MedTech

CHALLENGES AND OPPORTUNITIES IN 2020

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Introduction

The spread of COVID-19 has presented the global healthcare and life sciences sectors with unprecedented challenges. At the same time, it has underscored how quickly the industry can pivot to boost capacity in critical areas and support significant rapid changes in demand for technology and devices around the world.

As well as the immediate pressures on governments and healthcare services, COVID-19 has also unearthed important questions for the future of medical devices and technology. For instance, in years to come, which medical devices will be regarded as 'critical'? How will this affect the supply chains of the companies producing these devices? What government regulations and requirements will exist for safeguarding domestic populations?

Governments have woken up to the reality of a hugely competitive and globally integrated marketplace, and many will follow the lead of countries like the U.K. and U.S. in committing to scale national capacity in manufacturing[1] and diagnostics.[2] Because of this, we are likely to see a more fragmented medical device market, with nations unwilling to outsource, buy and sell equipment on a global scale to the same degree as in recent decades.

Even in this climate, the prospects for the medical technology space look bright. Several important trends, including an expanding middle class in Asian economies and aging Western populations, seem likely to result in increasing demand for technological innovation long into the future. Game-changing innovation in AI, connected data, and robotics stand to directly benefit the sector and maintain the pace of innovation seen in recent years.

Significant opportunities and challenges will present themselves to companies. The organisations that can adapt and adopt quickly will be in a position to gain long-term market share. We are seeing more targeted and focused M&A activity that focuses on strengthening core competencies and expanding to new technologies in robotics and data. The winners in this race have the strongest chance to develop best-in-class offerings for the market.

The opportunities and challenges that we discuss in this paper are designed to provide a rough guide to success in the medical technology space. At Alvarez & Marsal, we are leveraging our specialisms in operational transformation, transaction advisory and supply chain to guide leading enterprises through difficult times. We look forward to observing and contributing as the medical technology sector continues to develop.

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Managing Directors

[1] New York Times, 'Coronavirus Spurs US Efforts to End China's Chokehold on Drugs', March 11th 2020. https://www.nytimes.com/2020/03/11/business/economy/coronavirus-china-trump-drugs.html

[2] Financial Times, 'Germany's virus response shines unforgiving light on Britain', April 3rd 2020. https://www.ft.com/content/c4155982-3b8b-4a26-887d-169db6fe4244

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Executive summary

Key market trends

- **M&A:** Major medical companies are targeting bolt-on acquisitions of smaller players. We may have left the era of mega-mergers behind.
- **Technology:** Technological trends including AI, big data and robotics will enable greater personalisation of treatment, potentially changing the healthcare landscape dramatically for patients and providers alike. Navigating this complex landscape will require strong leadership to plan for the future in the current climate.
- **Outsourcing:** Healthcare firms have not outsourced to low-cost territories at the same pace as some other industries. Increasingly, contract manufacturing organisations (CMOs) are adding value throughout the supply chain rather than being used for one-off jobs. The response to COVID-19 may open new opportunities for more domestic manufacturing partnerships.

Strategic challenges

- **Go-to-market models:** The ability to reach new customers and grow in new and established markets are requiring a mixed model of direct sales organisations and distribution partnerships to gain scale at an effective cost.
- **SG&A ratios:** Selling, General and Administrative (SG&A) in the medical device sector generally compares unfavourably to other manufacturing sectors, such as automotive. High SG&A spend is putting pressure on margins and potentially opening the door for disruptive new entrants.
- **Supply chain:** Core supply chain metrics like asset turnover, Days Inventory Outstanding (DIO) and Cash Conversion Cycle (CCC) all lag comparable industrial segments.
- **Regulation:** It is currently difficult to predict when the EU's Medical Device Regulation (MDR) will be fully implemented, or the degree to which it will affect healthcare markets in Europe and beyond.
- **New entrants:** The size of the healthcare market means the biggest tech companies are eagerly searching for entry points. Key trends include the increasing penetration of app-based software throughout healthcare value chains.
- **Race for talent:** Companies around the world are searching for the technologists and researchers who can protect market share and spearhead new innovations. Competition for the best minds has never been higher.
- **Data security:** Cybersecurity can affect brand reputations and balance sheets as well as patient safety. A 'security by design' mentality must be the new normal for all new products and devices.

