CLARKSTON CONSULTING

2020 MEDICAL DEVICE TRENDS

The 2020 Medical Device Trends reflect the relentless pace of transformation, change, and growth impacting nearly every aspect of the industry. Whether it's the growing focus on sustainability, the continued growth in combination products, the rise of ingestible devices, or regulatory changes at home and abroad, medical device makers must be prepared to navigate a dizzying array of both opportunities and challenges facing the industry.

INGESTIBLE MEDICAL DEVICES

With a rise in the number of chronic diseases, an aging global population, gastrointestinal disorders, colon cancer diagnoses globally, and the shift toward preventative strategies in healthcare to tackle disease progression, ingestible medical devices will continue its growth trajectory over the next 5 years.

Ingestible medical devices are equipped with circuits and sensors that have shown to be a clinically relevant technology platform with biomedical applications such as drug delivery and optical imaging for disease diagnosis. New developments in sensor and ultrasound models provide the ability to image a disease or infection at the cellular and molecular level which leads to early diagnoses and treatments of diseases.

There are many benefits for the use of this burgeoning platform, specifically real-time patient monitoring of a drug's therapeutic effect on the patient; adherence to medication regiment; correlating patient outcomes with prescribed treatment; minimal invasiveness of the treatment; and enhanced drug bioavailability.

The global ingestible medical device market can be classified into drug delivery, disease diagnostics, and optical imaging in terms of application. The technology can be either absorbable or non-absorbable.

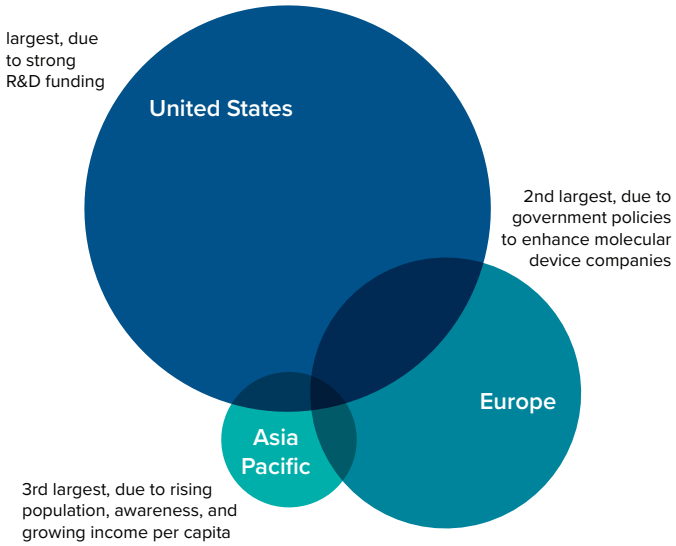
The technology's impact on diagnosing and treating gastrointestinal issues and types of cancer (e.g. colon cancer, esophagus cancer) cannot be understated. In 2015, WHO stated that the number of new cancer cases are expected to rise by 70% over the next two decades. They predict that 30%-50% of cancer patients can be prevented from acquiring different cancers by avoiding risk factors and early detection and management. The technology is expected to be widely adopted in the endoscopy screening market.

BY 2022, THE INGESTIBLE SENSOR MARKET WILL GROW TO

$680M (USD)

WITH A CAGR OF 20.2%

INGESTIBLE SENSOR MARKET SIZE:



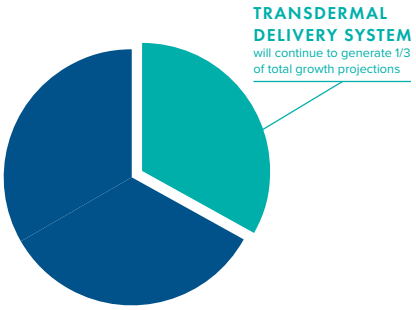
$100-$300B

IN AVOIDABLE HEALTHCARE COSTS-REDUCTION IN ESCALATED HEALTHCARE TREATMENT

DRUG-DEVICE COMBINATION PRODUCTS TO CONTINUE LARGE GROWTH TRAJECTORY

Due to the continual focus by the health care industry to invest and develop individualized therapeutics with precise delivery systems, combination products are expected to be a major growth sector. This is primarily due to the rise in incidences of chronic diseases, rise in the geriatric population globally, the exponential growth in technological advancements, the growth in the home healthcare industry, increased demand for minimally invasive products, increased demand of dosage consistency and simplicity, and increased demand for portable medical devices. The largest revenue growth globally is expected to be in North America due to the aging population of its citizens, the rise in per capita disposable income, and the growth in medical facilities. In terms of highest CAGR, the Asia Pacific Region will lead all other regions due to an increase in chronic health disease, an increase in healthcare spending, and rising awareness levels of physicians pertaining to the benefits of these products.

