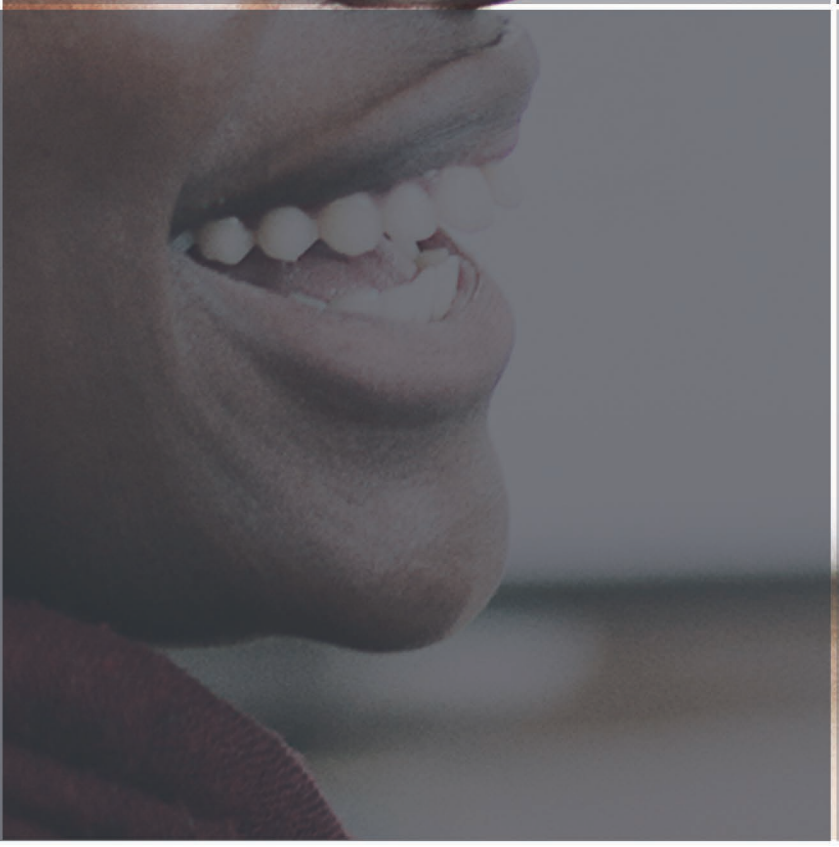
White Paper

Top 5 Medical Device Industry Trends in 2019



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The global medical device industry is expected to grow every year by about 5 percent, with annual sales worldwide reaching $800 billion by 2030, according to the consulting firm KPMG Global Strategy Group.[1] In the context of this rosy forecast, what can device firms, patients, consumers, and health-care providers anticipate in the near future?

In this white paper, MasterControl asked four medical device experts to share their insights on trends and developments that are likely to affect the industry in 2019.

Top 5 Trends

#1 Brace yourself for the impact of new regulations.

Regulatory changes in Canada and Europe that have loomed for quite some time are going to hit procrastinating companies the hardest. The following regulations and standards are going to have a considerable impact on the industry in 2019:

- In Canada, the Medical Device Single Audit Program (MDSAP) is replacing the Canadian Medical Devices Conformity Assessment System (CMDCAS) beginning Jan. 1, 2019.

- This is the last year for device companies to transition to the European Union's Medical Device Regulation (MDR), which is going to replace the Medical Device Directive (MDD). The European Parliament adopted both the MDR and the In Vitro Diagnostic Medical Devices Regulation (IVDR) in May 2017. In 2020, medtech firms will start competing in a more complicated European market when the MDR is enforced.

- The deadline for transitioning to ISO 13485:2016 is March 2019, which means device manufacturers must meet the new requirements by then to maintain their ISO 13485 certification.

"European quality assurance and regulatory affairs personnel seem to be overwhelmed by preparations for the new MDR. This realization has not quite hit American companies," said Rob Packard, a consultant specializing in 510(k) submissions and helping startup medical device companies address quality and regulatory requirements.[2]

Ready or not, however, the shifting regulatory landscape is going to bring additional costs that could prove to be a major obstacle for smaller companies. "The forever evolving regulatory climate stifles creativity in the medtech industry, in part due to the increased costs associated with compliance," said Christopher J. Devine, Ph.D., president of the medical device consulting firm Devine Guidance International and a columnist for MedTech Intelligence.[3]

Devine recalled that in 2014, compliance costs also went up when the requirement (2013/473/EU) for certified bodies to conduct unannounced audits at the sites of device firms and their critical contractors took effect. The requirement affected device manufacturers entering products into commercialization in the EU. "I have seen some of my clients make a conscious decision to leave the EU market after the costs of doing business there became cost-prohibitive," said Devine.

