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Critical failure factors for continuous improvement methodologies in the Irish MedTech industry

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Abstract

Purpose – The main objective of this study is to investigate what are the critical success factors that exist for continuous improvement (CI) methodology deployment in the Irish medical technology (MedTech) industry. The research will, in particular, seek to establish if the highly regulated nature of the global MedTech industry is an additional critical failure factor (CFF) for the deployment of CI methodology. The study involves the analysis of the benefits, challenges, CFFs and tools most utilised for the application to the deployment of CI methodologies in the Irish medical device (MD) industry.

Design/methodology/approach – A quantitative survey was utilised in this study. The main participants were made up of senior quality professionals working in operational excellence, quality consultants, quality directors, quality engineers, quality managers and quality supervisors working in both manufacturing and service sectors from Irish MD companies. A total of 94 participants from the Irish MedTech industry responded to the survey.

Findings – The main finding of this study is that 42% of participants perceived that a highly regulated environment was a CFF to CI, whilst 79% of respondents utilised Lean Six Sigma in their organisations, and productivity and financial factors were found to be the highest reasons for CI deployment amongst the Irish MedTech industry. The top CFFs highlighted for CI in regulated industries were fear of extra validation activity, compliance versus quality culture and a regulatory culture of being "safe". Another relevant finding presented in this paper is that just over 48% of participants felt that CI tools are very strongly integrated into the industries quality management systems (QMSs) such as the corrective and preventative action system, non-conformance and audit systems.

Research limitations/implications – All data collected in the survey came from professionals working for Irish indigenous and multinational MedTech companies. It is important to highlight that $n = 94$ is a low sample size, which is enough for a preliminary survey but reinforcing the limitation in terms of generalisation of the results. A further study on a wider European and global scale as well as a comparison with the highly regulated pharma industry would be informative.

Originality/value – The authors understand that this is the very first research focussed on the CFFs for CI in the MedTech/MD manufacturing industry with a specific focus on the highly regulated nature of the industry

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as a potential CFF. The results of this study represent an important first step towards a full understanding of the applicability and use of CI in the medical-device-manufacturing industries on a global scale.

Keywords Continuous improvement, Medical device, In vitro diagnostics, Ireland, MedTech, Lean six sigma
Paper type Research paper

1. Introduction

The MedTech sector in Ireland is recognised as one of the five global emerging hubs. The sector employs more than 40,000 people in Ireland and is the second-largest per capita employer of medical and technology professionals in Europe. As many as nine of the world's top-ten MedTech companies have a base in Ireland (Irish Medtech Association, 2020). MDs are also a major contributor to the European Union (EU) economy, which has more than 32,000 MedTech companies employing more than 730,000 people in high-quality jobs (Medtech Europe, 2021). The two biggest MD markets in the world are the USA at 43% and the EU at 27%, making up 70% of the world market for medical (Medtech Europe, 2021). The manufacturing of MDs is strictly controlled by authorities, and manufacturers must conform to the regulatory requirements of the region in which a MD is being marketed for use (Granlund *et al.*, 2020). The MD industry is one of the most regulated industries by laws that govern the safety and performance of devices across their lifetime, pre- and post-market lifecycle. Some of the challenges in a regulated industry are as follows: keeping track of rules, managing regulatory documentation, formats, need for an evolving information governance and designing a plan for meeting the various regulatory aspects (Iannarelli and O'Shaughnessy, 2014). CI is defined as "a learned and stable pattern of collective activity through which the organisation systematically generates and modifies its operating routines in pursuit of improved effectiveness" (Zollo and Winter, 2002). CI has been used very widely in various organisations; however, its application in respect to regulated industries has not been studied to date in any great depth (Brown *et al.*, 2008; Moore, 2016). Studies on CI in MedTech have acknowledged and discussed that the regulatory nature of the industry can be an obstacle to CI (Nicholas, 2019; Moore, 2016; Brown *et al.*, 2008; Byrne *et al.*, 2021; Bayon *et al.*, 2016; Granlund *et al.*, 2020). Furthermore, although organisations have widely implemented CI, sustaining the momentum of CI activities have been a challenge (Mauri *et al.*, 2010; Zollo and Winter, 2002). However, there has not been a specific study that investigates as to whether the regulated industry of the MD industry has been a CFF for CI deployment and culture. Thus, there is a need for a study analyses the applicability of CI activities in a regulated industry setup. This research contributes by investigating the critical success factors (CSFs) and CFFs for deploying CI methodology in the Irish MedTech sector. Further, the study also investigates if the highly regulated nature of the sector is an additional barrier to CI deployment. This research will explore the extent of the use of CI methods such as Lean, Six Sigma and Lean Six Sigma within the industry and the type of CI tools utilised. The authors are asking the following research questions:

RQ1. What are the CFFs for CI in the Irish MedTech industry?