With the global growth of this segment, regulatory authorities are clamoring to develop, approve, and publish regulations that can be followed by the industry. The current global regulatory environment is fragmented, inconsistent, and ambiguous related to definitions of the products, filing requirements, clinical trial applications and requirements, manufacturing controls, audit practices, and post marketing safety reporting.



BY 2024, DRUG-DEVICE COMBINATION PROJECTS ARE PROJECTED TO GROW TO **$177B**
WITH A CAGR OF 8%

EXPECTED CAGR:

PRE-FILLED SYRINGE: 10%
INHALERS SEGMENT: 9.5%
ANTIMICROBIAL APPLICATIONS: 10.6%

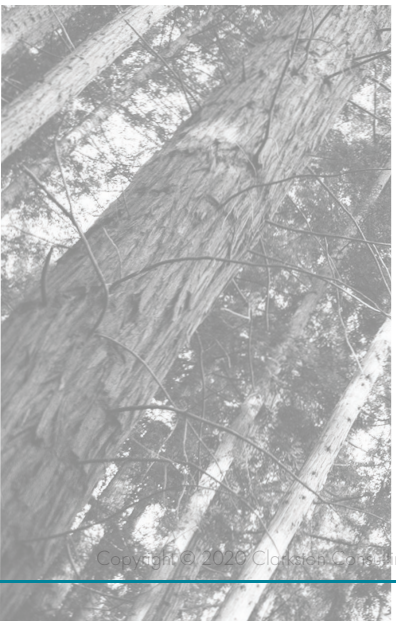
SUSTAINABILITY IN THE MEDICAL DEVICE INDUSTRY

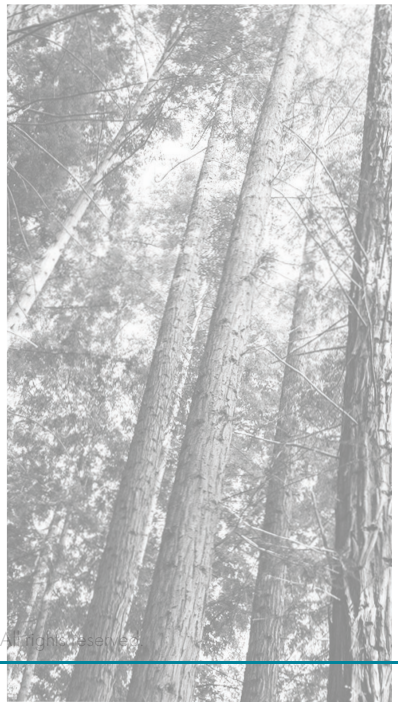
The medical device industry is not unique to other segments of the life sciences industry as well as broader industries in defining what sustainability is, its value to the industry and consumers, and how to implement sustainability goals. Other than where local, state, or federal governments require programs that are a benefit to sustainability, the life science industries, specifically medical devices, don't have a pressing incentive to be forward thinking or proactive in reducing their ecological footprint and setting goals and measuring their progress to achieve greater environmental sustainability.

There are two main drivers as to why this is the case. Firstly, medical device companies and brands are largely agnostic to customers and consumers; therefore, these groups are not demanding medical device companies to be more environmentally sustainable or they will transition to another company's products. Secondly, the industry's focus is first and foremost on product safety, effectiveness, and affordability. These goals outweigh any sustainability goals of a company. The only segments of the broad sustainability agenda and challenges that the medical device industry is currently invested in is disposability and material selection and use.

