Medtech Insight

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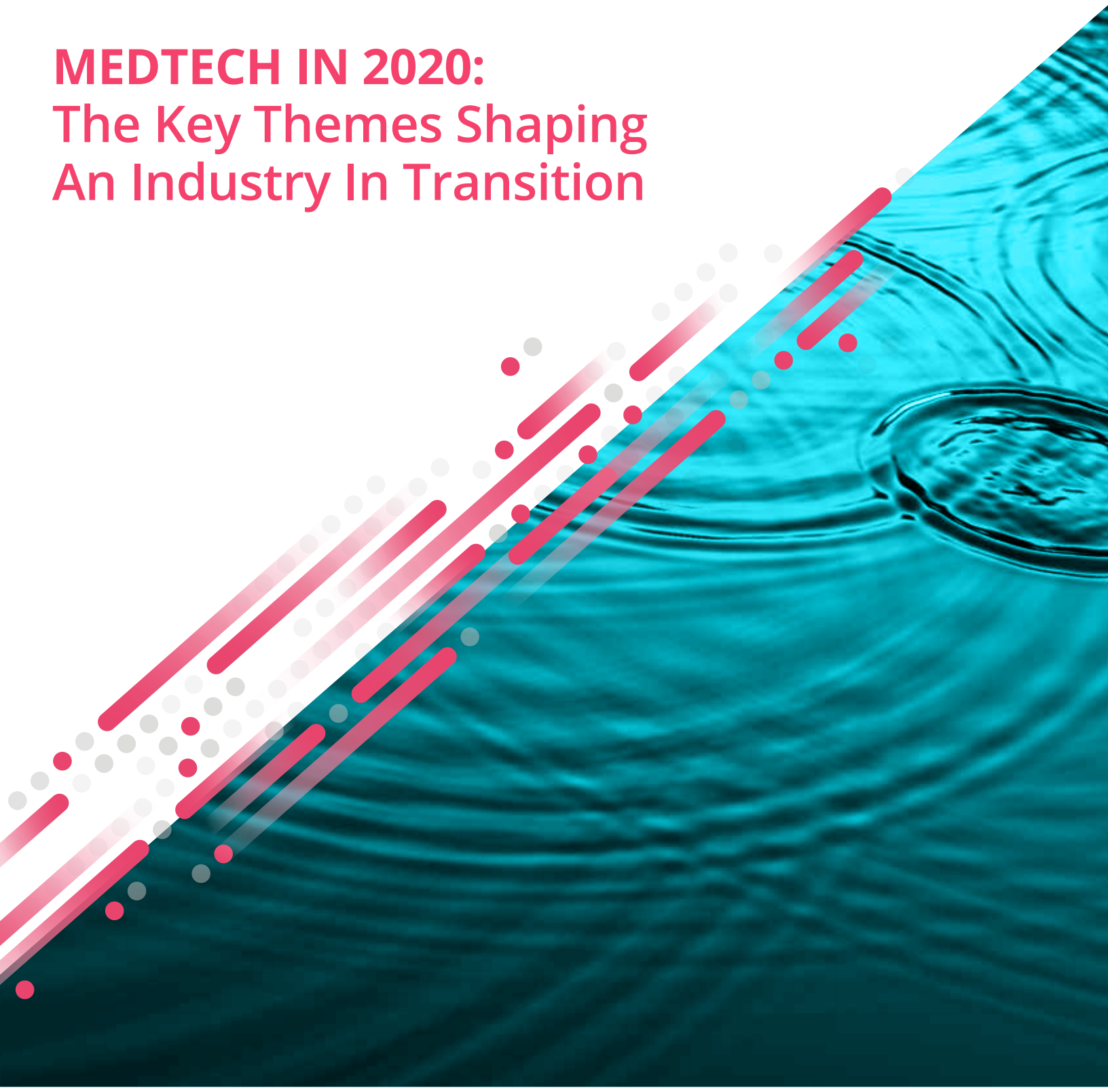
MEDTECH IN 2020: The Key Themes Shaping An Industry In Transition



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MEDTECH IN 2020:
The Key Themes Shaping An Industry In Transition

The medtech industry enters the new decade in a state of increasing flux. Major, time-sensitive changes are redefining the European and global regulatory environment with a ripple-effect of profound impact on well-established processes and even future product availability in certain markets. These regulatory changes are happening alongside massive innovation, continued impacts from mergers and acquisitions, advances in digital health and data analytics, and a fundamental shift in the focus of health care and payer-provider reimbursement models, creating a perfect storm that is reshaping operations and revealing new opportunities to improve the lives of patients.

