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More than 'license to operate'

How quality and regulatory compliance in MedTech became a driver of financial performance

MedTech companies reporting quality and regulatory deficiencies not only struggle to ensure patient safety. There is also a long-term impact of such deficiencies and product recalls on a company's competitive financial performance, which we analyze in this paper. While the stock markets did not seem to systematically punish poor quality and regulatory compliance in the MedTech sector in recent decades, our analysis finds that this has completely changed in the past few years. We now see a dramatically widening gap in stock market performance that can be associated with good and poor quality and regulatory compliance. The data indicates that the ability to consistently meet quality and regulatory requirements without impeding a company's agility and speed has become a strategic differentiator. In this paper, we discuss reasons for this shift and illustrate how MedTech companies are responding with targeted investments.

MAKING AN IMPACT THAT MATTERS since 1845

"The costs of poor quality are tangible, and their effect will cost you money, customers, and ultimately the success of your business."[1]

Subir Chowdhury

Introduction

Quotes like the above represent widely shared beliefs in the MedTech industry that quality and regulatory compliance are vital to ensure patient safety and, ultimately, must have an impact on a company's financial performance. While an FDA publication in 2011[2] showed that this was often true at individual company level, there was surprisingly no scientific evidence at that time to back up this claim at an aggregate industry level. On the contrary, relevant studies could not find any evidence of market penalties for medical device recalls at an aggregate industry level.[3] Therefore, investments in quality and regulatory compliance (it is estimated that EU MDR compliance alone will cost up to 5% of companies' annual revenues[4]), needed to be justified with the argument that it protects patients and, ultimately, the company's 'license to operate'.

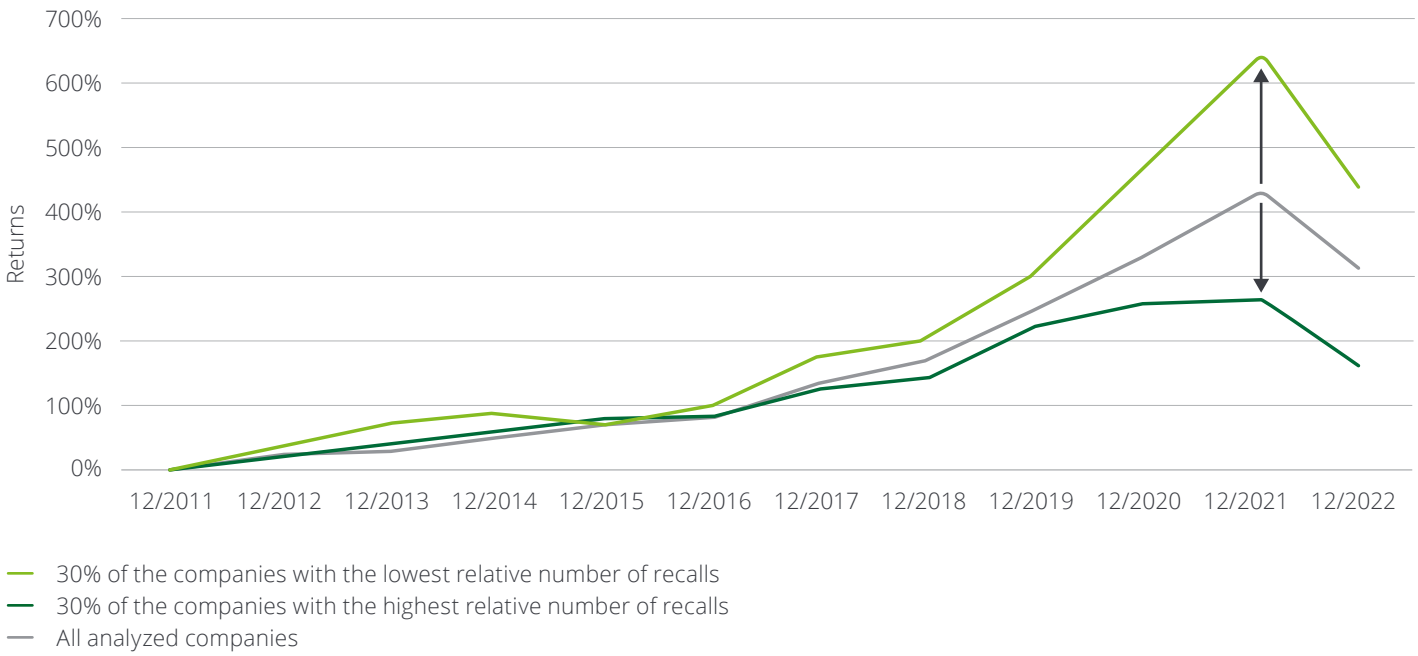
After a decade of significant changes in the MedTech regulatory and business environment, we used recent data to investigate whether quality and regulatory compliance remains a minimum standard to maintain a company's 'license to operate' or if there is 'value beyond compliance'.