RQ2. What are the most utilised CI tools?

RQ3. Does the highly regulated nature of the MedTech industry pose a barrier or CFF to CI deployment and culture?

Thus, the research will present the CFFs for CI within the Irish MedTech industry as well as exploring if the regulatory nature of the industry is a specific CFF.

The remainder of the paper is as follows: Section 2 describes the literature, followed by research methodology in Section 3. The results are explicated in Section 4 followed by discussion and implications in Section 5. The conclusion, limitations and scope for future research are elucidated in Section 6.

2. Literature review

2.1 Medical device industry

In order to understand why the MD industry in particular is a focus for the study the nature of the device industry in terms of its product diversity and the regulatory oversight is outlined below. The MD industry is one of the most regulated industries in the world. In the EU and globally, medical technologies are tightly regulated by laws that govern the safety and performance of devices across their lifetime, pre- and post-market life cycle. MDs range from simple Band-Aids and disposable gloves to sophisticated lifesaving products such as pacemakers and implantable facial prostheses (CDRH, 2020a). Classification of MDs (estimated to be more than 500,000 types on the market) drives many pre- and post-market requirements. The higher the classification of a device, the higher the risk and therefore the greater the regulatory controls required. In the USA, for example, Class I devices are deemed to be low risk and are, therefore, subject to the least regulatory controls, e.g. dental floss is classified as a Class I device (CDRH, 2020a). Class II devices are higher-risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device's safety and effectiveness, e.g. powered wheelchairs. Class III devices are generally the highest-risk devices and are, therefore, subject to the highest level of regulatory control and pre-marketing approvals, e.g. replacement heart valves (CDRH, 2020a).

Due to the highly regulated nature of the MD industry, any changes which may affect product functionality and safety may involve submissions or notifications to regulatory bodies, as these changes may impact product safety or compliance to their quality management system (QMS). The changes may be such that they affect the product's intended use, risk profile, intended user base or clinical performance. Not only do these submissions have to be very detailed and laid out according to regulatory procedures, but the approvals process for these changes can also take time, can be costly, can take up resources and take an inordinate time to get approved (Zaki *et al.*, 2019) as well as stifling innovation and CI within the industry. Regulatory hurdles are a well-recognised bottleneck in time and cost for MD manufacturers (Bayon *et al.*, 2016). The availability of regulatory authorities personnel and notified body (NB) services and resources can also be seen as a critical bottleneck in order to ensure that continuous maintenance activities can be performed in a timely manner and that submissions can be reviewed – but this service level is not often available (Granlund *et al.*, 2020).

2.2 Time taken for regulatory submissions

Analysis of the time taken for approval of regulatory submissions by Stanford University found that the time for approval of new Class II type devices in the USA and in Europe can take from 10 months to 31 months by the Food and Drug Administration (FDA) and up to 7 months by the EU. New Class 3 devices' approvals can take from 54 months in the USA and up to 11 months in Europe. The length of time taken for regulatory submission reviews can be costly for companies trying to get products onto the market (Makower *et al.*, 2010). Within the area of MDs, the MD quality standards, such as ISO 13485, de-emphasise CI when compared with the general ISO 9001 standards, suggesting that CI can be problematic in the context of regulatory processes (Brown *et al.*, 2008). The standard, by removing the emphasis from CI and customer satisfaction, places it instead on meeting regulatory requirements, risk management and maintaining effective and validated changes (Nicholas, 2019). An example of this fear of regulatory submissions is in a study by Byrne, McDermott and Noonan in 2021. They highlighted an example from a pharma industry case study where the most appropriate corrective action to fix issues with breaking tablets was not taken as it would require a regulatory submission, revalidation of the process and take time to get approval by the regulatory authorities (Byrne *et al.*, 2021). Many of the regulations and QMS requirements of

MD manufacturers have requirements to manufacture under controlled environments, validate products and processes and monitor field performance via post-market surveillance (PMS) systems, to name but a few. With all of the aforementioned interactions with regulatory authorities and procedures, justification of changes, updating of documentation, increased tests and data collection involved, there is a concern that a regulatory environment is stifling CI and innovation (Vetalice, 2010; Iyede *et al.*, 2018).