More than ever, patient care and quality of life are the driving force behind innovation to the medtech industry. The European regulatory changes can be traced back to a focus on patient safety, while the industry's use of digital health devices, real-world evidence, data, and advanced analytics also revolves around these most important of stakeholders. Patients and the medtech industry as a whole, have the opportunity to benefit from the renewed focus on the needs of the ultimate users of health products and services.

Understanding the external forces is only one part of the challenge for medtech companies in 2020. To emerge from this period of change as industry leaders, companies will need to find ways to steer clear of abundant headwinds while taking full advantage of available tailwinds of technology and outside resources with focused domain expertise. Required will be new ways of working that bring down barriers and enable collaboration and true orchestration truly cross-functional across the organization.

In this eBook, we look at the five trends reshaping medtech, from the move to patient-centricity that is touching every part of the industry through to the business process orchestration that is enabling companies to retool their operations and processes to thrive in the new normal. This eBook tells the story of an industry that is responding to significant external pressures and opportunities with equally significant internal developments, thereby positioning itself to better meet the needs of patients in the new decade ahead.

Nick Taylor
Medtech Insight

Bhavik Patel,
Senior Vice President, **IQVIA MedTech**

PATIENT CENTRICITY: THE DRIVING FORCE BEHIND THE NEW MEDTECH

Medtech companies have always been patient-centric organizations. Yet today, with the point of care moving from hospitals to homes and physicians evolving from authorities to guides, what it means to make patients the focal point of operations is changing. These changes interweaved with market access, value-based pricing and reimbursement, digital health, virtual trials, new regulations, and the pursuit of innovation are forcing transformation for companies looking for global excellence. Addressing these changes, companies need to orchestrate across their business processes to thrive.[1]

Patient-centricity has been a focal point of conversations about the future of medtech in the past, only for the promise of the concept to fail to fully materialize. That old gap between the promise and reality reflected unrealistic expectations, assumptions about decommissioning and restructuring that could not happen quickly, the vested interests of providers and difficulties reallocating budgets.

This time around, there are reasons to believe the industry will clear any barriers, in part because the changing nature of health care delivery has thrust patient-centric themes to the top of agendas. A focus on the specific needs and characteristics of individuals is central to many technologies that are reshaping health care, including companion diagnostics, imaging and robotic-assisted surgery.

The position of patients at the center of the new medtech is perhaps best exemplified by the rise of digital health, which, through the continuous collection and analysis of data from individuals, is unavoidably patient-centric.

HOW DIGITAL HEALTH IS REDEFINING HOW MEDTECH HELPS PATIENTS

The role of patient-centricity is further evident with the rise of digital health. Breaking digital health into its component parts, which include connected devices, software as a device, patient data and real-world evidence, and personalized devices shows the central role patients play and the importance of human data science in a digital health world.[1]

Connected devices that can be modulated to facilitate personalized care and remote monitoring are a direct manifestation of patient-centricity. Treatment can be monitored and tailored to the specific needs of the patient and the continued growth of 3D-printed devices exemplifies ways in which companies are leveraging innovation to meet both speed-to-delivery and patient-specific care. Patient-centricity is also evident in connected devices that can constantly gather data on patients. When combined with data captured by software as a device products, such as medical apps, which can include geo-centric and other physical and personal data, the output of connected devices in our IoT (Internet of Things) world we operate in today yields unprecedented insights into the day-to-day health of individual patients and can be used to identify clinical trial populations and even support virtual trials.[1]

Each component of digital health is powerful in isolation. However, their full potential only becomes apparent and fully realized when they are combined. Together, the components are facilitating virtual trials by enabling sponsors to remotely identify participants and collect data from them, streamlining the process of generating evidence to support claims about a device.[1]

Johnson & Johnson delivered the view that sensors and wearables are clearly a huge opportunity for the medical device industry, but the question is how to develop technologies that take advantage of the data that devices such as FitBits and Apple Watches deliver. J&J collaborates with Apple in research on the use of wearable technology on early detection of atrial fibrillation.