Measuring the capital markets' price tag on product recalls

In the following chapter we present recent Deloitte research on stock market performance of publicly listed MedTech companies which shows that the capital markets' price tag on recalls has increased dramatically in recent years.

The results exhibit that the quantile of 30% of companies with the lowest 'recalls per 1 million USD revenue' ratio outperformed their peers in the quantile of 30% of companies with the highest ratio by 256 percentage points (Fig. 1). Interestingly, this effect has only become (increasingly) significant during the last five years (since 2018). This observation is fully consistent with earlier research[3] that could not find evidence of market penalties for medical device recalls at an aggregated level at the time.

Fig. 1 – Cumulative weighted increase of market capitalization



Research method:
Our study included all companies that were continuously represented in the Dow Jones U.S. Select Medical Equipment Index from 2012 to 2022. This resulted in a list of 40 medical device companies in our research scope.[5] For each of these companies we then identified the number of recall events related to a medical device product as disclosed on the FDA website during the observed time period.[6] We then sorted the companies by the number of recalls and corrected for company size effects by measuring relative recall frequency as 'number of recall events per one million USD of revenues'[7] instead of using the absolute number of recall events. We used the companies' market capitalizations to measure and compare their financial performance over the observed time frame. Finally, we compared financial performance of groups of companies with a higher-than-average versus lower-than-average number of relative recall events using the weighted cumulative increase of their respective market capitalizations.

Seeking explanations for the growing impact of recalls on financial performance

Looking at the momentum change in Fig. 1 since 2018, the obvious question is, what has changed in the last five years that could explain why quality and regulatory compliance seems to have become much more than a company's 'license to operate'?

The overall number of recalls is unlikely to be a major factor since it has decreased slightly in recent years. A more likely factor may be the changing regulatory environment in the MedTech industry. The last decade has seen an unprecedented level of regulatory activity in the MedTech space, including EU MDR, IVDR, UDI, serialization, ISO 13485 and more. We also see growing public awareness and media coverage of adverse events, product safety concerns and lacking supply chain traceability posing risks to brand reputation. We may assume that capital markets are more likely to react to events with higher media coverage, which could explain the growing capital market gap in recent years. Since catastrophic product design failures were amongst the key root causes of a number of the publicly discussed product safety issues, design controls including ISO 13485 were gradually introduced into the regulatory framework. We will show later in the paper that – despite these regulatory actions – design failures and lacking design controls remain a key reason for recalls and may even contribute to the widening capital market gap. Devices have become more complex in and of themselves as well as within their ecosystem of interconnected devices, while, at the same time, the pressure to achieve a rapid market launch has increased. This combination of factors may have exacerbated the problems. Moreover, technology disruptions have led to the creation of innovative device categories such as SaMDs, although these are associated with additional challenges such as cybersecurity vulnerability, which could involve recall risk. Another aspect causing product design complexity and risk is the globalization of design requirements. Products are increasingly designed and manufactured to meet the user needs and regulatory requirements of a growing number of markets. In practice, this turns out to be an immense operational challenge for many MedTech organizations. They have to incorporate regulatory requirements from more and more markets into the design process at a very early stage and manage regulatory changes in these markets continuously throughout the product's lifecycle. M&A activity in the sector may also lead to increasingly fragmented and siloed management systems, IT architectures and data landscapes as some companies shy away from integration efforts in QA and RA following M&A transactions.