2.3 Specific critical failure factors (CFFs) of CI in MedTech industry

In 2010, the FDA commissioned a report on "Understanding the barriers to medical device quality" in recognition that there was a compliance culture within the MedTech industry rather than a quality-improvement culture (CDRH, 2010). This report was commissioned because recalls and adverse event reports were rising (Keyes, 2019). It was stated that serious adverse event reports related to MD use had outpaced industry growth by 8% per annum since 2001 (CDRH, 2010). The FDA did a full analysis in 2010–2011 and found that many factors drove the behaviours which lead to this. A predominant focus on compliance was a key one over and above quality and CI, with an industry focus that was on meeting regulatory requirements (or "compliance") rather than adopting the best quality practices. There was also overall low investment in automation and digital technologies, which did not promote CI to enable better processes and more responsive learning and action (Speer, 2018). In respect of compliance vs quality culture, the FDA launched the Voluntary Manufacturing and Product Quality Pilot Programme in 2018 to counteract this culture (CDRH, 2020b). Participants were offered reduced surveillance audits and faster submission turnaround times in exchange for their participation in a pilot with the Medical Device Innovation Consortium (MDIC) of an operational maturity model which promoted manufacturers' implementation of critical-to-quality practices during device design and production (MDIC, 2021).

Regulatory changes and updates increase the pressure on manufacturers to remain compliant. Recent changes to the International Standards Organisation QMS standard for MDs ISO 13485: 2016, which had not been updated in more than a decade since 2003, put pressure on manufacturers to ensure their QMS is compliant. Also, in order to increase control over manufacturing and ensure safe and effective devices, the European MedTech sector will transition from being regulated under the current MDs directives to two new regulations. The MD sector is regulated by Directives 93/42/EC and 90/385/EEC (European Medicines Agency, 2018). From 26 May 2021, the new Regulation 2017/745/EU has fully applied (EUR-Lex, 2021). This increased, more stringent regulation-replacing pre-existing directives will cause more regulatory workload for MedTech manufacturers (Emergo, 2020).

2.4 Regulatory reporting challenges

In order to obtain medical device regulations (MDR) authorisation for Class III and implantable devices, MedTech companies will be required to present a NB with a large volume of clinical data that supports the clinical performance of their products (Marešová *et al.*, 2020). MedTech manufacturers will also be required to increase reporting of PMS performance utilising the European Medical Devices Database (EUDAMED) (TUVSUD, 2021). This will result in extra resources and regulatory reporting within the industry. There is increased scrutiny and oversight within the new MDR for NBs and a requirement for them to be designated to audit to the new EU MDR. Many NBs are no longer available to certify MD manufacturers and have not applied for MDR designation. Only 22 NBs were designated to audit under MDR as of August 2021 (NANDO, 2021). This reduced number of available and designated NBs will put pressure on MedTech manufacturers in keeping their compliance status up to date.

Sales of MDs in China, India and Brazil are growing, and over the next 40 years, the combined economies of these countries could eclipse the G6 countries: the USA, Canada, the UK,

Germany, France and Japan (Brown *et al.*, 2008). The evolving marketing and regulatory requirements of both national and regional bodies necessitate constant monitoring of each market situation (Anast, 2001). The challenges associated with selling products in these and other emerging markets include multiple regulations that companies are obliged to comply with (Bergsland *et al.*, 2014; Emergo, 2020). These regulations often bring with them the challenge of multiple regulatory inspections. Regulatory authorities, competent authorities and NBs regularly inspect MD companies to ensure compliance with regulations and standards. For example, in Ireland, Irish manufacturers could be subject to multiple audits a year by different regulatory authorities from countries into which they export products. For example, Australia (TGA (the Australian Therapeutic Goods Association)), Brazil (ANVISA (Brazils Agência Nacional de Vigilância Sanitária)), Health Canada (Canada), US (FDA) and Japanese (MHLW (Japanese Ministry of Health, Labour and Welfare)), to name but a few may visit for an audit, as well as audits being conducted from various NBs who are authorised to assess the companies QMS on behalf of the relevant regulatory authorities. This increases pressure on manufacturers who must be "audit-ready", and resources can be taken up in audit readiness and in audit participation. Thus, a focus may be more on compliance than improvement.

