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Touching Lives One Device at a Time

MARKETWATCH

Weekly News Bulletin– Issue No.28 March 20, 2019

Countdown to European Medical Device Regulation- By Oliver P Christ

The implementation of the new European Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) has reached a critical momentum.

With only 20 months left in the transition period for MDR, medical device manufacturers that want to place medical devices on the EU market after 26 May 2020 are working diligently to implement the new regulatory requirements.

When it comes to budgeting and planning for additional regulatory resources, many manufacturers are still in gap analysis mode. The five hottest topics to meet compliance with MDR are:

- Clinical investigation and evaluation
- New roles and responsibilities for “economic operators”
- Post-market surveillance and vigilance, and market surveillance
- Risk management and usability engineering/ design input
- Overhaul of labeling and technical documentation

The first notified bodies under MDR notification are expected to operate by the second quarter of 2019, one year before the end of the transition period.

Compliance audits for MDR need to be prepared using ISO 13485:2016 as a basis for a compliant quality management system by adding in-depth processes required by MDR (e.g. for clinical investigation, postmarket surveillance, etc). The new MDR Annexes II and III contain more detailed requirements for technical documentation for all classes of medical devices.

Now is the time to update “old” medical devices directive technical files to the new MDR requirements in Annex I (General Safety and Performance Requirements). The graphic above shows the estimated costs of implementing the new regulation.

When companies do not have enough resources available in-house to do this job, external resources such as technical file development may be employed to manage the regulatory road map for success.

Waiting is no longer an option!

J&J to acquire surgical robotics firm Auris Health for $3.4bn

Johnson & Johnson (J&J), through its subsidiary Ethicon, has signed a definitive agreement to buy surgical robotics maker Auris Health for a cash consideration of around $3.4bn.

The deal also includes contingent payments of up to $2.35bn, based on predetermined milestones.

Auris Health develops robotic technologies and has a strong focus on lung cancer. Its portfolio includes the Monarch Platform, which is currently used in bronchoscopic diagnostic and therapeutic procedures.

The US Food and Drug Administration (FDA) approved platform is said to feature robotics along with micro-instrumentation, an endoscope design, sensing and data science. J&J expects the deal to drive its entry into the robotics markets and provide opportunities for expansion into additional interventional applications.

Johnson & Johnson Medical Devices executive vice-president and worldwide chairman Ashley McEvoy said: “In this new era of health care, we’re aiming to simplify surgery, drive efficiency, reduce complications and improve outcomes for patients, ultimately making surgery safer.

“We believe the combination of best-in-class robotics, advanced instrumentation and unparalleled end-to-end connectivity will make a meaningful difference in patient outcomes.”

The company added that the Monarch robotic technology will support its Lung Cancer Initiative and allow development of a differentiated digital solution to help patients with lung cancer.

Medtronic has reported positive results from the WRAP-IT clinical trial.

The randomised, multi-centre study evaluated the company’s TYRX Absorbable Antibacterial Envelope in patients with cardiac implantable electronic devices (CIED).

TYRX is a mesh envelope designed to hold an implantable cardiac device or implantable neurostimulator. It stabilises the device after implantation, as well as releases antimicrobial agents, minocycline and rifampin over a minimum of seven days. The envelope is fully absorbed around nine weeks after implantation.

WRAP-IT was performed at 181 centres in 25 countries across North America, Europe, Asia and South America in a total of 6,983 patients. The envelope was successfully implanted in 99.7% of procedure attempts.

Biotronik receives FDA approval for new cardiac devices

Biotronik has secured approval from the US Food and Drug Administration (FDA) for the use of its Acticor and Rivacor cardiac rhythm management (CRM) devices to treat heart arrhythmias.

These small 3 Tesla (3T) magnetic resonance (MR) conditional CRM devices have rounded edges to reduce skin pressure and help lower the risk of skin erosion. Their long battery lives ensure fewer replacement surgeries and reduce costs.

Biotronik president Ryan Walters said: “The Acticor and Rivacor device systems reflect Biotronik’s commitment to engineering solutions with a profound positive impact for patients, physicians and health systems.

“We remain focused on bringing cardiac solutions to the US market that streamline processes and improve the ability to deliver care without compromise.”

Wanted: Partners to collaborate on wearable sensors

Researchers from Purdue University in the US have developed a sticker-based sensor technology which they believe could hold serious potential for the medtech sector. The research was recently published in ACS Advanced Materials and Interfaces. The researchers say they are looking for partners to test and commercialise their technology.

“For the first time, we have created wearable electronic devices that someone can easily attach to their skin and are made out of paper to lower the cost of personalised medicine,” said Ramses Martinez, a Purdue assistant professor of industrial engineering and biomedical engineering, who led the research team.

The “smart stickers” are made of cellulose, which is both biocompatible and breathable. They can be used to monitor physical activity and alert a wearer about possible health risks in real time.

The technology is patented through the Purdue Office of Technology Commercialization. The researchers say they are looking for partners to test and commercialise their technology. “The low cost of these wearable devices and their compatibility with large-scale manufacturing techniques will enable the quick adoption of these new fully disposable, wearable sensors in a variety of health care applications requiring single-use diagnostic systems,”

Working double time: How Irish moulder doubled cleanroom capacity

Trend Technologies Ireland, a contract moulder of devices for the medical and life sciences sectors, recently opened its third ISO Class 7 (10,000) cleanroom at its extensive 7,000 square meter manufacturing facility in Mullingar, Ireland.