Other studies already found portfolio effects in their analysis, stating that 'firms with [...] broader product portfolios have a higher likelihood of device recalls'.[3] COVID-19 related changes in policy and behavior of industry and global regulators may have played a role as well. These have been explored in another recent Deloitte report: "Never the same again: How COVID-19 created seismic change in life sciences regulations".[8] Another observation is the index decline in 2022 which can be explained in the context of the general US stock market decline during this period, which was partly attributable to global supply chain disruptions and the associated impact on inflation expectations.

Whatever the key driver may be, we can conclude that a company's ability to consistently meet quality and regulatory requirements has clearly become a strategic differentiator in the MedTech sector.

Capital value loss drivers: Quality and regulatory non-compliance causes distraction in a highly competitive environment

It is well known from other sectors that the loss in shareholder value following recalls can significantly exceed the costs incurred to rework or replace defective products.[9] The gap has been explained by several factors including:

- Cost of remediation
- Cost of organizational distraction
- Competitor firm opportunities

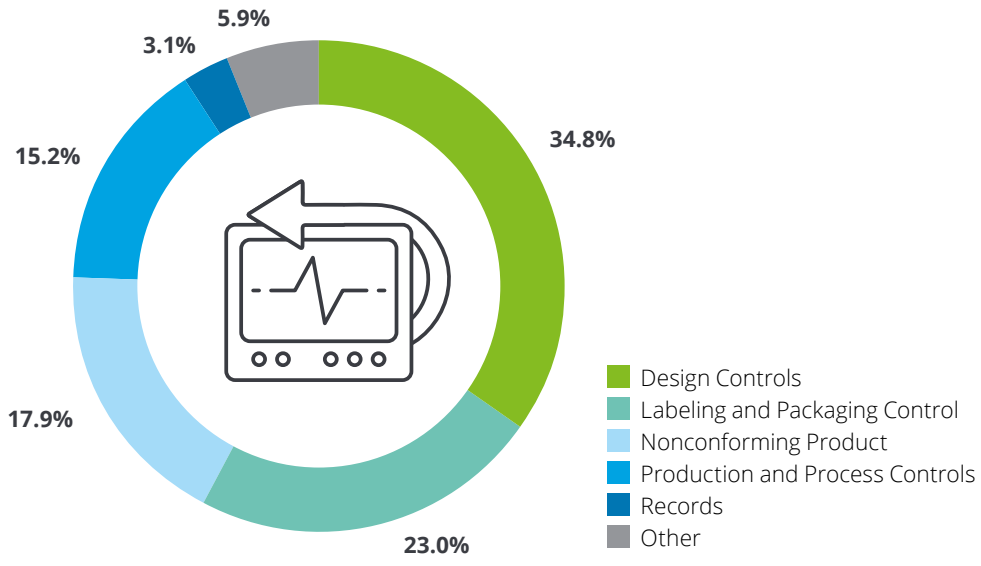
The cost of remediation usually includes correction of the deficiency, related legal and consulting costs and the cost of restoring trust with health authorities, healthcare professionals and patients. Even though these costs can amount to several hundred million US dollars in some cases, it appears that the cost of organizational distraction may be an even larger factor. Companies busy with remediation face the danger of 'losing ground' to competitors in the market, for instance because they have to reassign R&D resources to remediation work. In addition, research shows that competitors often use the opportunity to increase their number of new product submissions to gain market share.[10]

What are the early warning signs?

