICAL SYSTEMS

Connected Health represents a big shift. No longer do companies develop and launch products solely for use by experts in medical settings. They are launching connected medical solutions that are fundamentally different; firstly because these devices' uses include the need to work with the unpredictable behavior of non-experts in everyday settings, and secondly because they must be continually managed and updated remotely.

To effectively build, launch, and manage intelligent medical solutions, life science and medtech companies must evolve to become much more like software companies.

They must develop products that not only carry out regulated medical functions, but that also have the software and backend IT systems to collect, share, store, analyze, and visualize sensitive medical data.

These products must be designed to work outside of the safe walls (and firewalls) of health institutions, with some SaMD products running on users' own mobile devices and using internet connectivity. They must deal with messy real-world data on user behavior, and protect themselves from cyber threats. They must be backed by systems that manage connected devices on the market, across multiple countries with different regulatory requirements.

They must be designed to integrate with and adapt to multiple third-party mobile sub-systems and connected platforms, each with its own lifecycle, beyond the control of the medical device manufacturer.

But – despite all this complexity – companies must innovate rapidly, as both traditional competitors and tech startups move into this space, looking to eat their lunch.

To innovate at speed, companies must move away from the linear product development process still common in biotech and pharma, and set themselves up to launch products that exist in a continuously evolving environment. They must embrace the agile approach of tech companies, within the context of the medical world's strict adherence to legal requirements around safety and medical data.

Yet these are still medical devices that inform serious health decisions. So, in all of this, devices must meet a plethora of complex and evolving regulations, both around the device itself, and on data, software, and cybersecurity.

HOW TO SPEED INNOVATION WHILE REDUCING RISK

1 EMBRACE THE TECH STACK AND SOFTWARE FRAMEWORKS THAT SUPPORT YOUR ENTIRE DIGITAL PRODUCT PORTFOLIO

Most companies are already on their journey to digitizing products. This is too often done on a product-by-product basis, either designing each product and its software from scratch, or buying in software solutions and bolting them on to products.

For software-enabled products, a whole-portfolio approach is far more sensible than product-by-product. Companies innovate far faster when they have the software fundamentals in place to support their entire portfolio. This broadly falls into two categories: the tech stack and software frameworks.

A robust tech stack

The tech stack comprises the underlying interconnected technologies upon which your entire portfolio of devices will operate – consisting of a cloud-based platform and a related software development environment.

The cloud-based platform is the infrastructure on which applications are built and hosted, and the central point for managing accounts and devices, sharing data, and integrating the whole product ecosystem in a single place.

The software development environment includes the processes and tools to develop and manage the software product, including development, integration, test, pre-production, and production. It ensures speed and consistency across products.

Software frameworks

Building software-based products efficiently and at scale requires our second fundamental of rapid software innovation: frameworks.

Frameworks are tried-and-tested approaches for building certain types of products that reduce a great deal of the work. They can include approaches to iterative product development, the core building blocks of the products, and blueprints that tie the pieces together. Frameworks provide consistent ways of working to innovate rapidly, while making it easy for teams to collaborate and pick up each other's work.

A good framework will include a library of pre-built, pre-tested software modules. These are pieces of code, built on a common software foundation, that make up common elements of a medical product that can be deployed into a wide range of applications across your portfolio.

Modules cover services, such as accounts and access management, consent, prescription management, appointment booking, device connectivity, therapy management, and EMR/EHR integration.

A framework also includes blueprints that provide sub-sets of functions to fulfill specific use cases, such as treatment adherence, remote monitoring, disease management, or decentralized clinical trials. A good framework allows modules to be flexibly combined and should also be flexible enough to integrate custom or third-party components.

A library of modules for IMPS should only use modules that are compliance ready. Modules are compliance ready if they are built in a medical grade, design-controlled environment using ISO 62304 processes with qualified tools, all necessary documentation, traceability, and automated test cases. The framework should be compatible with GxP non-device medical data systems all the way up to FDA/EU MDR device Class III/IEC 62304 Safety Class C.

You may design an innovative diagnostics AI from scratch, but you can also use frameworks to streamline the approach and quickly develop the bulk of standard elements that make up the rest of the product and production. It ensures speed and consistency across products.

