Europe’s medical device industry: leadership challenges in a changing world
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As drastic changes hit the medical device industry, companies will need executives with different skill sets to lead unavoidable changes. In some cases, they will need to seek or develop new competencies. In others, they may need to recruit from non-medical industries to secure the talent they need to thrive.

The medical device industry, having enjoyed fast growth and healthy profits for many years, faces much tougher times ahead. The industry is operating in a drastically changed environment with reduced government funding exacerbating the difficulties. On the customer side, the decision-making is shifting from physicians to procurement departments. More innovative strategies are required to deliver solutions that not only improve patients’ health but also reduce overall healthcare costs.

The individuals who led companies through the bull market do not necessarily have the skills that will yield success in this setting. Identifying, developing, and attracting talent that can drive the necessary changes will be an important differentiator for companies looking to gain a competitive edge.

Trends shaping the sector

The main trends making it harder to achieve the same level of top-line growth and profit margins in Europe include:

Changing decision-makers. The power of physicians, once the sole decision-makers, is being eroded by hospitals’ centralised procurement departments. Sales teams today must manage not only the doctors but also procurement officers, hospital executives, other healthcare practitioners such as nurses and technicians, and even patient and consumer advocacy groups. Each of these groups has different priorities, increasing the complexity of the sales process.

Influential new entities. The sales process is being further complicated by the appearance of new powerful groups in the market. These include Group Purchasing Organisations (GPOs), which contract with suppliers on behalf of a consortium of hospitals that collaborate to pool their purchasing power and improve their negotiating position.
There are also government-driven centralised bodies, such as Health Technology Assessment (HTA) agencies, that produce independent research on the cost-effectiveness and broader impact of medical treatments for the healthcare authorities. Another example is the UK’s National Institute for Clinical Evidence (NICE), which provides clinical guidance and sets quality standards for the National Health Service (NHS) on drugs, treatments, and procedures. There are also regional healthcare officers who act between the hospitals and the national healthcare systems, such as the commissionaires in the UK.

**Price pressure.** National healthcare systems are beset by deficits, a crisis exacerbated by an aging population and an increase in chronic diseases. Constrained budgets mean reimbursement is getting tougher to secure and rates are being reduced in most countries. The trend is clearly that manufacturers must be able to establish clinical efficiency and attractive economics. Their focus will by necessity shift to productivity and efficiency improvements. John Wilkinson, CEO of Eucomed, says, “There is no doubt that, as in all walks of life, we live in a smaller and more transparent world. Buyers are increasingly sourcing information across borders and some are even operating trans-nationally. The implications of this are clear for the industry, which will need to develop more strategic approaches to pricing, and this will reduce the independence of individual country operations to set local prices on a deal by deal basis.” Gradually, cross-border price comparisons will intensify and prices across Europe will become more aligned.

**Complex regulations.** The regulatory process for approving new devices is becoming more complex. Policymakers are increasingly vigilant in relation to product safety. For example, there are currently discussions in the U.S. around changes to the FDA’s 510(k) clearance process that would result in the up-classification of some products. Today, depending on the classification, manufacturers need only to prove the new product is “substantially equivalent” to a predicate device to be able to market it. With the potential changes, however, more products would require human use data from a formal clinical trial in addition to laboratory studies.

A consequence of this “pharmaceutisation” trend is that the development cycle be longer and costlier. It is also causing companies to rereconsider the U.S. as the ideal entry... consider the U.S. as the ideal entry market for new products. Already many companies launch their products first in Europe.

In Europe, a CE Mark—indicating that the product has met the European Union health or safety requirements—doesn’t necessarily mean the product is market-ready. Healthcare payers still want more comprehensive trials to establish clinical efficacy and attractive healthcare economics. Without such data, companies need to be careful of spending a lot of time and money to promote the product.

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Compliance rules. The traditionally close relationship between medical device companies and physicians is coming under greater scrutiny by governments and industry watchdogs. New legislation, such as the U.S. Physician Payment Sunshine Act, is focused upon extensive reporting and disclosure requirements related to company interactions with healthcare professionals. Voluntary ethics codes, such as the one introduced by the medical technology trade association Eucomed, are following suit.