In order to better understand root causes and early warning signs for emerging non-compliance issues, we analyzed the most frequently raised recall reasons using the FDA Medical Device Recalls Database[11] which can be seen in Fig. 2. Unsurprisingly, poor design controls top the list by a large margin, accounting for 34.8% of recall reasons. It is followed by poor labeling and packing control (23.0%), non-conforming product (17.9%) and poor production and process controls (15.2%). Deficiencies in any of these categories are highly likely to put patients at risk and are therefore often the reason for recall decisions.

Unfortunately, the role of quality and regulatory compliance as a factor seems to be obscured by the primary recall reasons. While quality system-related deficiencies are not among the top recall reasons, they are often a key underlying factor leading to design deficiencies, product nonconformance or poor execution of production processes. Quality system deficiencies cause more indirect harm to patients than direct harm, and therefore products are not recalled because of poor quality and regulatory compliance, but because of the indirect consequences.

Fig. 2 – Root causes for FDA recalls



The statistics on FDA Warning Letters and FDA Form 483s are a good indicator. Violations of quality system regulations top the list of FDA Warning Letter reasons by far (58.7%).[12] This category includes subparts such as 'Records' (which also includes complaint files) as well as 'Corrective and Preventive Action', among others.

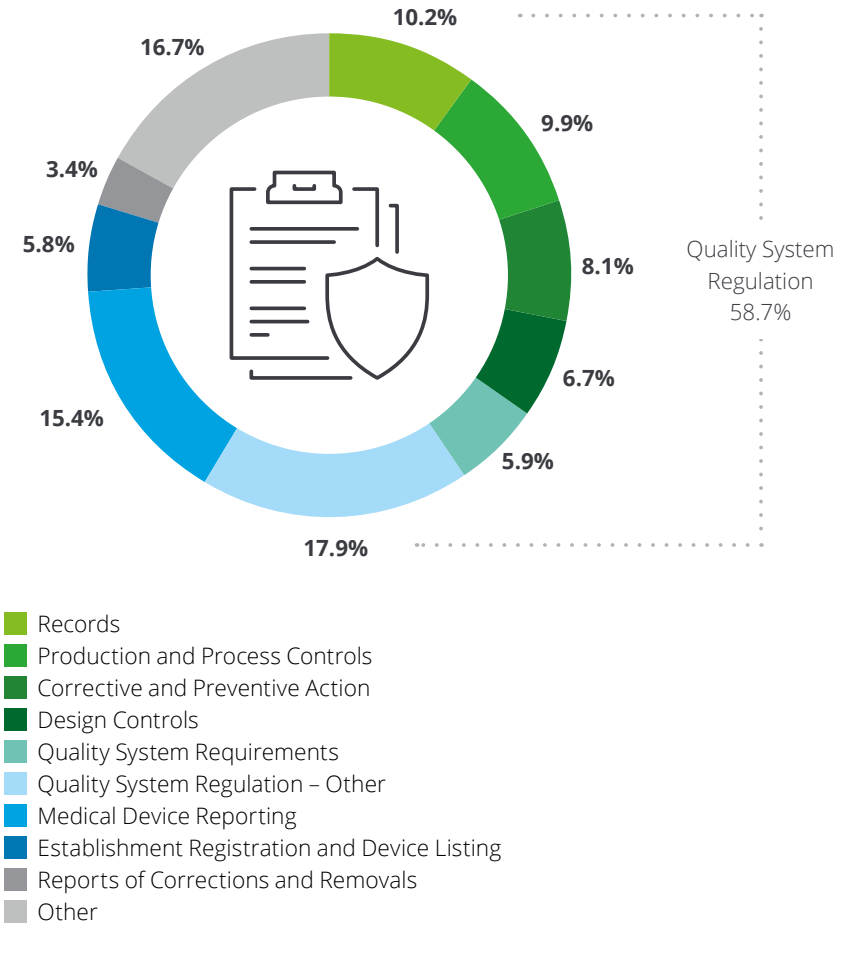
The most common Form 483 citation in MedTech organizations between 2018 and 2021 was, worryingly, that 'Procedures for corrective and preventive action have not been [adequately] established'.[13] This is a justifiable cause for concern.