Trend's capital investment in the facility and additional cleanroom space and equipment, including a number of Sumitomo Demag 50-tonne IntElect machines, has enabled the company to boost process stability and achieve shorter production runs.

Trend's site in Ireland is the company's 'Centre of Excellence' for injection moulding, and provides tooling, project management, Moldflow and Scientific Injection Moulding support to Trend Technologies sites globally.

"The Irish and UK medical device sector is in a sustained growth phase," noted Trend's manufacturing manager, Tom Kelly. "We are in the process of building another cleanroom, which when complete in the summer will expand our cleanroom manufacturing capacity by an additional 400 square meters. This is in response to the positive outlook for the sector and the increasing demand for high quality medical device components."

Items moulded on site by Trend form part of Class I, IIA, IIB and III medical devices and include wound care products, diagnostic laboratory consumables, ventilator housings, surgical handles and stent delivery sub-components. Most of these are highly customised, so when making the investment in new cleanroom machinery Trend focused on sourcing equipment that would automate process stability and increase product integrity.

To accomplish the combination of precision and repeatability, Trend makes full use of the activeLock technology installed on each IntElect. "We use it on every product moulded and activeLock saves us an awful lot of bother when dealing with such small shot weights. It means we don't have to run any decompression, which can draw air into the melt. This ultimately reduces rejects." Since installation, Trevor said activeLock has reduced defects in the process significantly. Industry 4:0 is certainly firmly on Trend's radar and the company has been approached by Sumitomo (SHI) Demag's UK Managing Director, Nigel Flowers to participate in a predictive maintenance trial. "From a production perspective, we are fairly Industry 4:0 advanced and use real-time data to work smarter, reducing programming complexity and production lead times," notes Tom. Already, the technology is improving the company's 24-hour breakdown response time by 80%, as well as increasing first time fix rates to over 90%.

6 PREDICTIONS FOR THE MEDICAL DEVICE INDUSTRY IN 2019

(AND HOW YOU CAN PREPARE)

#1. **WEARABLE MEDICAL DEVICES WILL BECOME MORE COMMON**

A wearable is often referred to generically by the FDA as a “general wellness” device. It makes sense in a world where consumers want to be more empowered to manage and monitor their own health, that wearables could assist with those efforts. This follows a broad trend for more personalized medicine and having the ability to take health and wellness into the hands of its rightful owner--you..

Companies that decide to go the extra step to have their product be classified as a medical device understand that they will be seen in a new respectable light by consumers, who will recognize the diligence that has been taken by the manufacturer to adhere to stricter regulations.

#2. **EU MDR CHALLENGES**

2019 is going to be a difficult year for medical devices in Europe . Part of the challenge is that the resources - third-party notified bodies and regulatory experts - are still learning about the changes to the European Union Medical Device Regulation (EU MDR). We’re a year and a half into those changes, at the time of writing this, and still no one fully comprehends all of the specific details. If we look at indicators from the introduction of ISO 13485:2016, we’ve seen a huge increase in the demand for contracting services of auditing organizations for a number of reasons. By the same token, there’s been a reduction of notified bodies who have the availability to contract their services. This will create big challenges heading into 2019 for those not already certified to the 2016 version of the standard.

Companies that realize there is a traffic jam in the EU system and work to get ahead of it now will be in a better position later on. If you’re just getting started in the first quarter of 2019, you only have a year to be compliant.

#3**. ISO 14971 REVISION**

Surprisingly though, even though ISO 14971 has been around since the early 2000s, there are still a number of companies that have not adopted the principles of the standard. This may be a challenge for those non-adopters moving forward.

#4. **FDA QSR HARMONIZING WITH ISO 13485:2016**

The good news is ISO 13485 is very much in sync with the FDA’s Quality System Regulation (QSR) already. The whole idea behind this is because 13485 is constantly being reviewed in order to be the globally harmonized standard for medical devices, so it makes sense for the FDA to align with it. ISO 13485 is a little more progressive and dynamic due to the frequent updates.

#5. **EXPECT FDA TO CONTINUE TO SHAKE UP REGULATORY SUBMISSION PROCESSES (IN A GOOD WAY)**

I predict that we will learn a great deal more about “Safety and Performance Based Pathway” in 2019. The press release in November included a few nuggets of information and hints of things to come. Apparently FDA Commissioner Gottlieb stated this announcement is "the most significant modernization" of the medical device review process in a generation.

In addition to changes to 510(k) pathways, FDA is in the process of making changes to De Novo. It's very clear that the agency is very keenly focused on facilitating ways to streamline the regulatory clearance processes. 2019 will be a very exciting and interesting year for medical device companies launching products in the U.S.

#6. **DISCUSSIONS ABOUT A GLOBAL FDA**

In recent years, with the digitization of healthcare and the spread of communication technologies, the idea of borderless health started to emerge, and we expect it to reach a tipping point and represent a widespread practice instead of a sporadic phenomenon soon.