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A White Paper

Medical Device Regulation and its impact in Digital Healthcare

Abstract

"Medical science has proven time and again that when the resources are provided, great progress in the treatment, cure, and prevention of disease can occur." – **Michael J. Fox**

The healthcare and medicine industry is undergoing continuous upgrades and changes owing to the introduction of new and improved technologies. In this whitepaper we delve deep into the fascinating world of digital healthcare and advanced medical devices; the past, present, and future. We will look at the detailed scrutiny that medical devices undergo by regulatory bodies and manufacturers who closely monitor the adverse effects of these devices, so that anomalies are corrected before they reach the public.

Digitalization of healthcare and how it has impacted the world

Innovation and digitalization in the healthcare industry is critical. The main goal being to optimize healthcare workers' processes, streamline systems, improve patient experience and reduce human error and costs. However, as per a Digital Trends survey conducted by Adobe, only six percent of healthcare companies are digital, compared to 15 percent of companies in other industries.

Since four billion people around the world are on the internet, the possibilities are endless for digital transformation in the healthcare industry as well. According to DMN3, a marketing consulting service based in Houston TX, consumers access the web to obtain medical information for the following reasons:

- 47% research doctors
- 38% research hospitals and medical facilities
- 77% book appointments

> **"AI will not replace physicians. However, physicians who use AI will replace those who do not" - Anonymous**

According to a report by Grand View Research, the digital health industry is expected to cross USD 500 Bn by 2025. Mhealth and wireless treatments are believed to be the main drivers of this growth. Digital health also attracts huge investments, mainly in the form of startups. This is seen in the funding pattern that increased exponentially within a decade from USD 1.1 Bn in 2010 up to nearly USD 14 Bn by 2019.

These whopping figures aren't much of a surprise given the benefits that aim to help maximum patients with minimum health damages, some of which are:

- **Reach and long-term sustainability**
  The adoption of digital health technologies aids healthcare workers and doctors perform complex medical procedures, diagnose diseases via online reports and testing, administer and prescribe medicine remotely with fewer errors, and then monitor patient progress consistently and effectively. Given how structured the industry is, digitalization of healthcare has led to focused drug development and supply-chain management. Working in conjunction with authorities around the world, initiatives such as online health record systems improve the healthcare provided to citizens and can help with the coordination of treatments.

- **Better patient care and reduced load on healthcare workers**
  Since people have easy access to monitoring machines, digital health technologies are especially helpful for patients with chronic illnesses to manage and monitor their health condition and keep a check on their symptoms for any anomalies. This kind of self-management of health also frees up healthcare workers to concentrate on serious cases. More importantly, the various devices available at competitive prices in the market help with early detection of issues and are of immense value for 'at risk' patients.

- **Improvement in patient doctor relationship**
  Since reports and treatments are transparent and easily accessible, digital health systems lead to better equations between patients and their health care providers, making them partners working towards a common goal. The shared access and detailed list of instructions which is available at all times, increases trust and reliability between patient and doctor. Important factors which play a role in affecting health, such as environmental stimulants, use and dosage of medications, time of day, and tolerance to medications can all be recorded in real time to view the complete patient history at a glance, thereby giving doctors a clear perspective of the patient's condition.

- **Freeing up healthcare professionals**
  Given that access of records and record keeping is digitized and available on demand, it significantly reduces the workload for healthcare workers by taking away the administrative and repetitive tasks off their plate. This frees up doctors to monitor more patients at any given time. This is especially of value in remote locations where the doctor patient ratio is significantly skewed. With such record keeping technologies, even rural residents can easily provide their medical history to visiting doctors.

- **Financial help and patient commitment**
  Access to affordable medical technologies reduces the financial liabilities associated with patient care and disease management. Many digital platforms also help patients set up financial aid as well. This helps immensely in reducing patient no show due to lack of finances. Apart from this, patients can also reach out to others experiencing similar health problems to draw encouragement from shared experiences.

Digitalization in the Medical Devices Industry

Digital transformation in healthcare shows the positive impact of technology in medicine. Innovation is key here with the main goal being streamlining health care professionals' work, optimizing systems, reducing human error, lowering costs and improving patient outcomes.

Thanks to technology, patients get access to better care with virtual reality tools, wearable medical devices, 5G mobile technology and telehealth. Simultaneously, doctors can streamline and ease their working conditions using artificial intelligence-powered systems.

