

## What Does 2019 hold for the medical device industry?



Credit: CMR Surgical

By Stephen Knowles, Managing Director, IDC

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Last year we asked IDC's MD, Stephen Knowles, for his predictions about the medical industry in 2018. As we start 2019, he reviews the highlights of last year, and forecasts what lies ahead for the medical device industry in 2019. His analysis points to a year full of exciting new technologies, increased regulation, but still plenty of opportunities.

**Q: What were your predictions for last year and what significant changes did you witness in the medical industry in 2018?**

A: Last year we highlighted a number of important growth trends. The key areas were: in-vitro diagnostics (IVD) and particularly point of care diagnostics, IoT and telemedicine, robotic surgery and the growth of generic drugs and delivery devices. All of these areas have continued to expand and that trend is likely to continue for the coming years.

In the IVD area, 2018 saw two very exciting breakthroughs in the development of IVD tests for cancer. Scientists at John Hopkins University in the US successfully trialled a blood test which can detect eight common forms of cancer. Their CancerSEEK process identifies tiny traces of DNA and protein biomarkers released by the tumours. Meanwhile in Cambridge, UK researchers are beginning a test of a 'Breath Biopsy' device to analyse patients breath to detect early-stage cancers. In 2019 devices for these and other techniques will require further development whilst new and exciting diagnostic tests emerge.

Point of care diagnostics continued to develop with a focus on in-clinic tests by family doctors for a range of indicators, including cholesterol, urinalysis, glucose, cardiometabolic function, coagulation, vitamins and many more. In developed markets, increasing availability and patient awareness will continue to power the growth of this segment (currently around 10% per year) while in developing countries, the ability to detect infection diseases is likely to drive growth. In both cases the rapid development of low cost electrochemical biosensors will continue to support the development of new POC devices.

In the field of robotic surgery the launch of the Versius robot for minimally invasive surgery by Cambridge Medical Robotics in the UK was a significant event, while in Hong Kong, researchers made the first surgical robot which could be operated inside a functional MRI machine. 2019 will see more products coming to market with IDC excited to be involved in one such development.

In 2018 Telemedicine continued its move into the mainstream of healthcare with significant investment and growth because of the great opportunities it offers for opening up healthcare to underserved communities, cost cutting and reducing waiting lists. From diagnosis to treatment, technology is making it possible to communicate remotely with patients and connected IoT devices are facilitating treatment in an increasing number of applications.

Less publicised but equally important was the growth in the treatment of diabetes in the developing world. With the incidence of diabetes continuing to rise across the world, access to cost effective injection pens is vital to allow proper treatment and management of the condition. In 2018 IDC continued our development of a platform of injection devices to enable affordable delivery of insulin and a range of other drugs. These will be available in 2019.

**Q: What changes will take place in the medical industry during 2019 or the near future?**

A: In 2019 we will see digital health technology growing very rapidly. According to a recent Forbes report, digital health services will grow by 30% to reach \$25 billion globally. But in addition to the growth of digital health, one of the exciting developments of the next few years is convergence of multiple technologies to deliver improved healthcare.

Artificial Intelligence (AI) has already shown its capabilities, with testing at London's Moorfields Eye Hospital showing DeepMind's AI based computer systems were able to match the performance of leading ophthalmologists and optometrists. Imaging diagnostics is likely to be one of the first areas seeing large scale take up of AI. However bigger advances will come as AI technology becomes paired with IoT devices and digital health to analyse the data sets that come from connected wearable devices to provide early interventions. One significant application for such technology is in wearable patches for vital signs monitoring, allowing hospital patients to get out of bed and even return home much sooner whilst providing hospitals with more effective monitoring of patient recovery.

At IDC we are getting involved in projects covering image diagnostics and vital signs monitoring and look forward to helping more innovations in this area reach patients and clinicians. In all connected medical device applications, data security is critical. We anticipate continued demand for our high level encrypted IoT modules and solutions.

Elsewhere, AI chatbots and voice applications will allow patient services to be streamlined and clinicians' time to become more focused on patient care.

With IDC's R&D presence in China, we are well aware of the innovation potential of the Asia region. This year is likely to see a continuation of the growth of healthcare R&D in the Asia-Pacific region, with significant areas being cell and gene therapies - where China has been taking a leading role. At IDC we are working with the Asia based R&D teams of Chinese and global multinational companies and we expect to see more global R&D projects coming out of China and Asia.

**Q: What will be the biggest challenges facing manufacturers this year when developing new products - are there any upcoming regulatory changes?**

A: The time and cost of getting new products to market continues to be one of the biggest challenges facing manufacturers and the process of getting regulatory approvals has a huge influence on time to market. The expectations of patients and users and the pace of technological development are driving demand for new and improved products but regulatory processes can hamper that.

In Europe the transition to the MDR is well underway. From discussions we have had with manufacturers, in many cases this is proving a headache, especially for companies with large product lines and legacy products requiring new certification. In the meantime in the US, all eyes are on the FDA, which is due to launch an alternative 510k approval process in response to large scale problems with the safety of some approved implantable devices. In 2018 IDC completed the transition to ISO13485 (2016) and any device companies who have not done so already will be making the change this year to bring in better risk control, better supplier management and more detailed design and development procedures.

Despite all the changes to regulatory processes and requirements this brings, there are still many opportunities for manufacturers to speed up time to market. One way to achieve this is by choosing to work with an experienced design consultancy which can maintain a rigorous development process but by-pass much of the internal overhead and distractions which inevitably tend to develop in larger corporations. With the right team and arrangement, the focus on user experience and innovation can be maintained whilst moving the project forward more rapidly.

**Q: Based on the outcome of 2018 and the forecast for 2019, how will you modify your business in 2019 and the near future?**

A: Based upon the trends we have observed in 2018 and 2019 IDC will be continuing to invest in developing our own enabling platform technologies to provide our partners with the key device building blocks to more rapidly get devices to market. The first products in IDC's generic injection pen platform will be launched this year and we anticipate further strengthening our relationship with key manufacturing partners to provide customers with a full end-to-end development and production service.

The increasing focus on connected devices and digital health solutions is likely to accelerate our investment in software development expertise and see IDC invest in AI technologies. In short, 2019 looks to be another exciting year in the Medtech sector with the pace of innovation showing no sign of slowing down.



**Stephen Knowles, MD at IDC**

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