2.5 Continuous improvement

CI is a valuable strategy for an organisation to improve productivity and quality, enhance products and services and attain a competitive advantage. There are not many studies addressing the use of CI methods in regulated industries like MD manufacturing or pharmaceutical production, but the use of CI is increasing (Nicholas, 2019; Moore, 2016; Brown *et al.*, 2008). Brown *et al.* (2008) found in a study that the use of strategies and tools associated with quality and CI in the MDs sector is lower than those reported elsewhere. Prior research has provided extensive reviews of the CSFs for Lean Six Sigma (LSS) and alike improvement programmes. There are several critical success factors for the deployment and implementation of LSS, such as leadership alignment, proper selection of people and projects, training, motivation, accountability, information technology, marketing and supply chain management (Sony *et al.*, 2020). Barclay *et al.* (2021) found that the larger number of employees trained in an organisation then the greater the success of the Lean programme and the greater the culture towards Lean. Other research has revealed that success factors for the implementation of CI or LSS projects are contingent on the context or industry in which such LSS projects are implemented. Lameijer *et al.* (2021) have discussed that when looking at the research on service-industry-specific idiosyncratic factors for CI deployment there it is found that within healthcare, factors such as the incentives stemming from laws and regulations should be accounted for when implementing LSS. These idiosyncrasies or contingencies depended on the industry type are CSFs which must be integrated and considered when deploying CI methods (Chiarini and Bracci, 2013).

CI methods such as LSS provide the methods, tools and techniques for CI. CI methodology is an effective leadership development tool as it prepares leaders for their role in managing CI and change (Antony *et al.*, 2017).

Successful implementation of CI is carried out using several process improvement tools (fishbone, flowcharting, check sheets, Pareto charts, control charts, value stream mapping, quick changeover, waste analysis and scatter diagrams) and other statistical tools (McAdam and Donegan, 2003; Zu *et al.*, 2008).

2.5.1 CI deployment and culture. Within CI deployment, organisational culture is an important critical success factor that must be considered. An innovation culture as part of organisational culture has been shown to be an important part of the success of a CI initiative (Terziovski, 2002). During a CI implementation, there is a need to understand and address the organisational culture, as these implementations are likely to impact on the core issue of

culture, as well as the strategy and structure of the business (McLean *et al.*, 2017). For instance, a culture may exist where a lack of empowerment is evident, and employees at the lower levels are not encouraged to participate and problems solve (Pinedo-Cuenca *et al.*, 2012). One effective way to do that is by focussing on solving real problems inside your own organisation and showing people the successes (Chandrasekaran and Toussaint, 2019). Kaye and Anderson (1999) put forward that working culture within an organisation encouraged CI and is influenced by open communications, spreading the word and raising staff awareness and understanding and training people in quality concepts.

In summary, the use and deployment of CI method within the MedTech industry has not been widely studied. This study aims to ascertain if there are contingencies in terms of the CSFs and CFs for MedTech CI deployment.

3. Methodology

The main objective of this study is to investigate what are the critical success factors and CFFs that exist for CI methodology deployment in the Irish MedTech industry, and hence, quantitative research based on an online survey was chosen as a methodological approach (Babbie, 2020; Creswell and Clark, 2017). The survey method was one of the most appropriate methods for this type of study, as it allows the collection of a huge amount of information from respondents in a short time (Couper and Miller, 2008). The advantages of online surveys include speed and reach, ease, cost, flexibility and automation (Ball, 2019). Besides, survey provides a cross-sectional and deductive approach that can be used to generate quantitative and objective outputs (Masood and Sonntag, 2020). Thus, authors wanted to investigate CSFs and CFFs; thus, a survey will help glean this information.

3.1 Instrument design

The survey instrument developed for this study was divided into two sections. The first part was to acquire general information about the respondents and their organisations. A specific question was asked, "*Do you feel that a regulatory compliance or regulated environment/ culture stifles continuous improvement programs in your organisation?*" to which the respondent could answer yes or no. If they answered yes, they were then asked to tick various options (whilst the "no" respondents were directed to move on to another question) as to why they felt regulated environments could be a CFF to CI. The second section was devoted to eliciting information about various aspects of the integration and use and types of CI tools within the organisation and within its QMS.