CAPA and complaint handling are good health indicators

When the CAPA process is ill-established, a MedTech company is unable to address observed deficiencies within a reasonable timeframe, identify root causes or verify the effectiveness of implemented measures. A poor quality culture may also lead to the CAPA process being (mis)used to compensate for lacking end-to-end risk management with short-term problem solving.

The ability to make use of customer feedback to improve product quality is another critical success driver – and one that bridges compliance and business/product development. Complaints are the most direct form of customer feedback for MedTech companies. It is therefore surprising to see that the inability of MedTech companies to respond to complaints in a timely manner (as increasingly required by regulations) is also among the most common Form 483 citations. Speculating on potential reasons, and the increasing globalization of product design, manufacturing and logistics complicate a company's efforts to track and resolve nonconformances, complaints and other issues across the global organization.

Fig. 3 – CFR citations of 'device' related FDA warning letters



Quality versus compliance – not all investments have the intended results

Do these observations therefore suggest even larger investments in seamless documentation and audit trails? An FDA survey shows that, contrary to widespread belief, many survey participants were concerned that an excessive compliance focus on audit readiness could distract companies from actually improving the quality of their products. It 'often diverts resources and management attention away from investments in quality towards compliance activities like documentation, which do not directly lead to improved quality outcomes' and does not necessarily eliminate the root cause or lead to higher quality products.[4]

In order to be perceived as facilitators rather than inhibitors of agility, speed and innovation, quality and regulatory leaders need to find smarter ways to improve quality outcomes and regulatory compliance. They face the challenge of consistently meeting quality and regulatory requirements without actually impeding a company's agility and speed, as well as facilitating compliant changes to processes and products faster than the company's competitors.

Rethinking quality assurance and regulatory affairs to gain real competitive advantage

MedTech executives have increased their efforts in recent years to innovate, automate, harmonize and simplify their quality management systems and regulatory affairs functions and to increase digitalization. Below we present selected areas of innovation in the quality and regulatory space:

Innovation area #1

'From documents to data' and automated workflows

The most obvious area for investment is technologies to leverage workflow automation, such as product lifecycle management (PLM) systems, regulatory information management systems (RIMS), electronic quality management systems (eQMS) and electronic document and content management systems (eDMS). If not managed well, however, these investments tend to simply make electronic versions of familiar manual, paper-based processes (digitization), rather than digitally transforming the business by establishing new ways of working (digitalization). A good example of the latter is the move from reactive towards predictive and preventive quality management.

Innovation area #2

Moving from reactive to preventive quality

Since audits are a retrospective means of assurance and can only provide a snapshot at a specific point in time, quality executives are increasingly investing in solutions that enable a real-time view or even a look into the future. The ambition of predicting and preventing quality events before they occur, however, requires a change in mindset, new ways of working, and a whole new set of capabilities. These include the ability to manage data from various sources centrally on a unified data platform as well as use of artificial intelligence (AI) and machine learning (ML) in regulated processes to make accurate predictions based on historical and real-time data.

Innovation area #3

Unchaining AI for use at scale in regulated processes to leverage AI validation models

Several MedTech companies have started to run AI pilots also in highly regulated process areas. This requires a more sophisticated approach to computer system validation (CSV) to address the fact that many AI applications leverage machine learning functionalities and, consequently, that the data used to train the algorithm needs to be in the scope of validation as well. Another challenge is the ability to explain the outputs of an AI model (often a 'black box') in inspection scenarios. These and other factors limit the scalability of AI minimum viable products (MVPs) in practice, so that they likely get stuck in the pilot phase before moving on to operations.[14]

Innovation area #4

Ensuring efficiency and compliance in modern agile engineering

Ensuring efficiency and compliance in modern agile engineering of medical devices, in vitro diagnostics (IVDs) and healthcare software is increasingly becoming a challenge in the sector and therefore represents another area of investment in new capabilities. While medical devices, IVDs and health applications are becoming increasingly complex, so too are the requirements and procedures for developing them. Improving and accelerating the product engineering process while implementing new regulations has therefore become another key capability and has, for example, led to investments in automated, end-to-end product development lifecycles.