Opportunities and challenges through a medical device's product lifecycle

Development/Ideation

Opportunity: how best to leverage new, cutting-edge AI research?

Challenge: might a big tech company with a bigger R&D budget be first to market?

Manufacturing

Opportunity: can we leverage our global supply chain to good effect?

Challenge: will our supply chain undermine our strong R&D?

Taking product to market

Opportunity: can we leverage our CMO partnerships outside the manufacturing cycle?

Challenge: might regulatory changes stop us from moving quickly?

Growing share

Opportunity: will this product boost margins and decrease SG&A ratios?

Challenge: can we grow while keeping SG&A under control?

Mature product

Opportunity: can we execute a targeted acquisition to build on our core product?

Challenge: will data security protocols still meet market standards?

Key market trends

We see three particularly important trends that are set to impact MedTech companies this year and beyond: consolidation, new technologies, and the outsourcing of manufacturing.

Consolidation

Major medical technology companies are continuing to acquire core and adjacent assets. Increasingly, larger players are identifying opportunities in niche, higher-margin sectors and they are looking to bolt on smaller, innovative competitors. Evidence shows that they are willing to pay a premium for the privilege. Major acquisitions of this nature that took place in 2019 included Acelity by 3M ($6.7bn), Auris Health by J&J ($5.8bn), Wright Medical and K2M by Stryker ($5.4bn combined), and Mazor Robotics by Medtronic ($1.7bn).[3]

Reduced reimbursements combined with the growing strength of Group Purchasing Organisations (GPOs) are driving major industry players to identify opportunities for growth. Another factor supporting a consolidation is the increasing cost of bringing new products to market. Acquiring innovative products while avoiding sinking excessive costs into research and development makes increased synergies highly appealing. Combine all of these factors with historically low financing costs, and the outlook for M&A continues to be strong.

The major challenge in executing consolidation projects is the subsequent integration. See 'The A&M difference: transaction advisory' box for more information.

The A&M difference: transaction advisory

A&M has more than 35 years of experience guiding companies through acquisitions and consolidation. Key ingredients in every successful transaction are performing strong due diligence followed by managing the integration of the newly acquired entity.

Typical pitfalls can include: insufficient thoroughness in the evaluation of potential acquisition candidates; a due diligence process that is delivered too quickly, and not allowing enough time for a proper evaluation of the complete value chain, not just regarding 'core' operations but also incorporating other business functions (SG&A) and intangibles.

The integration of the newly acquired company is then very often left to happen on its own, without working on communication that can win stakeholders' hearts and minds. Using well-planned strategies, workstreams that merge processes and create product synergies can positively impact morale and encourage further innovation within the new structure.

[3] Bioworld, 'Stryker agrees to hefty $5B buy of Wright Medical', 5th November 2019. https://www.bioworld.com/articles/430942-speculation-proves-correct-as-stryker-agrees-to-hefty-5b-buy-of-wright-medical

Technology

Healthcare is being transformed by technologies like AI, data analytics and processing, robotics, and the Internet of Things (IoT). The American College of Radiology's Data Science Institute lists 58 AI algorithms approved for use by the FDA.[4] In 2019, investors put $2.3bn of venture capital funding into healthcare startups in the UK alone.[5]

Identifying the right treatment for the right person is the future of healthcare.

IoT and robotics are predicted to bring significant benefit to certain medical disciplines.[6] The robotic surgery market, for instance, is expected to grow at a CAGR of 12.1% to 2025. This provides rich opportunity for both newer challengers and established incumbents. Data suggests that the use and prevalence of IoT in healthcare will increase at a CAGR of 22% between 2018 and 2025.[7]

Connected medical devices will enable healthcare to be delivered in new settings including standalone clinics and within the home.

While robotics and Internet of Things promise to transform many disciplines of healthcare, applications of AI have the potential to transform almost every aspect of companies' business models. (Of course, AI may also bring significant risks to organisations: see our section on data security below for more.)