These changes also mean new functions such as compliance officers and new internal processes are put in place. To date these changes have had the biggest impact on orthopaedic companies where they have changed the business model extensively. However, other therapeutic areas are being affected, particularly those that involve working closely with surgeons. The practice of direct sponsorship of doctors for third-party travel is rapidly becoming obsolete.

Commoditisation. Over the years, most approved devices have represented incremental improvements over existing products rather than true technological breakthroughs. Given the limited product differentiation and articulation of clinical benefits, the threat of commoditisation is high. This risk varies by therapeutic area, but in certain sectors companies mention that 30 to 40 percent of their existing product portfolio is vulnerable to commoditisation. Following on this trend is the entry of low-price competitors from countries such as China, Turkey, and Brazil, who are just beginning to drive prices down. This will force established companies to re-examine the product quality-versus-cost equation and ask themselves, “What is the customer actually willing to pay for?”

All these trends are shaping the fundamentals of how medical device companies operate and go to market. An increased cost-consciousness and a bottom-line focus clearly will be two of the direct results of these changes. The regulatory changes will mean increased time, cost, and risk to bring new products to market as more clinical trials and outcome studies are required.

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“The secret to continue growing in a changing market is to anticipate those changes in advance and adapt the organisation model to better answer customer needs,” says Laura Piccinini, president of Stryker Europe. “We are currently under attack from both high-end-innovation and low-end-price players. Commercial stakeholders are increasing in importance versus clinical ones, which causes changes in our sales model. Medical device companies need to become more innovative and understand what adds value to the customers.”
New leadership profiles

To remain competitive in this complex and fast-evolving sector, medical device companies need to create nimble, customer-focused organisations that can quickly capitalise on opportunities where others may fail. This often requires adjusting the organisational structure, particularly on the commercial side, to respond to the market changes. At the same time, firms may need to add whole new functional capabilities, or to elevate and better integrate certain others. Health economics and health policy are important functions today that will become even more critical in the future.

Medical devices leaders need to be change agents who will challenge the status quo and install a bottom-line focused culture. In addition, most functions will demand new sets of skills and competencies. Below we will comment on some of the key functions.

General management

General managers today are no longer responsible for manufacturing and are much more hands-on in sales and marketing activities. They are often, in essence, senior commercial executives.

“Going forward, the core algorithm is the same: it is all about people, innovation, and customer focus. The challenge is that this equation is changing after being constant for several decades,” says Scott Herring, Covidien’s president of surgical devices, EMEA. “For example, technology and innovation can no longer succeed on the cool factor alone. It has to be complemented by an economic proposition that ultimately delivers a cost-effective solution to the market.” It is essential that the general managers work directly to influence the local health policy and regulatory framework, a function that is often absent today.

General managers must possess the ability to develop good working relationships with key customers, opinion leaders, regulators, and policymakers. They must likewise demonstrate that they can be strong collaborators and influencers.

At the same time, because of the increasingly global nature of the business, international experience and a global mindset are a must for today’s general managers, even those in local roles. Equally important is the ability to manage geographically dispersed teams, as rarely do organisations today have all their employees under one roof. Effective communication skills are also critical to stay connected with such a virtual workforce.

One of the most important aspects of general management is to challenge the status quo and drive changes where they are needed. “Fair weather managers” who have successfully led the organisation during the good
years when the business grew on its own, will not, necessarily, be effective in more stringent times. As growth stagnates and margins erode, companies need change leaders who can instill a new type of culture that is cost- and profit-focused and has a strong emphasis on compliance. As there will be pressure on the bottom line, general managers must be able to put the right structure and processes in place to support the business needs, while also doing more with less. At the same time, they should maintain the entrepreneurial spirit that has been a critical driver of the industry.

These new leadership requirements offer real opportunities to those with the ambition to create distance from the competition. Companies that are able to attract, develop, and retain this type of management talent gain a competitive advantage over those that fail to adapt. “Talent management and succession planning are high on the agenda and need to become more quantitative and metric oriented,” according to Alexandre Conroy, president for Western Europe at Becton Dickinson. “How can we measure the results of our investments in these areas? If there is pressure on the resources, we need to show we are doing the right things. It is key to develop talent, but often we could be more results oriented.”