AI can be used in all areas of work, from the disruptively innovative to the more prosaic, such as ensuring health-care staff clean their hands before and after touching patients. This particular project is owned by Radius Innovation, which used an AI application to synchronize the number of hand sanitizing events across a hospital, resulting in proactive uptake and more hand-washing.

Regulatory pathways for AI-based devices have been the focus of US FDA attention, which sees the compliance landscape as continually evolving as technology advances. That, and reimbursement, are huge outstanding issues for an industry that once again is seemingly ahead of government and central decision-makers on pivotal medtech market access themes. AI comes under the headings of "value generation" and "reduced overall health system burden." The hope is that driving for better outcomes and cost-effectiveness at an early stage early will deliver a clear-cut value proposition.[2]

UNLOCKING THE POWER OF REAL WORLD EVIDENCE, DATA AND ANALYTICS

Importantly, patients are increasingly in charge of the data behind these insights. Ownership of data is shifting from institutions to consumers, putting patients in control of how their information is aggregated for population-level analyses that improve care. Analysis of digital health data is part of a broader effort involving real-world evidence. That effort is based on four main sources of

longitudinal data: medical records, prescription data, hospital encounters, and claims from payers, hospitals and drug plans. While RWE is typically thought of in the postmarket context, the value of its insights extends across the value chain. RWE informs everything from device concepts and trial designs to health care professional training and the generation of evidence to support premium pricing in a value-based health care environment. Thus, it is a concept to consumer and back again environment that requires business process orchestration to fully leverage the benefits. Business process orchestration permits such company-wide use of RWE by breaking down silos while overlaying quality, regulatory, safety and other functions from clinical to commercial that span the entire product life cycle. That means people working at each step in the value chain from concept to market have access to information both upstream and downstream of them.[1]

Innovation In The Big Data Digital Health Era

The proliferation of data is happening in unison with a related expansion in advanced analytic capabilities. Faced with the need to analyze data from sources such as connected devices and other external data sources, medtech companies are leveraging the power of cloud computing along with machine learning (ML) and artificial intelligence (AI). These advanced technologies are enabling companies to get insights from big data and perform predictive analytics and better risk management.

Medtech companies have always innovated faster than their pharmaceutical counterparts. The rise of data and advanced technologies is further accelerating that pace by equipping companies to quickly make data-driven and risk-based assessments of what patients need and develop products that address them. Patient-centric digital transformation is mirrored by changes in physical products, which can now be personalized to individuals.

New products are only one part of the innovation story, though. To meet the needs of patients around the globe, medtech companies also need to understand the regulatory pathways and requirements to get existing devices into new markets. Orchestration across regulatory intelligence data (RID) and regulatory information management (RIM) along with enterprise quality management (eQMS) solutions are the backbone of getting products more quickly and efficiently into new markets. In some cases, medtech companies can enter additional markets with minimal new trial efforts or trials and approvals from other markets, thereby quickly bringing benefits to millions of patients. Where trials or data are required for market approval, business process orchestration and real-world evidence will facilitate accomplishing this more effectively without adding significant costs.

Entering new markets extends the life cycle and overall profitability of products and maximizes the benefits they provide to patients. However, the effectiveness of innovation and compliance strategies rests on a company's ability to operate from an overall business process orchestration perspective globally across traditional functional and geographic silos. Integrated solutions implemented in a business process orchestration fashion in concert with one's clinical, compliance and commercial operation systems and processes can quickly identify the best opportunities, improve decision-making and facilitate operational excellence.[1]

Leveraging Data To Optimize Clinical Operations

Human data science is an emerging discipline that relies on precision data rather than the law of averages to drive patient solutions. Data analytics can help predict which sites can deliver the right patients, increasing enrollment speed up to 30%. Meanwhile, using data to take a holistic view of trial sites and identify patients at higher risk means actions can be triggered across the study team to avoid issues before they occur.