3.2 Data collection

The authors utilised an online survey for data collection targeted at MedTech professionals working in quality, regulatory, research and development (R&D), PMS, engineering, CI, and other functions throughout the MedTech industry in Ireland. The Dillman approach was utilised in this survey research, which is designed to increase survey response rates (Dillman *et al.*, 2009) allowed for increased contact with potential participants who were quality professionals (Stokes *et al.*, 2019). Quality professionals were contacted via LinkedIn to participate in this study through emails and the LinkedIn personal messaging system (McDermott *et al.*, 2021; Sony *et al.*, 2020). A pilot study was conducted during the survey development process to ensure the design and approach was appropriate. The online survey protocol was first piloted (Boynton and Greenhalgh, 2004) with ten experts. These experts who participated in the online survey protocol pilot were academics who have published more than five articles on CI and CI professionals who have more than ten years of experience in implementing CI in their organisations. The purpose of piloting the survey was to validate the

instrument and ensure that the questions aligned with the research questions set by the researchers (Couper and Miller, 2008). The comments and feedback from the pilot study were subsequently used to review the survey questions and make the questions more readable and relevant to the research.

The revised online survey link was sent out to over 300 MedTech professionals who are working in their respective organisations in various roles that support the MD product realisation life cycle such as quality, engineering, regulatory, supply chain, market vigilance, product development and other functions. Distributing to a wide variety of functional professionals will enable the authors to glean knowledge from a high calibre of experts from the survey participants, who are responsible for various aspects of the product life cycle in their respective MedTech organisations.

3.3 Sample characteristics

A total of 94 valid responses were collated over 12 weeks, yielding a response rate of 31.33%. Easterby-Smith *et al.* (2012) argue that a 20% survey response rate is widely considered to be sufficient. The number of years of experience of the survey respondents was given in Figure 1. The respondents were also asked about their length of experience within the MedTech industry, and 75% of respondents had over two years of experience. The reliability of the survey was measured using Cronbach's alpha coefficient which was found to be 0.8348. Cronbach's alpha is a popular method to measure reliability, in quantifying the reliability of a score to summarise the information of several items in questionnaires (Christmann and Van Aelst, 2006).

4. Key findings

The respondents were asked basic questions about their location and industry type – all respondents were working in the MedTech industry in either MD manufacturing or *In vitro* diagnostic manufacturing and were based in Ireland. The analysis plan is detailed in Figure 2 given below.

As shown in Table 1, the respondents came from a broad range of functional areas within their organisations. These functional areas were all functions associated with the MedTech total product life cycle (TPLC) from R&D and Design Assurance (DA) right through to Manufacturing into Shipping, Logistics and PMS functions. The majority of respondents