Now that we have seen the benefits of digitalization of medicine, let's take a look at a few emerging trends and where we stand as of 2020.

- **Medicine 2.0**
  Web 2.0 refers to a series of highly effective online platforms, social media pages, blogs, and forums that allow individuals to contribute and provide their side of the story in online health conversations. These conversations give valuable insights and provide opportunities to improve healthcare efficiency, by engaging users in creating first-hand medical resources, improving public health education, or enhancing clinical experiences by providing the right perspective. Intertwined closely with Health 2.0, Medicine 2.0 also considers the research and scientific aspects of medical care. In simple terms, Medicine 2.0 is Web 2.0 technologies that include user participation on a much larger scale.

- **Internet of Medical Things (IoMT)**
  An amalgam of networking devices linked to healthcare medical technologies, Internet of Medical Things (IoMT) helps with remote monitoring of patients, which is especially useful in the face of large-scale medical emergencies. Connecting medical devices to networks is gaining a lot of traction, and experts predict that IoMT market will cross USD 136.8 Bn by 2021. A word coined from Internet of Things (IoT), IoMT allows any medical device to record, analyze, monitor and send data across the web. Divided into 3 parts; in clinic, at home and on the body, medical devices can be connected to each other via wireless technology for a flawless monitoring experience.

- **Medical robots**
  Created with the idea of meeting the rising demand for advanced health care, medical robots are highly skilled machines that aid healthcare workers in the operation theater. They allow surgeons to navigate through difficult medical procedures by using miniaturised cameras and precision lasers to conduct minimally invasive surgeries thereby aiding faster patient recovery. The robotics market is expected to be around USD 24.6 Bn by 2025 with medical robots being used extensively for diagnosis as well as interventions.

- **3D-printing and Bioprinting**
  Especially useful when dealing with global pandemics, the technology involves creating three-dimensional solid objects from a digital imprint, by adding layers of material one on top of the other. This enables a lot of medical components to be created at a fraction of its cost, and also allows flexibility to customise and experiment with a wider range of materials. Going one step further, Bioprinting is the recreation of organs using live patient cells and enabling the regeneration of tissues. Although in the nascent stage, the results have been promising.

- **Wearable technology**
  Wearable medical equipment allows for the continuous monitoring of patient health and to improve the accuracy of clinical assessment. From detecting heart rate, cancer cells in blood to electrolyte loss in athletes, and walking data for predicting Alzheimer's disease, wearable technology is innovating at lightning speed.

As per recent data, there are currently over 500,000 different types of smart, inter-connected medical devices that can gather, analyze, store, and share patient data and protected health information (PHI). This figure is expected to rise by leaps and bounds in the near future.

As the numbers increase, and the data stored and produced by them grows in volume and complexity, it is imperative for companies to ensure that their data strategy and digital infrastructure factors in cybersecurity and protection of patient details.

The regulatory framework means that compliance forms the crux for all medical device businesses and the penalties for non-compliance can run into millions. How companies manage patient data, along with the security systems they put in place for continual compliance will ensure financial progress and operational functionalities. A compliant, safe way to protect PHI and allow access to concerned stakeholders plays a huge role in the future of digital healthcare. Private patient data must be governed by a core body to ensure proper visibility while being securely stored. Concentrating the power on one single authority will ensure ownership and better control of resources.

Challenges faced by medical devices manufacturers

The vulnerabilities and security issues in systems is known to have an impact on product quality, produce high recall rates and the likelihood of patient harm.

Although threats and vulnerabilities cannot be eliminated, the FDA and other regulatory bodies are working to control it to a certain degree by implementing mandatory tools to track device performance and identify any risks. Apart from this, manufacturers are required to comply with the pre and post-market cybersecurity laws, before product launch where they conduct extensive tests prior to its launch and implement the patches after product release.

The New Medical Device Regulation & Amendments

Medical device manufacturers must adhere to product safety standards and rules laid down by regulatory bodies. Medical devices include all equipment from thermometers to MRI machines.

The new MDR was published in April 2020, amending the MDR Date of Application to 26 May 2021. As per the amendment, from 26 May 2021, new devices will have to meet the requirements of the MDR.

