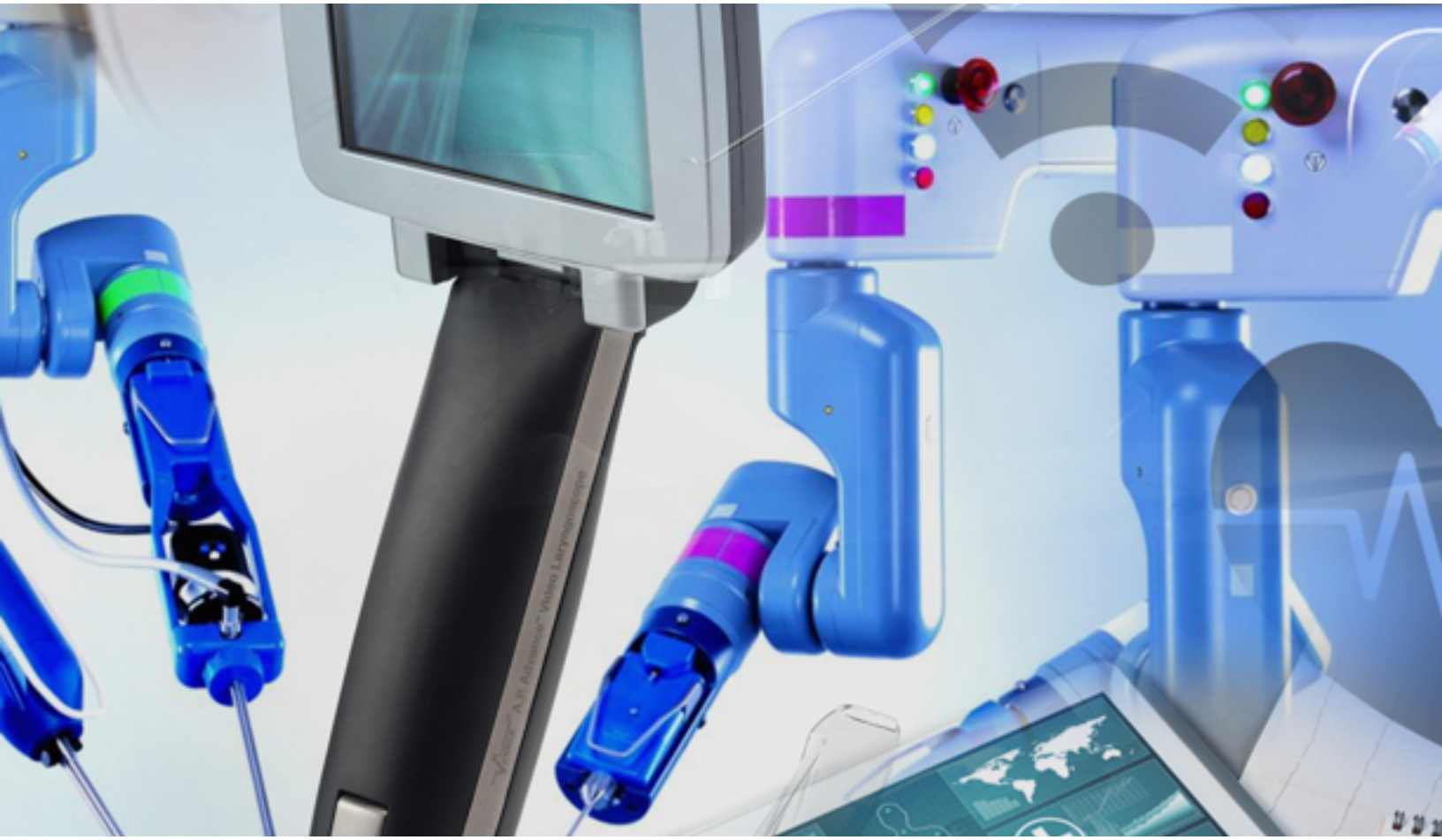
Trends for
medical devices



By Stephen Knowles, Managing Director of IDC

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IDC's MD, Stephen Knowles, gives his thoughts about trends for medical devices in 2018

"In a nutshell, 2018 holds lots of exciting technological developments, all happening at once. It's a very complex picture – really the challenge for manufacturers is to focus on what customers want and deliver the innovation that the market needs. All this, while meeting regulatory requirements, so that the new technology can actually make it to market. At IDC we're extremely excited about what the year holds, both for the industry and as a consultancy. We're at a pivotal point with rapidly developing technologies such as IoT and robotics, which could bring widespread benefits throughout the medical industry."

Q: Which medical device sector has attracted the investors' attention in 2017 and will this trend carry on in 2018?

A: Capital investment in 2017 supported the development of devices for minimally invasive surgery, with the potential it brings as a tool for faster healing - this is certain to continue in 2018.

Point of care testing is also a hot medical issue. In the past, if patients provided a sample for testing, there would be a time delay before results were available, the trend now is to provide both testing and diagnosis while the patient is present. There are many benefits to this approach such as a better experience for the patients, with greater understanding of the diagnosis, as well as reduced time and resource requirements for the hospital. Because of this, in-vitro diagnostic equipment will attract capital investment in 2018.

There is also a big focus on mobile health and the development of apps for fitness and health. These are useful in helping to diagnose conditions and monitor treatment. There are

currently many apps available, but investment will only be made in apps that can demonstrate real value to medical professionals.

Q: What medical sector do you think will expand in 2018 and why?

A: Point of care testing, in vitro diagnostic (IVD) equipment and the Internet of Things (IoT) will continue to grow in 2018. There are more and more technologies emerging for IVD, but the major challenge facing designers is making them more cost effective, while still maintaining the highest quality standards.