All changes are different; however, Korn/Ferry’s experience in designing competency frameworks for companies embarking on change suggests that companies need leaders who can take their people on a journey across the full change cycle. Many leadership teams falter at the “commitment threshold.” Most are able to promote awareness of the need for change, help people gain understanding of the strategy, and generate enthusiasm for the rewards if successful. It takes a rare leadership team to move their businesses to the full adoption, institutionalisation, and internalisation of a new set of behaviours.

A critical competency to look out for when ensuring the right team is on board to drive change is learning agility, which is also a strong indicator of high potential in an organisation. We will come back to this point later in the article.

**Sales management**

Given the new rules of the game in medical device sales, product features and price are no longer the only levers in the decision-making process. Today’s sales executives must be able to address cost-of-care and efficiency improvements, value-added services, and comprehensive solutions. Sales executives must also understand the needs of varied stakeholders—including clinicians, procurement staff, hospital executives, and local policymakers—and be able to communicate effectively with each type of customer. This requires not only solid relationship-building and negotiating skills, but also a firm understanding of health economics and the mechanics of reimbursement.

Sales reps, who traditionally were remunerated based on volume alone, must now be able to balance profit versus volume. This requires...
different skills and a more strategic mentality, and in many cases the existing sales team may be unable to make the transition. When assessing the required competencies, look for the critical skills of learning agility and adaptability.

“One way of justifying price premiums will be through services. We must be seen as a partner of the hospitals that are helping them solve their problems and acting as a full-service provider. It is critical to build up competencies in key account and tender management,” according to Rob ten Hoedt, president for Europe at Medtronic.

One way to address the varied competencies that sales roles require today is to split the role into two parts: key account management and product specialists. Key account managers are focused on specific customers and handle all of the sales negotiations for all departments and product lines for that particular customer. They are senior executives and strong negotiators who can manage complex relationships on multiple levels. In contrast, product specialists are technical experts who know the products inside out and are better able to understand clinicians’ needs and decision-drivers. This role is more focused on promoting the product features and benefits to physicians and hospital staff, as they speak the same language. Smaller companies will find such an organisational setup challenging, though, because already limited resources would be even more fragmented.

However, this division of roles creates a stronger sales organisation that better reflects the changes in the marketplace. Rob ten Hoedt also thinks that key account managers won’t necessarily come from sales, but from other areas of the business. “They are able to make large deals, connect with senior leaders, and have abstract thinking. On the other hand, new technologies will be adopted by the doctors first, and here it will be important to have product specialists interfacing with them.” Regardless of the setup, sales reps overall need to have a much better understanding of health economics, the mechanics of reimbursement, and how to influence policymakers.

Another related function already on the rise is the sales force effectiveness role, which seeks to maximise the return by determining the optimal sales force size, structure, and allocation of resources. Already an established discipline in the pharmaceutical industry, this function will become increasingly important for medical device companies as they are forced to be more efficient.

**Marketing management**

Medical device companies face more pressure than ever to differentiate products, provide solutions, and build brands impervious to price erosion. However, marketing skills in the industry today are sparse. In our experience, most marketers are either technical product specialists or sales supporters who develop promotional materials for the sales teams. Few are strong strategic marketers who can influence the
business strategy, drive product development through in-depth customer/patient knowledge, and command a seat at the leadership table.

Marketers must be able to understand and articulate how new products improve healthcare system efficiency and reduce hospitals’ costs per episode of care. They need to tailor the messages to the customers and the patient groups. All this requires an enhanced comprehension of reimbursement systems, and a deep understanding of customers and decision-makers. It is critical that marketers are able to influence both the upstream R&D process as well as downstream sales, and injecting their deep knowledge of customer insights into these areas will create a more customer-focused process.

“Marketing needs to be done differently in medical device companies,” explains Fred Hrkac, president for EMEA at Boston Scientific. “Traditionally most people have come up through the industry, which was fine as markets were growing. However, as markets are shifting it is no longer sufficient. New capabilities need to be built so companies can link with specific patient groups, but they need also to help payers deal with the cost issues. Another point is to educate referring physicians to propose procedures rather than putting patients on pills.”