The amendments in the new MDR are as follows:

- **Product scope expansion -** To make it more inclusive, the framework of medical devices and active implantable medical equipment will be significantly expanded to also include devices that do not necessarily have a targeted medical purpose.

- **Reclassification of devices -** The MDR expects device manufacturers to review the amended classification rules and update their technical instructions accordingly by considering the fact that class III devices will have higher clinical requirements and regular checks. Devices will be further scrutinized as per risk, contact duration and invasiveness.

- **Rigorous clinical evidences -** Manufacturers will be required to conduct clinical investigations in case they do not have sufficient data to support the claims done on both safety and performance of a device.

- **Systematic evaluation of Class IIa and Class IIb devices-** Manufacturers will need to familiarize themselves with the new rule and realign their clinical evaluation and also consider under which circumstances it is justified to not conduct a clinical investigation.

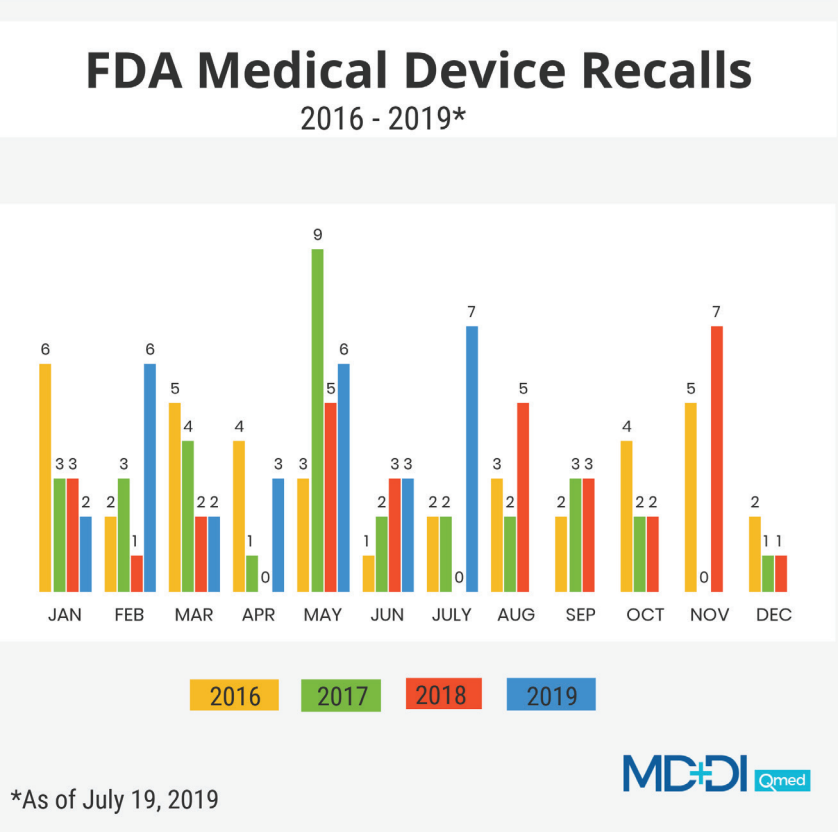
- **Stringent documentation -** Documentation rules have been updated to reduce loopholes and ensure all information is properly relayed to consumers and healthcare workers to ensure clarity and transparency.

- **Identify the compliance officer -** To ensure that a single person can take the onus and is answerable to the authorities. To remove the ambiguity around the process and make communication easy.

- **Implementation of unique device identification -** This is especially helpful when a device malfunctions or is reported as having some issues. Recall and traceability becomes easy with this new rule.

- **Rigorous post-market oversight -** To keep regular checks on the launched products for a certain amount of time to ensure that they are working well and fulfilling all the functions that they claim to have.

- **No "grandfathering" provisions -** To give everyone a fair chance, all current certified medical devices and active implantable devices have to be recertified as per the new amendments and rules.



source: https://www.mddionline.com/regulatory-quality/medical-device-recalls-spike-again-updated

Some of the common challenges faced by medical device manufacturers are:

- **Ensuring product quality**
  Manufacturers dealing with medical devices need to understand that they are responsible for monitoring people's vitals. For a medical equipment manufacturer, product recall spells a lot of trouble and negative impact, so ensuring product safety is of utmost importance. With competition swelling, reliability and security are of utmost relevance.