The benefits of a modular approach

Using such modules makes everything more agile and can reduce new device development effort by 50% or more. Modularization and automation of as much as possible – especially in software verification – are fundamental to speeding development, increasing product quality, and reducing post-launch maintenance and compliance efforts.

A modular approach represents a sensible balance between designing from scratch and buying off-the-shelf software solutions for your medical product. The former puts you in complete control, but is slow and costly, and introduces lots of potential points of failure. The latter may be faster and cheaper, but makes it difficult to adapt and improve products post-launch.

A modular approach using frameworks removes a lot of the hard development and testing work, while enabling ongoing customization of individual building blocks without having to redesign the whole product whenever user or regulatory requirements change.

2 BUILD ROBUST DEVICES AND PROVIDE INTUITIVE USER EXPERIENCES

Designing and building state-of-the-art medical devices and platforms requires deep expertise in the product, the data, and the software environments.

Software must be written to work for the product, and the context in which it will be used. This includes an understanding of the sensors and inputs, and the connectivity used to interact with all other software involved. The importance of communication within the system makes deep consideration of cybersecurity and privacy essential. That is simpler if you own and control the device, but much medical software is designed to run on a phone, laptop, or third-party medical device, and so a clear cyber strategy is essential.

Additional thought needs to be given to how third-party systems outside your control may change over time (Apple releases a new major version of its operating system every year, for example, but also released 17 interim security updates in the past year). Maintenance costs can account for over 75% of total lifecycle costs. Wrong decisions in software design that don't build in sufficient flexibility can cause maintenance costs to explode and destroy the business case.

AI is the jewel in the crown of medical-device innovation, offering the potential to personalize advice and predict health outcomes. But AI can also be opaque.

High accuracy is not enough – we must be able to understand the reasoning. That means not only that the approaches to data collection are rigorous, but the whole AI design must be ethical – and include considerations such as clearly defining the benefit, transparency, explainability, privacy, safety, and development by diverse teams to minimize risk of bias – so both patients and doctors can understand and trust the recommendation.

Attention must also be paid to designing the user interface so that users want to use it. This means making human factors central to design for simplicity of use and visualization of data, but also to provide behavioral nudges through gamification and personalization to incentivize desirable behaviors (such as drug adherence or making the device part of a routine).

All this needs to be supported by robust and efficient processes to ensure products progress quickly, from feasibility studies, model-based systems engineering, design, and development, with checks throughout to solve problems before they become ingrained.

3   ENSURE DEVICE SOFTWARE WORKS EFFECTIVELY IN THE HIGHLY REGULATED WORLD OF MEDICAL CARE

When developing medical-grade software products, we must give due consideration to regulatory compliance. A small error can mean failing regulatory approval, setting projects back months, undermining market confidence, and potentially losing out to competitors. Remediation efforts, especially in response to an FDA warning letter, are usually extremely expensive.

The FDA list of **software-related recalls** makes for sobering reading: "software defect," "false upstream alarms," "firmware error," "login error," "software bug," "sensor failure," "cybersecurity vulnerability."

But compliance is also time consuming and can account for up to 30% of total product development costs.

Complexity is amplified as compliance expands into unfamiliar areas such as analytics, real-world data, AI diagnostic recommendations, remote patient monitoring, and sensor data interpretation – all of which are subject to still-evolving regulations, which may be new to life sciences and medtech.

The most efficient route to launching compliant products is to build compliance into the device lifecycle from the onset. Ensure your software development frameworks are aligned with regulations, with relevant checks and testing as you go. This can be accelerated by using pre-built compliance-ready modules for non-bespoke elements, as discussed above.

Speed overall compliance with different processes for different risk levels

It is also expedient to divide the product into modules for compliance purposes. That way, lower risk and non-medical components can be developed with less effort, reducing the overall burden.

We can think of a core of SAMD-components performing the heavy lifting – analyzing and processing medical data and generating insights and recommendations – and these usually need to meet pre-and post-market regulation. Other routinely used components, providing support functions such as communication, user guidance, and routine task administration, often do not need to meet the same

standards. Both FDA and EU regulators recognize that medical devices can have both medical and non-medical functions.