The last technological trend capturing more boardroom attention is personalisation. Mark Laret, CEO of UCSF Health in San Francisco, has referred to personalisation not only as a "growth strategy" but as a "survival strategy."[8] To put it simply, identifying the right treatment for the right person is the future of healthcare. Patients are playing a larger role in treatment decision-making, and healthcare innovators will be able to create an experience for the 'customer' in a similar way to retail, leisure and other sectors. This will extend to the home, not just to the clinic or hospital: the potential for diagnostic chatbots and other mobile-native healthcare interfaces is nascent but has already shown impressive progress in a short time.

[4] American College of Radiology Data Science Institute, 'FDA Cleared AI Algorithms'. https://www.acrdsi.org/DSI-Services/FDA-Cleared-AI-Algorithms

[5] UKTN, 'The UK looks to healthcare startups during the pandemic', April 27th 2020. https://www.uktech.news/news/the-uk-looks-to-healthtech-startups-as-coronavirus-pandemic-puts-spotlight-on-fast-growing-sector-20200422

[6] 'Surgical Robots Market Size, Share and Industry Analysis 2019-2026', Fortune Business Insights, July 2019. https://www.fortunebusinessinsights.com/industry-reports/surgical-robots-market-100948

[7] 'IoT in Healthcare Market is Projected to Grow USD 206,236.12 Million by the end 2025 at a CAGR at a 22.01%', Valuates Reports, March 2020. https://www.prnewswire.co.uk/news-releases/iot-in-healthcare-market-is-projected-to-grow-usd-206-236-12-million-by-the-end-2025-at-a-cagr-at-a-22-01-valuates-reports-832954898.html

[8] Glenn Lopis, 'Healthcare in the Age of Personalization', Forbes, 10th March 2019. https://www.forbes.com/sites/glennllopis/2019/03/10/healthcare-in-the-age-of-personalization/#13b5f4f353f4

Asia has become a powerhouse for sourcing and manufacturing products and components, particularly in developing new technologies.

Outsourcing

Companies are slowly shifting some operations to low-cost countries (LCCs), but the healthcare space is still lagging behind other industries: LCCs currently represent between 5% and 25% of all medical production. However, some major industry players are planning footprint programmes years into the future and optimising for future regional growth.

2020's global COVID-19 crisis has exposed deep imbalances in countries which lack critical supply of products and devices. The COVID-19 challenge has underscored the importance of maintaining a balanced production network, so that manufacturers can predict supply into the future and provide robust support to the private and public sectors. We are likely to see additional government regulations about domestic stockpiling and on-shore manufacturing in response to the COVID-19 crisis, requiring companies to adapt to a new supply chain model.

Asia has become a powerhouse for sourcing and manufacturing products and components, particularly in developing new technologies. Talent at senior and mid-levels is another factor that may drive these decisions: world-leading expertise in healthcare is no longer seen as unique to Europe and the U.S.

Meanwhile, Contract Manufacturing Organisations (CMOs) are increasing in share and becoming more competent. They are no longer being used for 'one-off jobs': instead, they are adding value right through the supply chain.

The A&M difference: outsourcing and transfers of production

A&M has taken an active role in many transfer of production programmes. Companies often seek improvement to margins and cost bases by transferring operations and footprint to LCCs.

Defining the portfolio of products and activities to be transferred is a key determinant of success. Another important challenge is enabling a sustainable high-quality performance at the new location. Identifying resource gaps early on with detailed research, as well as defining plans on how to meet expectations and standards, helps determine project timelines of the transfer and ensures high-quality delivery.

Strategic Challenges

Despite significant opportunities in the medical technology space, MedTech companies must confront several key challenges. As well as margins and supply chain issues, the risks of regulatory shifts and new competitive entrants should be taken into account.

Go-to-market models

The ability to reach new customers and grow in new and established markets is challenging in any industry, but particularly so when medical devices are at the centre of business models. The ability to train and upskill medical professionals to use new technology can mean longer, more labour-intensive sales cycles. To successfully scale sales operations, companies should utilise a mixed model encompassing direct sales organisations and distribution partnerships to deliver market share growth while carefully managing costs.