Innovation area #5

Risk-based approach and Quality by Design

Another exciting development in the quality and regulatory space is the move from compliance-based thinking to risk-based thinking. Effective prevention of issues requires advanced risk management capabilities in order to understand what could actually go wrong and what really matters. Systematic consideration of risk in the design of quality management systems (risk-based QMS concept) and in product design processes (Quality by Design (QbD) concept) requires a risk-oriented mindset. Building a culture of preventive, predictive and risk-based quality and regulatory compliance, and winning hearts and minds are cornerstones for success.

Innovation area #6

Balancing local and global governance

QA and RA are no longer local endeavors. Regulators increasingly demand evidence of oversight across sites and along the entire global supply chain. QA and RA functions are often designed to meet local regulatory and business needs, resulting in substantial variance in procedures across regions. In addition, companies are adding new quality systems and product registrations with every new acquisition – often shying away from integration and harmonization efforts. Investing in the optimal balance between local empowerment and global oversight can significantly reduce the workload and – most importantly – create a culture of end-to-end thinking, ownership and cooperation in the organization.

Innovation area #7

Increasing the agility and speed of controlled changes

For many organizations, managing day-to-day regulatory activities while keeping a finger on the pulse of regulatory change (regulatory intelligence) can be challenging. Partly automating the monitoring of regulatory trends across multiple languages can be an effective way of anticipating changes while minimizing RA and QA resource needs. Aside from simply subscribing to regulatory news feeds, translating regulatory insights into actionable market and product-specific company-internal procedures represents a key challenge. Text mining and structured content authoring solutions address not only this issue but also the challenge of re-using modular text fragments in large submission dossiers or complex quality system content landscapes. Moreover, the clearly defined, automated linkages between regulatory requirements and product submissions mean it is becoming possible to assess and even predict timescales for submission reviews and probability of success. Proactive regulatory systems can ultimately contribute to building trust between the organization and regulatory bodies.

Innovation area #8

Providing on-demand guidance for employees

In the highly regulated MedTech environment, quality system managers increasingly see themselves as providers of advanced and intuitive employee guidance. Tools like chatbots, smart watches and augmented reality (AR) are much better suited to providing guidance on-demand to shop floor employees than lengthy block text SOPs. Feeding devices with reusable, modular, step-by-step instructions is therefore an evolving content management challenge that has the potential to save time and effort spent searching, opening, and reading regulated content.

Innovation area #9

Role-specific, on-demand training instead of 'read and understand'

The training process is a painful and bureaucratic experience for many employees in MedTech companies . 'Read and understand' concepts for employee training are very common and require new hires to fight their way through tens – or hundreds – of learning assignments as part of their onboarding journey. Innovative approaches are emphasizing employee training in a more holistic way and aim to deliver specific guidance on demand – when it is actually needed to complete a task. This increased flexibility requires out-of-the-box thinking, advanced capabilities of the learning management system (LMS), and the willingness to actively approach regulators and explain and defend the approach in inspection situations.

Summary, outlook and invitation

The regulatory and business environment for the MedTech industry has changed significantly in recent years. This has accelerated the rise in cost of regulatory non-compliance. The ability to consistently meet quality and regulatory requirements without inhibiting a company's agility and speed has therefore become a strategic differentiator and driver of financial performance.

In future research we aim to further expand our investigations to individual firm-level factors. At present, we find there is a lack of factual evidence as to how exactly the (business) case for quality and regulatory compliance is supported by the aforementioned investments and others including compliance culture, QA/RA headcount, QA/RA organizational structures, digital maturity, production strategies, etc.[15]

We therefore invite our readers to support our future research efforts by participating in more detailed firm-level analysis and benchmarking activities.

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