Regulatory alignment will be quicker if we define the boundaries of the medical and non-medical modules and assign risk categories (high, medium, and low). Then, we can apply appropriate standards and testing to each, as well as check that the non-medical parts will not compromise the system as a whole. But there is no need to test everything according to the standards appropriate to the riskiest component.

A risk management exercise

Meeting regulation is one of the most time-consuming and risky parts of product development, with many potential points of failure. Using compliance ready modules from risk-based IMPS frameworks helps reduce complexity, allowing risk management to the focus on new innovative elements rather than the whole product, reducing the total effort. This also decreases time to market.

Developing software for medical devices that is compliant with software and data regulations can be daunting, especially for those who do not yet feel mature in the world of compliant software for medical devices.

Those who do not yet have the full suite of in-house software and regulatory compliance skills may consider working with a partner that can also act as a certified legal manufacturer. Such an organization

can take on the risk and complexity of compliance and related activities, such as post-market surveillance. Such a partner will not only have full engineering development capacity and a workforce experienced in using frameworks, processes, and modules, but also the extra elements needed to develop software for medical devices that meet regulatory standards, submit regulatory documentation, and manage compliance post launch.

Organizations that are legal manufacturers work closely with you to define needs and goals but use their own approaches to software development and, ultimately, take full legal and financial responsibility for pre- and post-market regulatory compliance of any SaMD product.

4 NEW SKILLS, ECOSYSTEMS, AND CULTURE

Many life sciences and medtech companies lack the core software skills and culture, more typically found in tech companies, to routinely build, launch, and manage intelligent digital products and to ensure that software aspects align with regulation.

To ensure they innovate at their full potential, these companies will need to bring in more software expertise. This must include expertise in designing software in regulated industries, across traditional domain boundaries of standalone medical devices or clinical systems, and into the real world.

This will need to be done through a mix of recruitment, retraining, and outsourcing. Not everything can be done in house, nor should it be (anyway, there simply are not enough software engineers for every digitalizing company to meet all their needs in house). Most successful digital transformers focus on developing their core digital IP in house and outsourcing everything else.

These companies will also need to build an ecosystem of partners to provide the parts they do not have themselves, from cloud providers such as Amazon, Microsoft, or Google, to companies providing advanced technologies and services for device connectivity, to software development and testing consultants. This large ecosystem may be managed through the supply chain function, or via a single systems integrator.

They will also need to create a culture that joins traditional medical product developers with digital teams. Device engineers will need to understand the needs of the software teams and work closely with them. Some software engineers – especially those recruited from tech – may find the approach of launching beta products and improving quality through testing and feedback needs to be retrained to be better tuned to the rigor of the medical industry.

The medical industry can and should profit from agile and continuous integration/continuous delivery principles that apply small, incremental, or frequent updates to improve quality at speed, rather than large irregular upgrades. However, this needs sophisticated engineering practices and management, along with careful cross-training and teambuilding between teams from very different backgrounds.

MINIMIZING THE PAIN OF TRANSFORMATION

The connected health market is heating up, with competitors, startups, and deep-pocketed big tech all regularly launching new digital medical products. Taking too long to get to market means missed opportunities. But substandard products could spell the end of a business line. Putting the right fundamentals in place accelerates time to market, while reducing risk at every step.

Many in the medical industry already have programs designed to address these concerns. But many still struggle with the complexity, the breadth of change that comes with a connected ecosystem, and the addition of the whole new area of regulated medical device software to their business.

Recognizing this, Capgemini has developed a suite of offerings, called Intelligent Medical Products and Systems (IMPS), which can support the whole software development lifecycle. Our recent approval to act as a legal manufacturer means that we can take on the entire SaMD development program, from end to end.

This combines our development capacity, software architecture capabilities, world-class human-factor design studios, and test automation strategy and tactics – all supported by a harmonized global approach to risk and quality management. All this gives us the confidence to take on the risk of taking products all the way to regulated markets on behalf of our clients.

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Learn more about our Intelligent Medical Product & Systems Offer and Legal Manufacturer Services. To discuss the issues raised in this document or find out more about how Capgemini can help, please contact our experts:

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