On top of sales coverage, strong tender management and pricing controls are needed, particularly in the European region. GPOs have consolidated across countries and the region as a whole and enable far stronger negotiating leverage for partner organisations than in the past. In some ways this has hampered the adoption of new technologies, as surgeon preference has continued to decrease in influence while GPOs have continued to implement a 'price-first' and clinically adequate approach to contracting.

The A&M difference: go-to-market models

Salesforce effectiveness, motivating compensation models, distributor partnerships, and effective pricing and tender processes are critical to commercial success.

A&M has driven turnaround and go-to-market model innovation across Europe and the globe for leading medical device manufacturers, leading to more cost-effective sales growth, stronger pricing controls, and improved overall margins.

SG&A ratios

After years of comfortable margins, analysis of the MedTech sector indicates that with SG&A ratios running at an average of 62.5%, margins are coming under increasing pressure. Revenue per employee, meanwhile, varies from company to company but can be anywhere from €139k to €415k with an average of €259k.

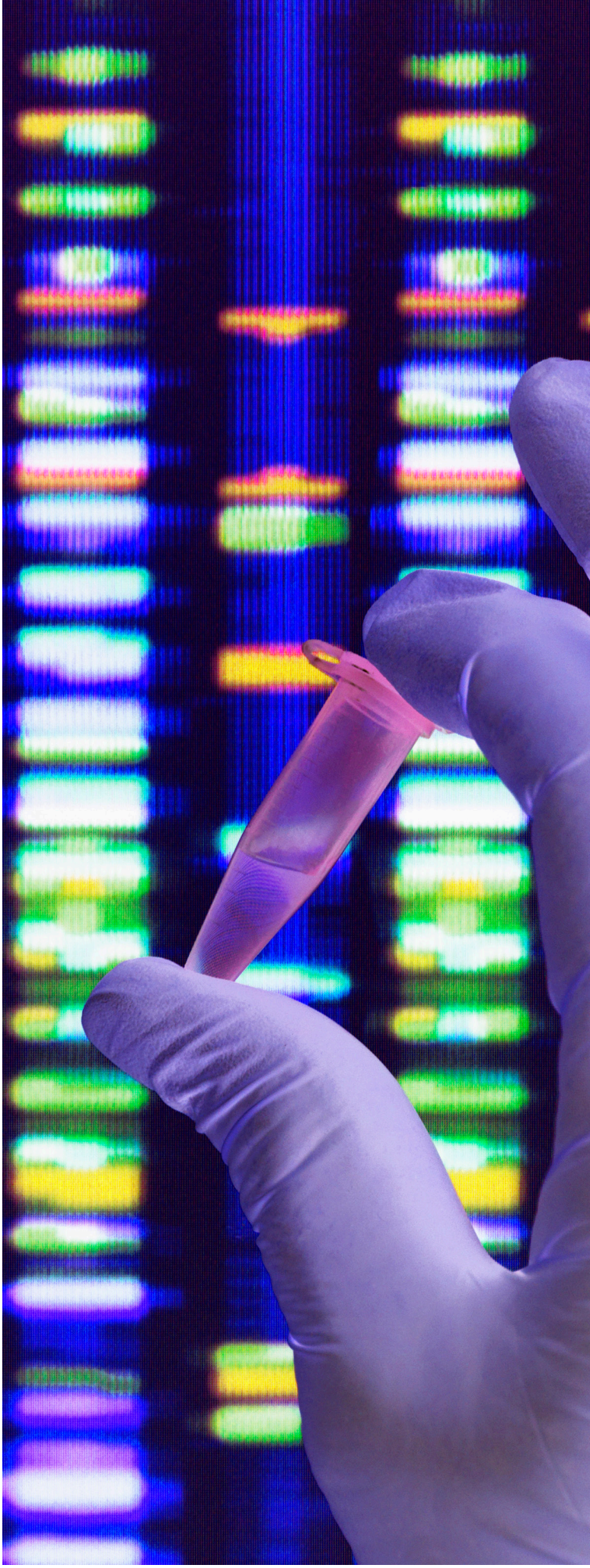
It is useful to think about healthcare technology in the context of another high-tech manufacturing industry: automotive. The auto sector's average SG&A ratio is 9.1% and revenue per employee is €659k. Though automotive is a very different industrial segment with its own unique pressures and revenue streams, it is always worthwhile to learn from best-in-class practitioners and optimise processes and structures accordingly.