At present, the medical industry is at a relatively early stage with the Internet of Things. This is an area of technology that has attracted a lot of attention, but is still yet to be developed sufficiently to meet real needs. IoT has many potential applications in the medical field, but safety of data transmission and reliability of data analysis are crucial. Artificial intelligence is likely to contribute to the analysis of data but challenges remain in verifying the AI analysis. There is still much work to be done with IoT, but manufacturers are keen to explore this growing area, and it is sure to be a focus in 2018.

We are currently supporting clients in the development of IoT devices by providing electronic IoT modules which offer high level, multi-layer data encryption to solve data security issues. The modules can be used in many types of electronic products, including personal medical devices, and comply with ISO 60601 and ISO 62304 hardware and software regulations. This has helped clients resolve the issue of data security.

Q: How will regulatory changes affect medical device development in 2018?

A: 2018 will be about companies transitioning to new regulatory systems. Regulatory changes were made during 2017 to achieve better risk control, as demonstrated by the European Medical Devices Regulation's (MDR) need for more detailed technical documentation and auditing.

Over the next three years in Europe, the MDR will completely replace the current Medical Devices Directive (MDD). The new MDR requires greater scrutiny of technical documentation and there are now stricter demands for clinical evaluation and post-market clinical follow-up, with better traceability of devices through the supply chain. These new rules are designed to reflect the fact that all medical and in vitro diagnostic equipment should use the latest technology and innovation – which should be a welcome addition. The new rules provide manufacturers and importers with greater transparency and legal certainty to enhance their international competitiveness and innovation in strategic formulation.

ISO13485 has also just been updated, which will bring better risk control, better supplier management and more detailed design and development as medical product developers transition to the new 2016 standard.

In China the CFDA's have increased requirement for clinical trials with a whole range of devices now needing clinical data before being able to be launched.

If manufacturers choose to work with an experienced design consultancy, they will be supported with the more demanding risk management processes during the period of transition to the new regulations; actively participating in key steps such as document creation and core technologies. The process is full of challenges, but medical device manufacturers need to compete based on quality, safety, reliability, and cost, while maintaining the two elements of user experience and innovation.

Q: The use of robots in medicine is an exciting area of technology. How has this developed and do you think it is likely to grow internationally?

A: Indeed so. Robots offer great potential in medicine with precision, stability and reliability in the medical field. In terms of trends, they do not replace the doctor's job, and they are important as a tool to assist the doctor's work. Currently, robots are able to provide valuable support to diagnosis, surgery and treatment to patients. In surgery, they are able to reach parts of the patient that are small and inaccessible to doctors or other tools, as well as making results more repeatable and reliable.

In the West, the cost of robotic development is still incredibly high and this means that the technology is restricted to the wealthiest parts of the world. However in the near future, the development of technology and the maturity of applications will lower the cost threshold and bring the benefits of high-quality medical services to more patients.

Q: The concept of intelligent hardware is very popular right now for domestic use, what's your view of this in medical developments?

A: Intelligent hardware and devices take much longer to establish in the medical world than in the domestic environment, because of the regulatory requirements. The companies that are fully up to speed with regulatory processes are the ones who will be able to develop these devices most effectively.

Other areas of interest are apps and systems that can monitor treatment behaviour, such as checking patients take drugs and therapies when they are supposed to. Over recent years we have seen the development of many 'Health' Apps which make medical claims but are not accurate and reliable enough to actually meet medical needs. I believe we will see a more cautious approach to investment this year. As well as this, the stringent regulatory requirements will also restrict many developments. There needs to be a thorough understanding of user needs and a focus on data security and clinical reliability to gain the trust of medical professionals.

Q: Any particular trend you expect in the medical device or drug delivery sector in 2018?

A: There's still a big opportunity for generic drug manufacturers and associated drug delivery devices in 2018 and beyond. Patents in the US are starting to expire, providing an opportunity for drugs be sold cost-effectively into developing countries. A lot of these generic drugs need delivery devices to be developed at a cheaper price. Manufacturers need to ensure that as patents expire, there will be devices available to deliver the drugs cheaply, so they can be made available to more people. This is a big international trend that will continue for the next 5-10 years. It has huge implications for developing countries in making better medicines available to poorer populations.

Design and development of drug delivery devices must take account of the effectiveness of different drugs (capsules, powders, liquids) and the way of administration (inhalation, injection, etc.), the amount of residue, product morphology and other elements. Of course, the difficulty of designing and developing drug delivery devices to be safe and efficient means that greater investment is required. IDC is working in partnership with several pharma companies and a world leading contract manufacturer to bring devices to market at a reduced cost and timescale for a range of therapies.

Q: 3D printing has been popular in the last few years – will this continue to influence the precision, reliability and speed of medical developments?

A: 3D printing makes a great contribution to the design and development of medical devices, enabling quick model making or the most detailed of final prototypes for testing. Its high cost, however, means that it is most suitable for supporting product development rather than mass medical applications, though it has a growing place in personalised medicine where treatments are custom made for individual patients.

In personalised medicine, it is increasingly used in the dental industry for 3D printing metal or ceramic tooth implants. It also offers exciting opportunities in reconstructive surgery, where it offers a solution for building body parts such as bone scaffolds. One of the most exciting areas is the development of 3D bio printing processes and systems. Last year saw the first blood vessels 3D printed from stem cells, successfully implanted in animals. Much focus on these areas will continue in universities and research institutes, bringing the possibility of 3D printing human organs that much closer to reality.

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