Given the explosion in online marketing tools and direct-to-patient marketing techniques, marketers also need to be technologically savvy and stay current on the latest channels to communicate with both clinicians and end users.

In order to attract better marketing talent, companies need to start by upgrading the role internally and seek marketers with a proven ability to understand and address customer and patient preferences and behaviours. These skill sets are difficult to find today within the industry.

Sometimes companies have looked to the pharmaceutical industry to bring in stronger marketers, but this very often fails because pharmaceutical and medical device companies are fundamentally very different.

Where then to go for marketing talent? A better solution is to bring in junior marketers from other industries, such as technology, that have a stronger consumer focus but are used to working with technical products; they can learn the products and the regulated healthcare environment. In this way, a pipeline of stronger marketing skills is added to the organisation’s competencies. However, success will come only if the changes are supported by senior management.

**Health economics/market access**

Health economics and market access are relatively new disciplines for the medical device industry but are now emerging strongly given the escalating importance and complexity of reimbursement. “Many of the large multinational companies have had it for several years, but this

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function has often been missing in the mid-sized or small companies,” says Pierre Guyot, CEO of Mölnlycke Health Care. “In the future, this will be a requirement, both locally and internationally. It is very important to understand the regulatory and reimbursement bodies. However, the difficulty is in finding the right talent.”

As the need to demonstrate product value and overall savings to the healthcare system grows, many companies are looking to develop health economics expertise and market access capabilities in-house. And to Pierre Guyot’s point, there is a shortage of this type of talent in the medical device industry.

Essentially there are three ways of finding these professionals:

- Train someone internally who expresses an interest and passion for developing this area.
- Recruit graduates at universities specialising in health economics.
- Hire from the pharmaceutical industry as this function has been established there for a long time. Again, these executives need to present a good cultural fit and receive the appropriate training to make a successful transition from pharmaceuticals to medical devices.

Public and regulatory affairs

Public affairs is another function that is assuming a more central role because of its impact on reimbursement. This role is needed both locally and on an EMEA level, and companies must promote a better understanding of its contribution throughout the company. On a local level, the general manager often acts as an ambassador of the company. It is important to build this capability on a local level because trusting relationships need to be developed with health authorities. Only then can companies understand what the authorities are looking for, and try to deliver against those requirements.

Best-in-class talent in this area often comes from hiring ex-politicians, senior health civil servants, or clinicians. For more junior profiles, look for graduates in European studies, EU law, or political science.

In regulatory affairs it is important to be able to prove socio-economic and patient value, and to have a clear clinical value proposition. Given the increasing cost and complexity of the regulatory process, the regulatory affairs function is evolving and gradually merging with economic affairs.

Overall, increasingly legal, economic, medical, political, and business capabilities are needed in regulatory affairs. Regulatory affairs executives must also be involved in the infancy of R&D projects to prevent issues further on. Unfortunately, the pool of candidates who display these skills and attributes is relatively small. Candidates with backgrounds in clinical, bio-engineering, local market, and EU law often do well.
Quality assurance
Often overlooked, quality assurance is an area that is ripe for transformation. This is a critical function for all device companies, but perhaps even more so for companies that deal in implants, where reports of quality defects often make the front-page headlines of newspapers. Nevertheless, many companies still have patchy quality control systems, which are reflected in the high number of warning letters issued by the U.S. Food and Drug Administration agency, and the quality function is too often reactive rather than proactive.

Medical device companies need strong leaders in quality assurance who are able to change the company culture so that quality is embedded throughout the organisation. This effort will also certainly require the active support of the full senior management team.

Research & development
Peter Byloos, president for Europe of C R Bard, thinks that as the cost threshold goes up, the number of projects in the development pipeline will go down. “This means that companies really have to focus on the most promising projects,” he says. “Start-up companies will have a harder time. The lifecycle will be three or four years instead of eighteen months, and the costs two to three times higher.”

This means that companies need to be extremely good at managing the product through its full life cycle. Alignment early in the innovation process is crucial. To ensure that a company is developing products that hospitals are prepared to pay for, R&D, marketing, regulatory affairs, clinical affairs, public affairs, and health economics need to work in an integrated way. R&D executives understand and respond to greater evidence-based requirements and the need for smarter but cheaper products that enhance hospital efficiency.