The A&M difference: margin improvement

Evaluating a company's cost base and defining scenarios for an improved cost structure is one of A&M's core capabilities.

A&M approaches issues with a three-step process. Identifying major cost drivers and the means for reducing headline costs is a first step. Second is determining the business impact of margin improvement programmes, and making cost reduction sustainable is the third step.

It is useful to think about healthcare technology in the context of another high-tech manufacturing industry: automotive.



Supply chain

Supply chain is regarded as a chronic inefficiency within the MedTech space, with inventory management being the main pain point for manufacturers. Among similar industrial segments, MedTech finishes at or near the bottom on operating metrics like asset turnover, Days Inventory Outstanding (DIO) and Cash Conversion Cycle (CCC).

An A&M analysis of the current working capital performance of MedTech companies indicates that CCC runs at an average of 109 days, compared to 37 in the automotive industry. DIO, meanwhile, is at 77 days in MedTech as opposed to 63 in automotive, with a larger number of SKUs. While European MedTech companies run at a Days Sales Outstanding (DSO) average of 60 days, best practice in the automotive industry is 29 days.

The A&M difference: supply chain

A&M's experts have driven substantial performance improvements through global supply chains. Key areas of expertise include product portfolio reviews, sales and operations planning, and working capital process optimisation.

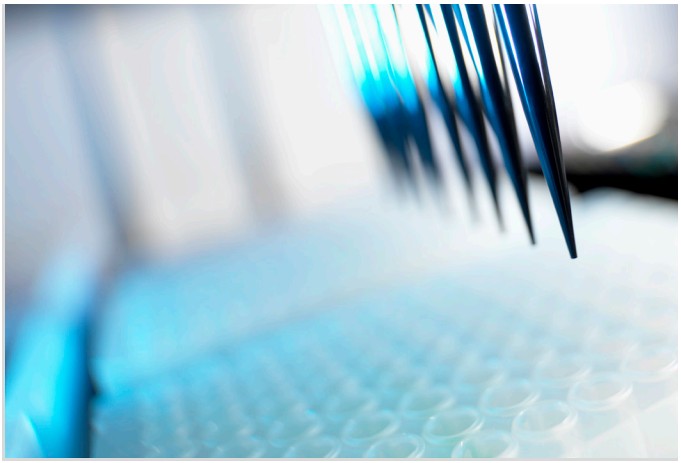
A&M clients have achieved double-digit improvements to working capital performance, driving improved cash conversion and reducing inventory costs.

Regulation

Another test for the public and private sectors will relate to international regulation and other national policies. Europe's Medical Devices Regulation (MDR) may yet be postponed after a new proposal from the European Commission, but MDR is set to tighten regulations on medical device standards when it is eventually fully implemented.

At the same time, the FDA intends to evolve its approval processes for medical devices in the U.S, devoting more resource to exploring the culture and practices of companies producing AI and machine learning technologies.[9]

Technological progress may well require a different regulatory approach in years to come. Strategic disciplines like Health Economics and Outcomes Research (HEOR) are well advanced in other healthcare subsectors but has room to grow in influence within MedTech.



Meanwhile, governments around the world are facing budgetary pressures relating to healthcare. Responding to this, in certain markets payers are forming purchasing groups to drive more competitive pricing. Private insurers and government programs have moved to limit payments for many medical treatments that require medical supplies or devices. Value-focused payment activity may continue to increase into the future.

[9] 'FDA grapples with AI medical devices', Gopal Ratnam, Rollcall.com, 7th May 2019. https://www.rollcall.com/2019/05/07/fda-grapples-with-ai-medical-devices/

Consumerisation and new entrants

The biggest tech companies – including Alphabet, Apple, Microsoft, Amazon and IBM – see medical technology as a ripe opportunity. Key opportunities include integrating health and wellness drivers into consumer devices, as well as developing applications designed specifically for medical practitioners. The next generation of wearables promises to blur the lines between tech accessory and medical device. Google Glass has transitioned from a consumer product into an enterprise device over the last five years, building market share and developing a predictable revenue stream.[10]

Market entry points include partnerships with existing players as well as developing 'own-brand' software and hardware. The size of the total addressable market for healthcare – $7.8 trillion in 2017[11] – means that the 'big tech' incumbents can justify enormous amounts of financial resource and manpower. For legacy medical device players, it will be important to effectively take ownership of core competencies and potentially prioritise brand investment so as to ward off the challenge of new disruptive entrants.