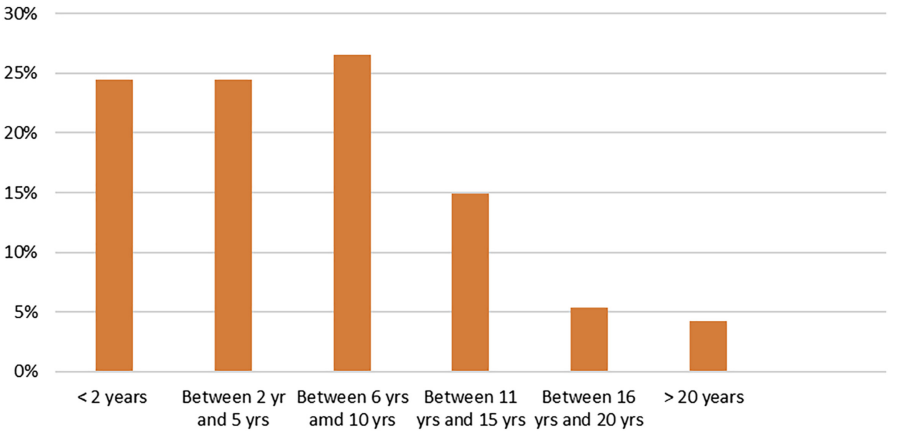

Figure 1.
Years of experience of respondents in working in the MedTech industry

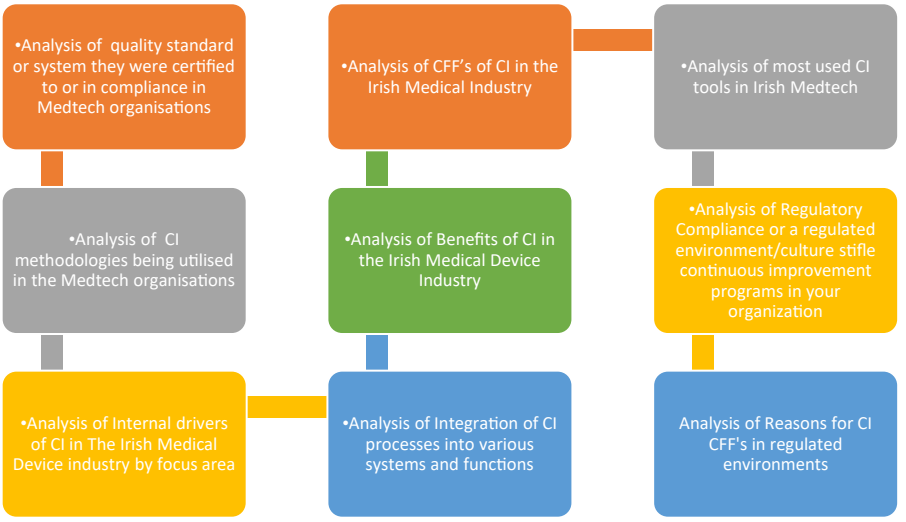

Figure 2.
Analysis plan

Functional areas of respondents	%
Operations quality	17
Manufacturing/Process engineering	15
Production/Operations	12
Regulatory	10
Quality systems	9
R&D/Design	6
Complaints/Post-market surveillance	4
Supplier quality	4
Technical writer	4
Continuous improvement	3
Project management	3
Validation	3
Warehouse/Shipping	2
QC lab role	3
Logistics	2
HR	1
Supply chain	1

Table 1.
Functional areas of respondents

worked directly with the manufacturing floor. The manufacturing respondents came from support areas such as operations quality, manufacturing engineering or were based on the production line as supervisors or operators.

Respondents were also asked what type of quality standard or system they were certified to or in compliance with within their organisations, and the results are outlined in Table 2. They were given options such as ISO 9001:2015, ISO 13485:2016 and USA FDA 21 code of Federal Regulations (CFR) part 820. Some organisations may have been certified to be in compliance with all three of the aforementioned certifications or could be certified or in compliance with two or just one.

Of respondents, 51% stated they were certified to ISO 9001: 2015. It was expected that the majority would have ISO 9001:2015 certification, as the ISO 9001:2015 certification is the most

widely utilised standard for a QMS. However, ISO 9001:2015 is not required to support MD regulatory approval in any country globally. ISO 13485: 2016 is the mandated harmonised QMS standard by the European regulatory authorities. Other regulators have a system in place for "recognition" or "harmonisation" to underline the special status of the standard (Linders, 2020). The standard is utilised, integrated, endorsed or proposed as guidance within other global countries regulatory systems such as Canada, Japan, Australia, Malaysia, Singapore, Saudi Arabia, to name but a few. Although not yet implemented, the US FDA has issued a proposed rule to harmonise their US Quality System Regulations for MD manufacturers (21 CFR Part 820) with ISO 13485 and make ISO 13485 mandatory (Schmitt, 2020). In total, 89% of respondents were certified to ISO 13485: 2016. As the survey participating companies could not manufacture in Ireland or in Europe without ISO 13485:2016, it is expected that the percentage utilising ISO 13485:2016 should be higher than 89% and that some respondents were simply unaware of the standard.

Many of the organisations in this study are authorised to ship and distribute products into the USA as the main export market outside of Europe. Under FDA regulations, MD manufacturers must meet the requirements of 21 CFR Part 820 and are audited to ensure compliance with the requirements by the FDA. Of the respondents, 66% within this study confirmed that they were in compliance with the requirements of the United States FDA under 21 CFR Part 820.