- **Localization of medical devices**
  Multi-national companies face the brunt of competition from local manufacturers who offer customized products which are created keeping in mind local health issues and constraints. Since their market research is strong and up to date, they tend to fill the gaps in the market, which their multi-national counterparts are unable to achieve.

- **Cybersafety & Cybersecurity**
  The most talked about concerns in the healthcare world are cybersafety and cybersecurity. Although innovation is the name of the game, the fact remains that cloud-based technology which holds personal data is open to attacks and breaches. This not only includes loss of data, but may also lead to direct attacks on individuals, leading to loss of lives. This is concerning because sensitive personal information becomes accessible to unauthorized persons and can be sold in the gray market. The Credibility of organizations takes a major hit when such incidents occur, hence they are constantly on the lookout to better their security measures and this often leads to massive investments as well.

- **Cost of product development**
  Since this technology is still slowly gaining traction, cost of developing new machines and technologies is time consuming and expensive. The cost of regulations and security concerns adds to the total cost of the final product.

Garnering government support for research and development, expediting approvals, and tax and financial aid are some of the other major challenges.

The changing face of Digital Healthcare Testing

Medical Device testing forms a critical part before releasing new devices in the market. Testing is a fool proof way to ensure the quality and viability of a product.

Machine learning and algorithm based regulatory checks have the capacity to optimize the workflows in hospitals, by providing early diagnosis and accurate medical care for patients. Testing is generally done to check the complete lifecycle of a device from analysis to maintenance. Some of the intensive forms of device testing are as follows:

- **Agile testing-** This adopts continuous integration and automation using a framework that integrates various tools without hassle. Work is divided between designated teams to ensure end-to-end testing of products and quality assurance. Thorough check for adherence before signing off on the project is conducted as well.

- **DevOps-** This offers automated and continuous quality monitoring, provisions for stimulated test environments, end-to-end test automation, and reporting.

Some other types of testing include GUI performance testing, non-GUI testing, compliance testing, interoperability testing, behaviour testing, reliability, and user acceptance testing which provide different parameters to enable the safe and accurate launch of medical devices.

QA is an integral aspect of medical device testing and it has multiple benefits, such as:

1. Ensures compliances are met as per various regulatory bodies such as HIPAA, PCI DSS, FDA, etc.

2. Ensures that healthcare CRMs, mobile apps, medical devices software, and patient information systems work seamlessly and are well integrated.

3. Integration testing enables proper connectivity between devices.

4. Clinical effectiveness of devices is closely monitored.

5. End-to-end testing mitigates risk of device failure.

Covid-19 impact on Digital Healthcare

In light of the Covid-19 pandemic, telemedicine and online pharmacies have gained a lot of prominence. Studying the demography of a particular region can give medical device companies first-hand knowledge of specific patient populations and patterns. The pandemic has in strange ways allowed the world to pause and rethink strategies to build more resilient communities.

It has presented the opportunity to go completely digital and optimize medical practices around the world. Collaborative ventures with healthcare workers to align manufacturing goals with user needs will help medical device companies gain impetus over competitors.

Telemedicine, robotics and remote consultations will gain prominence over face to face meetings. Analysts predict that the impact of Covid-19 on medical device industry could lead to greater demand of device production and renewed focus on diagnostic devices.

Artificial Intelligence (AI) and Machine Learning (ML) will help enhance research and development activities and software as a medical device (SaMD) will continue to grow.

Technologies will continue to develop in the healthcare field creating disruptive changes for not only patients, but healthcare workers as well. While new technology is welcome, it also comes with its share of problems. The largest problem that stems from new technology is the aspect of training that it requires to bring people up to speed. As more and more of the healthcare field gets automated, healthcare workers must be trained to acquire technological skills that were not very prominent in the past.

As we look to the future, the medical device industry has tremendous scope and opportunities ahead. New markets are emerging at a rapid scale, and the introduction of the Affordable Care Act has brought into focus new patient populations while existing patients continue to demand new ways of medical care and faster sustainable solutions. Having said that, uncertainty lies ahead with new regulations, healthcare requirements evolving, rules becoming more complex, and companies facing an increasingly competitive market to thrive. With technology at the crux of the system many of these challenges can be tackled head on as it creates the possibility of customized personal devices and better healthcare facilities.

Reference Links:

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