A key trend is the increasing penetration of app-based software through healthcare value chains. The healthcare sector's tolerance for 'minimum viable product' iterations of technologies has increased in recent years. This shift in attitude is allowing lower-cost manufacturers into the market and potentially compressing margins.

The race for talent

One of the biggest issues for healthcare companies worldwide is ensuring a balanced supply of skilled workers focused on new technologies – from engineers to researchers to data scientists – in order to preserve a competitive advantage and maintain the pace of innovation. As an opportunity, companies can access to government-supported programs that work in concert with industry to produce qualified employees. Companies must ultimately reimagine their hiring profiles and bring in the talent that will help them develop the next wave a technological innovations, specifically in the connected data space.

[10] 'Google Glass still exists: Meet Google Glass Enterprise Edition 2', Ars Technica, 20th May 2019. https://arstechnica.com/gadgets/2019/05/google-glass-still-exists-meet-google-glass-enterprise-edition-2/

[11] WHO, 'Global Spending on Health: A World in Transition', 2019. https://www.who.int/health_financing/documents/health-expenditure-report-2019.pdf?ua=1

Data and cyber security

Cyberattacks and data breaches are the main risk success factor for MedTech companies at present, and the threat is not going away.

As part of the expanded MDR regulations, manufacturers are required to document as part of their risk and quality management plan how they identify key hazards arising from both intended use and 'reasonably foreseeable misuse'.

A 'security by design' mentality is now the default for teams building new products and devices. Designing protective measures where risks cannot be eliminated, as well as providing clear guidance to users and operators across a device's life cycle, are table stakes.

Companies must weigh security and safety risks against the medical benefits offered by the device, calculating the degree of residual risk the company can accept. It is vital to remember that as well as the first priority of patient safety, brand reputations are on the line.

The A&M difference: data security

A&M has significant experience determining potential cybersecurity risks and designing solutions. We can analyse the state of security across a business and recommend an appropriate path forward for clients which balances risk mitigation and commercial priorities. A hypothetical cybersecurity risk assessment:

- Identify key cyber risks within organisation, weighing against the medical and patient benefits of existing processes.
- Plan to reduce key risks to an acceptable level (inc. defining what 'acceptable' looks like).
- Establish full lifecycle support plan for devices and the wider business.

A 'security by design' mentality is now the default for teams building new products and devices.

A&M: LEADERSHIP.ACTION.RESULTS.℠

A&M has worked with some of the largest European and global organisations to stabilise financial performance, transform operations and accelerate results through decisive action. When traditional improvement activities are not enough, A&M's restructuring and turnaround heritage brings fact-based, action-oriented leadership to transformation and delivers rapid results.

Favourable demographics and growing purchasing power in countries around the world mean that the opportunity for successful MedTech companies is enormous. All the same, MedTech leaders are coming under increasing pressure from different directions.

A&M's Health and Life Sciences and Corporate Perfomance Improvement practices have decades of experience helping to create value for healthcare businesses. To learn more about our work and to identify how we could help your business, please contact us.

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ABOUT ALVAREZ & MARSAL

Companies, investors and government entities around the world turn to Alvarez & Marsal (A&M) when conventional approaches are not enough to drive change and achieve results. Privately held since its founding in 1983, A&M is a leading global professional services firm that provides advisory, business performance improvement and turnaround management services.

With over 4,000 people across four continents, we deliver tangible results for corporates, boards, private equity firms, law firms and government agencies facing complex challenges. Our senior leaders, and their teams, help organizations transform operations, catapult growth and accelerate results through decisive action. Comprised of experienced operators, world-class consultants, former regulators and industry authorities, A&M leverages its restructuring heritage to turn change into a strategic business asset, manage risk and unlock value at every stage of growth.

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