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The need for an integrated team and a much broader perspective on the economics of the products has implications for R&D leaders. Not only do they need to have the technical knowledge that has always been important, but they also need to bring a strong level of business acumen. In addition, there is a greater need for collaboration and the ability to work effectively in highly demanding cross-functional teams – both formal and informal.

The requirement for collaboration extends beyond the development of products internally. Recognising that there are more challenges to product development and innovation internally, companies also need to ensure that they capitalise on the opportunity to collaborate with external partners. Hence, R&D leaders need to work highly effectively with their colleagues in the business development function as they pursue the acquisition of new intellectual property as another vehicle for driving innovation.
Supply chain

For many device companies, supply chain remains a decentralised and outdated function, largely because of the high margins that the industry enjoyed for so many years and the lack of a need to do things differently. However, from a cost point of view, the potential savings that can be made could be huge.

Often manufacturing is done in a large number of plants in high-cost countries and purchasing is equally decentralised. Logistics and warehousing are also handled locally. However, in today’s cost-driven environment, companies need to exploit the significant untapped cost savings in these areas. The trend is clearly towards a reduction of plants and a migration towards countries with lower labour costs. Purchasing is becoming centralised to maximize the purchasing power, and the same applies to logistics. However, to really drive radical change, new ideas need to come from outside the industry.

As the supply chain traditionally hasn’t been a focus area for the medical device industry, best-in-class talent comes from industries that have been forced to be much more efficient with their supply chain management. The automotive industry is one such industry. Hiring change agents from non-healthcare related industries can bring significant improvements and benefits.

Succeeding at change management

Recognising that all of the above requires a huge amount of change, perhaps the fundamental challenge, then, is how to effectively plan for and navigate this change. Companies tend to be very good at the technical aspects of managing change, especially in this industry. Systems and technology are rolled out, tools like RACI are implemented, and process re-engineering is tackled with a vengeance. But the parallel people issues often elude companies. Consequently, wherever we turn we see the results of failed change efforts.

There is a common denominator to those that successfully address the people issues: agile leadership. Leadership teams who complement strong change programs with even stronger people leadership can create organisations that thrive even through turbulent times.

Creating an agile organisation starts with developing leaders who are agile themselves. They are able to learn from their previous experiences and adapt that learning to new and different situations. Agile leaders exhibit many of the characteristics we find in the best executives in general: they are intelligent, they have strong experience, they are motivated and technically competent. What differentiates truly agile
leaders, though, is their skill at dealing with complex and challenging people issues, and they never stop learning. In addition to driving results and dealing comfortably with complexity in their environment, agile leaders understand how others are motivated. They read people well, are expert communicators, and are savvy in the way they motivate and engage their organisations. Agile leaders not only thrive in changing environments, they also make change happen.

The good news is that most organisations already have leaders who are agile. The key is to find them and deploy them in positions where they can influence the business in a meaningful way and where they can continue to develop personally. These agile leaders are your change leaders. These are the people to lead your formal change programs and drive more informal culture change in the organisation.

In addition to ferreting out the existing agile leaders, it is equally important to hire agile leaders. The changes coming to the medical device industry will necessitate bringing new leaders aboard, even in a tough economy. When selected effectively, these new leaders can be key agents of change in the organisation.

The third place to build organisational agility is within the executive suite. It is crucial that the executive team reinforces and supports a culture of agility—a culture where people can ask questions, take risks, and fail at trying something new without being punished. Ideally, many of your executives will themselves demonstrate agility.

Developing agility throughout an organisation both drives progress today and creates a foundation to take a company forward into a future that we can be confident will be characterised by even faster rates of change and greater complexity.

Conclusion

As an industry, medical device companies are in the difficult position of “changing the fan belt while the engine is running.” There is a clear need for change that is multi-faceted, will affect all aspects of the business, and place significant demands on its leaders.

While this can be daunting, our experience in working with companies to navigate change of this magnitude confirms that it can be done. Organisations that tackle this early are those that gain market share, retain talent, and are ultimately positioned ahead of the competition. As we work with clients to address these challenges of change, talent management, and leadership, we see time and again that the investment in addressing them proactively leads to great potential for rewards, both in the short and long term.

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