In relation to types of CI methodologies utilised within the Irish MedTech industry, respondents were asked to answer the question, "*Which CI methodologies are you utilising within the organisation in which you work?*" The percentages of the types of CI methodologies utilised are shown in Figure 3. Of respondents, 79% indicated that they utilised LSS, with 10% utilising Lean only and 5% using Six Sigma only. In total, 6% stated that none of the aforementioned CI methods are utilised in their organisations, but it is suggested that

Table 2.
Type of QMS/QSR utilised by the Irish MD Industry

Quality system	%
ISO 9001:2015	51
ISO 13485:2016	89
21 CFR 820	66
Don't know	3

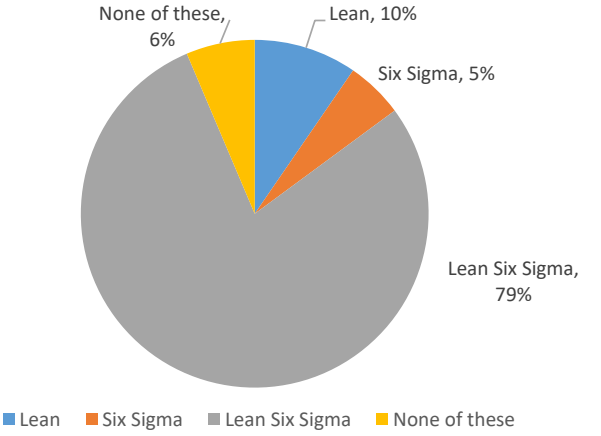

Figure 3.
Percentage of the types of CI methodologies being used in MedTech organisations

perhaps these respondents are in functions that may not use CI methods regularly or at all or may not have CI methods integrated into their roles.

The respondents were next asked, "*what are the internal drivers of CI in their organisations in terms of Productivity, Customer/patient focus, Quality, Regulatory and Safety drivers*". There were asked to distinguish between these drivers in terms of whether they were high drivers, drivers, moderate drivers, low drivers and not a driver whatsoever of CI.

Productivity was seen as a *high driver* at 70% and *a driver* at 24% – there was an overwhelming consensus that a Productivity focus drives CI in MedTech. It was surprising that Productivity and not Quality or Customer/patient focus, which came in at 49 and 51%, respectively, was a higher driver of CI. In fact, Finance was seen as a higher driver of CI at 57% (a high driver) and 31% (a driver) compared to Quality (49% high driver and 37% driver) or Customer/patient focus category (51% high driver and 22% driver). A Regulatory compliance focus was seen as the lowest-ranked area in the high driver of CI methodology category at 26% but was the highest-rank driver in the "driver" category at 39%. This was a surprising finding given the fact that the industry is so highly regulated in order to provide safe products which are vital inpatient treatments and could result in life or death situations. The results are outlined in Table 3.

The respondents were asked how integrated they felt that CI methodology was in certain subsystem areas of their QMS and within other department functions and systems. Respondents indicated that CI tools were "*Very Integrated*" into the following areas in order of ranking: (1) corrective and preventive action system (CAPA) (59%), (2) non-conformance event system (NCE) (50%), (3) audit system (internal and external) (48%), (4) customer complaints investigation/PMS system (34%), (5) supplier corrective action report system (SCAR) (32%), (6) design assurance (DA) systems (28%) and (7) the management review process (26%). The results are outlined in Figure 4. Customer complaints and supplier performance data can provide an important source of data and failure modes for feedback and input to CI programmes and be utilised to drive better product design assurance and functionality improvements. The results indicate that complaints data, supplier performance data and design assurance data are not utilised in CI programmes, as the respondents ranked these areas at only 34, 32 and 28%, respectively, in considering CI practice in these areas to be very integrated.

As all regulatory authorities require manufacturers to show evidence of some type of corrective and preventative action or improvement system within their QMS, it is not surprising that CI tools are considered very integrated (59%) into the Irish manufacturers QMS. The FDA specifically calls out CAPA requirements in their quality system requirements (QSR) 21 CFR Part 820 Subpart J Corrective and Preventative Section 820.100 – Clause 8: Measure, Analysis and Improvement in ISO 13485: 2016 requires documentation of improvement efforts (ISO 13485:2016). The purpose of the corrective and preventive action subsystem is to collect information, analyse information, identify and

	High driver	Driver	Moderate driver	Low driver	Does not drive a CI focus whatsoever
Customer/ Patient focus	51%	22%	20%	6%	0%
Productivity	70%	24%	3%	0%	2%
Quality	49%	37%	12%	1%	1%
Regulatory	26%	39%	18%	13%	4%
Financial	57%	31%	10%	1%	1%
Safety	46%	31%	18%	5%	0%