Companies that are able to leverage data solutions to glean these types of insights are more successful at managing change, Dr. Christopher Fang, vice president clinical solutions, IQVIA MedTech noted. Using advanced analytics, human data science can also reveal more about complex treatments as more data is captured from patients. It integrates the study of human science with breakthroughs in data science and technology, building an ecosystem of knowledge based on a better understanding of human experience.

"Because of connective devices and the internet, we have the ability to capture more data from a lot more people, including geo-tagging it. Capturing opt-in information from people's Apple Watch or Fitbit allows us to know exactly how active someone is and more, by measuring the steps one takes from where and when and what one's heart rate and blood pressure are," Fang said. "This data, when triangulated with other health and medical history, can be helpful when looking for certain trial patient populations. Now, at a touch of a button, one can have the information and demographics to identify certain trial populations and candidates. It used to take weeks or months to identify such trial groups."

As the world becomes more digitally connected, data can be the silver bullet if MedTech firms leverage it to optimize clinical operations and to orchestrate across other business operations. In this way, silos can be broken down so that clinical data and regulatory interoperate, as do commercial units and manufacturing, from concept to market across the entire business to better guide and align strategy and execution.[3]

Data Insights Support Market Success

Companies that want to achieve commercial success should ensure data from all business areas is harmonized and integrated into every unit in the organization. This is especially true against the backdrop of consolidation and intense pricing pressures in the health care sector.

Real-World Evidence Findings

In today's emerging era of value-based health care, safety, efficacy and quality data that used to be sufficient to get products to patients in even the most demanding of market access environments are falling short. Payers want to see stronger evidence of need and the positive effect that is delivered.

Apparent is the importance companies are placing on real-world evidence. Such evidence can persuade payers and providers to cover and use products by showing how they positively affect outcomes in the real world.

Likewise, almost two-thirds of respondents think RWE in clinical trials is very or critically important. However, people are far less certain about how to act on this knowledge. More than two-thirds of respondents are unsure how RWE can help them, are just starting to learn how to use the real-world evidence, or are finding their activities constrained by limited access to high-quality data.

Less than 20% of all respondents said RWE in trials has been the cornerstone of their activities for some time, although that figure shot up to 33% among executives, once again suggesting siloed workers may have led to an artificially low overall survey result, and the need for companies to better orchestrate across business processes.

(Source: How Medtech Is Responding To Changes Set To Reshape The Industry report, 2019)

Harmonizing data and operations allows companies to apply artificial intelligence and machine learning for analytics and deep insights that justify pricing policies. For example, they are able to consolidate and analyze their data on reimbursement options and budgets, surgical outcomes, procedure costs,

hospital infrastructure and patient goals, as well as regulatory requirements and product demand in each target market.

Meanwhile, real-time, real-world data generated from the use of products can provide unique insights into patient and provider perception of value, leading to product improvements, new products and better pricing strategies. Such data-driven pricing strategies position device makers to compete in a value-based world.

Data insights also promote safer products. For example, harnessing artificial intelligence and machine learning allows firms to capture adverse event data and create cases automatically, before a complaint or event is reported. Machine learning and artificial intelligence can be applied to social and other data to anticipate and automate cases for investigation ahead of time-sensitive problems. This can also provide useful information to design product updates and adjust product capabilities.

To be useful, rich data must be aggregated from numerous sources such as de-identified patient records, global sales figures, internet of things data feeds and more. Integrating multiple disparate sets of data can be challenging. In health care, this becomes more daunting given the need to protect patient privacy and account for geographic differences and partial data sets.[5]

CRUNCH TIME: HOW REGULATORY CHANGES ARE RESHAPING COMPLIANCE

The European Union's Medical Device Regulation (2017/745/EU) comes into full effect in May 2020. The changes it will introduce are a major concern for medtech firms worldwide. Many device makers don't have the resources and deep understanding of the MDR requirements or lack a complete strategy for dealing with all the ramifications as well as opportunities. The MDR builds upon the medical device and active implantable directives, tightens pre-approval requirements and adds unique product tracking and additional post-market requirements. Some already-marketed medical products have been or will have to be reclassified, requiring new regulatory approval, new CE-marks, and consequent investment of time and effort.

Preparing For MDR

In their work with medical device and diagnostics companies around the globe, IQVIA MedTech consultants have seen the degree to which companies are trying to prepare for the MDR and the significant burden on the industry.