#2 Human factors engineering (HFE) is more important than ever.

Two years after the FDA issued HFE guidance documents, the concept has become more important than ever, according to Alex Butler, manager of medical device solutions at MasterControl.[4] "'Human factors' is a buzzword in the industry because it's essential. Regardless of what your device is, you need to make sure every person who uses it will be able to use it properly."

In an FDA guidance on HFE, the agency stated that it "considers human factors testing for medical devices as a part of a robust design control subsystem." It recommended the inclusion of HFE data in premarket submissions for devices with risk analysis that shows incorrect use of the device could result in serious harm. An accompanying guidance specified the types of devices that should include human factors data in premarket submissions.[5]

The importance of human factors is highlighted in a recent warning letter sent by the FDA to a medical device company for failure to conduct a postmarket HFE study and testing. The FDA warned the company that without HFE, the failure of the device could cause infection and possibly serious adverse health consequences.[6]

#3 The following products are likely to gain momentum: devices for minimally invasive procedures, light-therapy-based devices, and human cells, tissues, and cellular and tissue products (HCTP).

Devine felt positive about the popularity of minimally invasive devices based on what he was seeing with his own clients that are on the leading-edge of the design and development of next-generation products.

"Small openings into the body equate to a reduction in the post-surgical infirm and recovery times for patients, regardless of procedure," said Devine. He cited micro-catheters used to treat peripheral artery disease, radiation-therapy devices for treating breast cancer that require only small incisions, urological-drainage catheters that significantly reduce episodes of urinary tract infections, and next-generation bone screws as examples.

"The biggest trend I expect in 2019 is a big increase in devices that are not medically necessary," said Packard. "The FDA has already decided not to regulate some of these products, but the technology is pushing the envelope and will exceed the FDA limitations." Asked to give examples, he mentioned devices that "melt" fat, barbed sutures used for face-lifts, and diagnostic monitoring devices for healthy people to improve performance.

Michelle Lott, principal and founder of Lean RAQA, anticipated an increase in on-indication developments in the human cells, tissues, and cellular and tissue products (HCTP) as a result of FDA guidances issued at the end of 2017. "We will start to see HCTPs with specific on-label indications cleared by the FDA and supported by clinical data. To facilitate biologics license application approvals, the FDA has opened five new pathways to expedite and facilitate review," she said.[7]

Lott also forecasted there will be more devices based on light therapy, noting that the number of FDA clearances of such devices has increased. "As the science and understanding behind light-therapy devices grow, we will see novel indications and conditions for unmet needs," she added. She cited Kyndermed, currently in consideration for a breakthrough designation, as an example. The company has a novel application of light technology that reduces preterm contractions in pregnant women.

#4 The pace of regulatory change will increase even more.

"In fiscal year 2018, the FDA had planned to release 20 new guidances, but in reality, it issued 65! For fiscal year 2019, the FDA's agenda includes another 27 new guidances," said Lott. "And that's not to mention the fast-approaching MDR implementation date in May 2020."

Butler agreed that the MDR will have a huge impact. He said device firms that want to stay in the European market need to invest the time and manpower to evaluate their new requirements under the MDR. "MDR is the perfect storm and it's coming," he said.

#5 The role of medical devices in digital health will continue to grow.

The FDA's "Digital Health Innovation Action Plan" encourages innovation in digitally enabled devices through a pre-certification program, which allows pre-certified developers to market their lower-risk devices faster.

FDA Commissioner Scott Gottlieb heralded the marketing authorization of two medical apps for Apple Watch Series 4 on Sept. 12, 2018, as a "significant step forward for the agency's overall approach to the development of digital health."[8]

The first app is an electrocardiogram monitor, which can detect heartbeats that are too low, while the second app can detect irregular heartbeat. Both apps can send alerts to the wearer. The devices were De Novo applications. The FDA granted them marketing authorizations as opposed to a clearance or a premarket approval.

"I expect an increase in the number of De Novo applications and small human clinical studies to support efficacy," said Packard.