On disposability, the rationale to transition from reusable devices to disposable ones is sound and advantageous (i.e. eliminate routine sterilization, eliminate disease transmission, etc.); however, the result was a larger waste footprint and a laxed approach to cleanliness in facilities where medical devices are used. On the subject of material selection, medical device manufacturers are looking to select better grade materials when designing and manufacturing product which supports the overall reduction in environmental costs. With better grade materials, this can be the catalyst to reduce the complexity of medical device designs or overengineering which will also drive improvement in environmental sustainability.

The medical device industry is aware that they need to keep up with the ever growing public and private focus and requirements related to sustainability. An updated standard published in 2013 by the International Electrotechnical Commission, IEC 60601-1-9 provides a formal way to verify sustainability claims, including guidance for the design phase that can be leveraged to develop sustainable medical devices





LEVERAGING 'IOMT' AND ANALYTICS IN MEDICAL DEVICES

Growth in wearable health sensors and other internet of medical things (IOMT) devices has opened the door for improving health outcomes with analytics. Companies can now leverage data from activity watches, sleep tracking devices, and wearable ECG monitors to develop models that can benefit their own devices and improve health outcomes for their patients. The use cases are endless: monitoring other health factors that could impact a new device, improving a diagnostic device by considering lifestyle choices, predicting the performance of an interventional device, and many more. AI or machine learning models driven by this new data gathered by IOMT devices can provide assistance to clinical or non-clinical users in the form of recommendations or automated responses.

As this is a hotbed of new activity, the FDA is piloting programs to determine the best way to ensure patient safety while also gaining the benefits of the technology. Additionally, governments and the general public are taking a more scrutinous look at the data being collected and shared, warranting a cautious approach and analysis of your data privacy and security measures. In order to get the full benefit of these new technologies, companies should start their own analytical journeys, understand what data they have available, and determine the highest benefit use case for them while balancing new regulations around data and the models themselves.

A SINGLE PAYER SYSTEM IN THE US AND ITS IMPACT TO THE MEDICAL DEVICE INDUSTRY

As the 2020 election for the US presidency comes into view, one of the most important issues that continue to grab the attention of constituents is the subject of healthcare. At the center is the debate to transition to a single payer system from the current private insurance model. Depending on the pricing models set forth, two likely scenarios could come to fruition with the single payer system: negotiated pricing and value-based pricing.

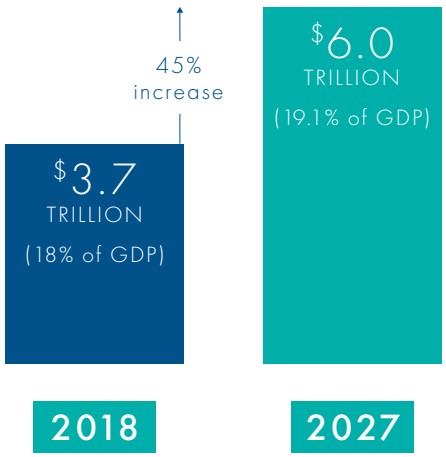
A single payer system would allow the U.S. government to negotiate medical device prices with manufacturers, a process currently executed by private insurers. For the largest present U.S. subsidized program, Medicaid, federal law prohibits the department that manages the program to negotiate prices. The U.S. government would have far more leverage over private insurers in negotiating prices with the medical device companies, driving down the cost that they would pay for these products. If the medical device companies could not offset these price reductions this would potentially impose budget restrictions on R&D.

Under a value-based pricing model, medical device pricing is set based on the cost-benefit of the device. In this system, the U.S. government would pay for a device only if it has demonstrable benefit over an existing one. A marginal improvement may not be enough for the device to be fully reimbursable under the program,

During the post marketing approval phase, the medical device companies may be required to submit information on a device's cost-benefit or to submit it after the device has been commercialized over a certain period.

Medical device companies may find very little financial incentive to innovate on devices that provide negligible improvements over other existing devices. Looking forward, medical device companies must continue to collect and analyze device data to fully understand the therapeutic impact of their devices and be prepared to report on those outcomes.

COST OF U.S. HEALTHCARE SYSTEM:



EUROPEAN UNION MEDICAL DEVICE REGULATIONS

On May 25, 2017, the EU adopted the new Medical Device Regulations (MDR) to replace the Active Implantable Medical Device Directive (AIMDD) and the Medical Device Directive (MDD). After a three-year transition period, medical device manufacturers will be expected to comply with the new regulations by May 26, 2020. Any certificates issued with respect to the MDD or AIMDD during the transition period will expire four years after the May 26, 2020 implementation date.