Under the MDR, there are several changes affecting the quality management system. These include new process requirements that manufacturers will have to adopt, and new device technical file requirements that companies will need to meet. Device manufacturers need to make adjustments to their risk and quality management processes and systems to have the required data and reports available for audit.

In the case of regulatory changes involving product reclassification, preparation may require additional clinical data, and maybe even new clinical trials to support Clinical Evaluation Reports (CERs) and provide the information needed by Notified Bodies and regulators for approval.

At the same time, companies must manage increased post-market vigilance and safety efforts to address the new and expanded reporting requirements, as well as the accelerated timeline for vigilance reporting, which has been reduced from 30 days to 15 days under the MDR and IVDR.

In light of these changes and challenges, some companies may have to choose between investing heavily to maintain or expand product placement in key markets and pulling or delaying market launch of certain products. This has the

potential for broad supply chain and even patient care ramifications.[6]

Fortunately, complying with these regulatory changes and keeping track of new requirements worldwide can be made easier by:

- Working with consultants that have deep MedTech regulatory expertise
- In-sourcing additional resources to assist with the new demand
- Applying better automation and technology to increase efficiencies and management
- Leveraging tech-enabled managed services providers to manage some of the clinical and data needs

Key Findings

- Almost 40% of executives with operations in the EU said the impending Medical Device Regulations will have a significant or critical impact on their businesses.
- Faced with the need to recertify products in compliance with the new, tougher rules, almost 20% of respondents expect to withdraw devices from the market rather than go through the revised regulatory process.
- Across the whole data set, 83% of respondents said they are yet to reclassify any products.
- A significant minority of respondents think they currently capture less than 20% of the data required by the new regulations.

(Source: How Medtech Is Responding To Changes Set To Reshape The Industry report, 2019)

How Patients Are Reshaping Regulation

Changing regulations are also driving companies to relook at how they orchestrate compliance across their operation. Patient-centricity underlies changing regulations and product innovation and improved safety is a by-product. The focus on further enhancing patient safety, manifested in new and constantly evolving regulations, will require medtech companies to capture and report additional data on their prod-ucts. These regulatory changes may create challenges related to product reclassification and approvals through notified bodies in the near term, but medtech companies that adapt effectively to the new regulatory environment will be best positioned to reap the benefits long term.[1]

Those benefits stem from the fact that companies as well as regulators will have more and better data on their products. Regulators glean insights from the data that enable them to take a more informed, risk-based approach to oversight, reducing auditing of some companies on the grounds that the data provide confidence in their compliance. That too will benefit patients by increasing scrutiny of high-risk products and companies. Medtech companies, in turn, can use data captured in orchestrating their business processes from research and development and clinical trials through commercial operations and service providers for not only compliance but additional evidence and analytic capabilities to further innovation and operational excellence.

Compliance

While the clinical department is dealing with trial timeline and enrollment pressures, the compliance department is grappling with risk management, quality maturity, postmarket vigilance, product safety, commercial compliance, and the need to track and react to shifting global regulations and audits. MedTech firms that fail to properly manage these challenges, face regulatory actions and loss of market share.

These consequences are a growing concern, particularly as many medical device firms are still underprepared for the MDR, set to take full effect in May 2020, says Larry Ferrere, senior director, strategy & marketing, MedTech Center of Excellence, IQVIA MedTech. For example, many haven't updated their quality management systems to report the additional clinical data and safety events required under the new regulations. They also face the risk that reclassified products that require a new CE certification and notified body involvement will not be approved in time to meet the looming regulatory deadlines and will have to be withdrawn from key markets.

While the MDR is a significant concern in the EU, in particular, there is also a ripple effect where the CE mark has been used as a basis for certification in other markets. If a new EU CE mark is required under the MDR, companies will need recertification in their other markets, as well.

And at the same time these changes are taking place, MedTech firms must continue to track evolving regulatory requirements in more than 100 key markets, with updates coming as frequently as every 20 minutes.

These needs and changes create opportunity, and leading companies are embracing the changes as a driver to take steps forward. By applying advanced technology versus assigning more staff to existing processes, and by examining which processes can be outsourced to managed services providers with the right people-power and domain expertise, companies can focus resources on core processes that differentiate them in their market while remaining compliant.