Lott agreed, saying that a number of new policies open up new pathways to facilitate innovation and faster clearance or approval of medical devices. "Medtech companies need to embrace regulatory change and use it to their advantage to get their products to market and make money faster," she said.

Tips for 2019

Asked to give one piece of advice to medtech professionals, Lott emphasized the importance of keeping abreast with new developments. "Know what guidance documents or regulatory changes are going to impact your business strategy and do a gap analysis so that you can make a plan. Start yesterday," she said.

For Packard, the new year is a great time to evaluate old, paper-intensive processes and tools. His advice: "Become paperless, make software validation a strength, implement post-market clinical follow-up for all devices, and update your entire quality system to the new MDR before the end of 2019."

Devine highlighted the urgency of new regulations. "From a regulatory standpoint, if your organization has not started migration to the EU MDR, there's no time like the present to begin that journey. What was considered 'optional' under the old regulation will become mandated," he said.

How MasterControl Can Help You

Medical device companies face fierce competition in the global marketplace and a constantly changing compliance landscape. MasterControl can help improve your competitive edge and strengthen your regulatory compliance through technology-driven processes.

Equip your organization with essential solutions and tools to increase efficiency, reduce costs, accelerate time to market, and ensure compliance. These next-generation solutions are tailored for medtech firms like yours:

MasterControl Quality Excellence

MasterControl Regulatory Excellence

MasterControl Manufacturing Excellence

MasterControl Validation Excellence

MasterControl Spark

MasterControl Bill of Materials

Conclusion

The five trends discussed above all point to a healthy marketplace and a dynamic compliance landscape. The medical device industry has every reason to be optimistic about its prospects for 2019. Keeping abreast of changes and understanding the underlying reasons will help your organization stay proactive and make informed decisions.

References

(1) "Medical Devices 2030: Making A Power Play to Avoid the Commodity Trap," published by KPMG Global Strategy Group in 2018.

(2) Rob Packard is the president of Medical Device Academy, Inc. He has 25 years of experience in the medical device, pharmaceutical, and biotechnology industries. He has served in senior management positions at several medical device companies, including as president and CEO of a laparoscopic imaging company. His quality management system expertise covers all aspects of developing, training, implementing, and maintaining ISO 13485 and ISO 14971 certification.

(3) Christopher Devine, Ph.D., president of Devine Guidance International, has 32 years of experience in quality assurance, regulatory compliance, and program management. His consulting firm specializes in providing solutions for regulatory compliance, quality, supplier management, and supply-chain issues facing the medical device industry. He's a senior member of the American Society for Quality (ASQ) and a member of the Regulatory Affairs Professionals Society (RAPS) and Project Management Institute. Check out his MedTech Intelligence column.

(4) Alex Butler, manager of medical device solutions at MasterControl, oversees development and continuous improvement initiatives for several MasterControl core products, including MasterControl Regulatory Excellence. He has an extensive background in medical device technology and innovation, with over eight years devoted to product development, strategic planning, quality assurance, and process improvement. Prior to MasterControl, he served as a product development manager for Opal Orthodontics, where he was directly involved in the development, quality and compliance, risk management, registrations, and launch of several Class II medical devices.

(5) From the FDA's guidance documents, "Applying Human Factors and Usability Engineering to Medical Devices," and "List of Highest Priority Devices for Human Factors Review," both issued in February 2016.

(6) FDA warning letter to Olympus Corporation, issued on March 9, 2018.

(7) Michelle Lott is the principal and founder of Lean RAQA, a regulatory and quality system solutions company. She has nearly 20 years of health-care product experience, including holding executive roles for international regulatory and quality operations. She's currently serving on the FDA's Device Good Manufacturing Practices Advisory Committee as an industry representative.

(8) "FDA Budget Matters: Advancing Innovation in Digital Health" by Scott Gottlieb, FDA commissioner, Sept. 26, 2018.

About MasterControl Inc.

MasterControl Inc. creates software solutions that enable life science and other regulated companies to deliver life-improving products to more people sooner. MasterControl's integrated solutions accelerate ROI and increase efficiencies by automating and securely managing critical business processes throughout the entire product lifecycle. More than 1,000 companies worldwide, ranging in size from five employees to tens of thousands, rely on MasterControl cloud solutions to automate processes for new product development, clinical, regulatory, quality management, supplier management, manufacturing and post-market surveillance. MasterControl solutions are well-known for being scalable, easy to implement, easy to validate and easy to use. For more information, visit www.mastercontrol.com.

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