The EU MDR eschews a focus on the pre-approval phase of medical device manufacturing and instead encourages medical device makers to adopt a life-cycle approach.

The intent of this new regulation is to increase safety, quality, transparency, and innovation. The European Commission believes the May 2020 deadline is "achievable and realistic" and do not intend to allow for extensions, many medical device manufacturers are already feeling at risk for missing the deadline.

Some of the notable changes are as follows:

1. New classification rules now including products without medical purposes
2. Shared responsibility between Non-EU medical device manufacturers and authorized representatives
3. Unique device identification (UDI) requirements
4. Implementation of the EUDAMED database

As of November 7, 2019, only seven notified bodies have been designated under MDR 2017/745.

REPROCESSED MEDICAL DEVICE MARKET

The reprocessed medical device market is one of the most critical niche markets in the life sciences sector as it not only provides critical products for health service providers such as hospitals and ambulance services, but it also reduces their comprehensive expenditures on the products and mitigates medical waste. As health service providers continue to use these products, they are demanding the same quality, efficacy, and sterilization from the sellers that they did from the original equipment manufacturers (OEM). Medical device products that are reprocessed include compressions sleeves for arms and legs, electrical surgical tools, catheters, and blood pressure cuffs.

The environment for reprocessed medical devices is ripe for the continuous growth of the sector. Firstly, the FDA is an advocate for this market and continues to establish necessary regulatory guidances for the industry, specifically manufacturers, to comply with. The regulatory guidance titled Reprocessing Medical Devices in Heath Care Settings: Validation Methods for Labeling was issued in 2015 and was updated in 2017. The guidance provides recommendations for the formulation and scientific validation of reprocessing instructions for reusable medical devices and provides recommendations for the review of labeling instructions of new medical devices for their reprocessing into reusable medical devices. Wider adoption of reusable medical devices is expected to expand in developing nations as the safety profile continues to be established.

Secondly, the increase in chronic illness diagnosis and an aging population will continue to place pressure on the private and public sectors to find efficiencies in the supply chain to drive down costs to make healthcare affordable. The reprocessing of medical devices and their acceptance by the health services sector as safe and effective will be one lever in doing this. Lastly, the prevalent forces within the public and private sectors to drive all industries to be more cognizant of their current and future impact on the environment will drive OEMs in the medical device sector to design, manufacture, and distribute devices that can be reprocessed in order for their use to be extended, which in turn, will reduce medical waste.

CYBERSECURITY AND THE ROLE OF THE FDA

Following on recent trends of the increased use of smart devices, IoT, artificial intelligence, and machine learning, the need for cybersecurity is essential to any medical device with embedded software, mobile health applications, or stand-alone software used to make care decisions. It's a strategic imperative that all stakeholders involved in the design, development, manufacturing, distribution, and use of medical devices are aware of the cybersecurity risks as more and more interconnected and interoperable products come to market. Fortunately, as of late 2019, the FDA is not aware of any patient injuries, adverse events, or deaths associated with a security breach of a medical device. However, these threats exist and controls must be continuously implemented and monitored to ensure risks to patient safety are minimized.

The FDA has played a prominent role in developing comprehensive guidances to support both medical device manufacturers (MDM) and health care delivery organizations (HDO) in reducing the risk of security breaches that could impact the safety and effectiveness of a pre-market or post-market medical device. Since 2005, the FDA has issued 4 guidance documents, 9 safety communications, and 3 distinct reporting requirements for manufacturers, health care providers, and patients respectively related to cybersecurity; as well as a simple but effective fact sheet addressing misinformation around the FDA's role in cybersecurity. Moving through 2020 as digitalization continues to spread in the industry, each point of connectivity represents a potential risk, making it even more critical for medical device makers to assess and update cybersecurity protocols with a holistic approach.

The 2020 Medical Device Trends encompass a wide variety of disruptions that will impact the industry far beyond the year ahead. Medical device businesses must employ new modes of thinking, hire or train for new skills and capabilities, and implement new technologies in order to realize the benefits for growth and transformation afforded by these landscape shifts.