For example, the MDR can be a driver for companies to abandon obsolete and disparate quality processes for an orchestrated, enterprisewide quality management solution. Such a solution should include support for MDR

and risk management for concept-to-market quality compliance needs, along with improved data and safety features.

A more effective compliance program includes integrated solutions that automatically track new requirements and regulatory changes, orchestrating alerts and updates across the extended enterprise. Solutions that are powered by artificial intelligence techniques, including natural language processing and machine learning, and that leverage big data from connected devices, market insights and social media signals, can improve decision-making and overall business and product effectiveness.

Managing regulatory changes and maintaining compliance is easier with up-to-date, integrated regulatory intelligence, regulatory information management, and quality management systems that track global regulations and orchestrate across myriad business processes, says Donal Cumiskey, senior director of compliance solutions strategy for IQVIA MedTech. This is particularly important

amid the heavy regulatory change and merger and acquisition activity that has marked the MedTech space, so companies can harmonize and optimize across divisions, sites and markets globally.

Better compliance solutions also allow companies to track patient safety events more effectively and sooner. These events and other real-world evidence in turn give firms more supporting evidence if they are subject to an audit, and they also allow a postmarket feedback loop that can inform decisions in other departments.

All of these improvements drive quality maturity, which lowers the cost of both maintaining high quality, as well as the frequency and cost of addressing events related to quality problems.[7]

BUSINESS PROCESS ORCHESTRATION: THE GLUE THAT BINDS THE NEW MEDTECH

Companies will, and are, moving past a focus on simply integrating disparate systems and siloed groups to one that fosters and operates in a true cross-functional and extended enterprise collaborative fashion. Operating across business processes, including the systems and technology to support the needed business process orchestration illustrates how leading companies will further adapt to the transformation and leverage being driven by digital health and patient-centricity.

Why Business Process Orchestration?

To achieve this entails taking a business process view of the full medtech product life cycle, from concept to market, and bringing together the technology, products, services, consulting, data and technology-enabled managed services necessary to combine each link in the value chain. In practice, these changes will require medtech companies to use the collective resources and industry expertise they possess and that of their trusted partners.

Business process orchestration is a new way of working for many medtech companies but it is a necessary change. Companies that make this transformation with be best positioned to emerge from these times of change as industry leaders. As patient-centricity, digital health and regulatory changes are behind many of the forces reshaping the medtech industry, companies that put the patient and data at the center of their innovation will be the long-term winners.

Successful companies will leverage deep and unmatched domain expertise, transformative technology, unparalleled data and advanced analytics while adopting business process orchestration, equipping them to improve their operations while keeping patients at the center of every decision.[1]

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BUSINESS PROCESS ORCHESTRATION

IQVIA MEDTECH

Why is business process orchestration necessary for medical device and in vitro diagnostics companies?

In today's competitive and changing market, MedTech companies must abandon traditional siloed business approaches and adopt business process orchestration — linking data, processes and people all the way from R&D through commercial operations — from concept to market.

Orchestration means
BETTER INNOVATION

Orchestration means
COMPLIANT OPERATIONS FROM END TO END

Orchestration means
GREATER SUCCESS IN THE MARKETPLACE

ORCHESTRATION MEANS: BREAKING DOWN THE SILOS

RESEARCH & DEVELOPMENT needs the market insight and real-world evidence to make effective strategy decisions, drive effective clinical trial programs and gain timely approvals

COMPLIANCE requires meeting ever-changing quality, regulatory and safety requirements on a local and global basis from R&D through commercial

COMMERCIAL OPERATIONS is not just getting product to market; it provides post-market data and safety input for clinical, commercial and regulatory compliance; patient and provider feedback drive future innovations; all while managing reimbursement, market access and overall commercial performance

From concept. To market.

For business orchestration across the entire product lifecycle.

Whether you need time-sensitive MDR/IVDR assistance, local or global clinical trial assistance, specific medical device or in vitro diagnostics expertise.

If you are looking to insource, outsource, implement advanced technology and solutions, or Real World Evidence. If you want to improve operations efficiencies, or just need a trusted partner to manage processes with or for you, contact IQVIA MedTech today. We're here to help.

Others may offer a way forward.
IQVIA gives you a way further.

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