Table 3.
Internal drivers of CI in the Irish MD industry by focus area

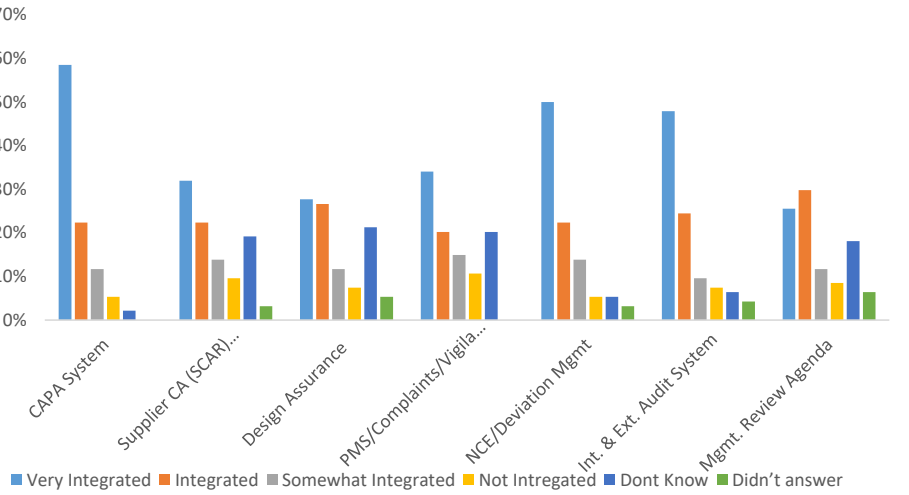

Figure 4.
Integration of CI processes into various systems and functions

investigate product and quality problems and take appropriate and effective corrective and preventive action to prevent their recurrence (CDRH, 2020a).

Within any organisation, leadership plays an important role in strategy and, in particular, within CI deployment and adoption (Antony *et al.*, 2018; Näslund, 2013). Only 26% of respondents felt that CI was integrated into their management review processes and reviewed regularly and supported by their senior management teams. This lacking management support may explain why respondents felt that CI is so poorly integrated into other parts of the quality systems and support functions.

In terms of the benefits of CI to their organisations, the respondents ranked the following in order of preference (1) improved product quality, (2) improved productivity, (3) improved standardisation of processes/procedures, (4) reduced defect rates in processes and (5) achieved greater cost savings. Enhanced customer/patient satisfaction, improved communication between functions, improved employee satisfaction and increased understanding of patient wants/customer needs were in the lower-four rankings. Increasing understanding of the patient/customer wants and needs was ranked the lowest of all of the CI benefits. The view that CI customer/patient satisfaction and understanding of customer needs was not a driver of CI aligns with published findings. The FDA's findings in their 2010 report and Stanford's university 2010 report of a focus on compliance rather than quality and the FDA's effect on MD innovation via approval delays indicate that it is not surprising that CI benefits to customers/patients were not obvious within companies (CDRH, 2010; Makower *et al.*, 2010) (see Table 4).

The top CFFs to CI was seen as (1) poor communication about CI from senior management, (2) lack of training and education, (3) resistance to culture change, (4) lack of resources (financial, technical, human etc.) and (5) lack of awareness of the need for LSS and its benefits. The senior management and leadership role features as a recurring theme in the questionnaire responses in terms of poor communication about CI from senior management (ranked #1), and the fact that only 26% of respondents felt that CI reviews were strongly integrated into the management review processes and systems. As support for CI and training comes from leadership support and direction, as does enabling of CI culture, it is not surprising that lack of training and education and resistance to culture change is the 2nd and 3rd ranked CFFs after poor communication about CI from senior management.

Benefits of CI	No. of responses
Improved product quality	86
Improved productivity	73
Improved standardisation of processes/procedures	60
Reduced defect rate in processes	59
Achieved greater cost savings	59
Improved customer/patient safety	44
Improved speed/timeliness	41
Increased employee engagement	38
Ensures compliance	36
Enhanced staff efficiency	31
Enhanced customer/patient satisfaction	23
Improved communication between the departments	17
Improved employee satisfaction and morale	10
Increased understanding of customer/patient wants/needs	9

Table 4.
The benefits of CI in the Irish MD industry

A lack of resources can also be attributed to a lack of support from leadership as well as an already heavy compliance workload (see Figure 5).

The respondents were next asked, "*Which of the following tools have you utilised in your current organisation as part of CI initiatives or are you aware of as being utilised (please tick all that applies to your organisation)?*" The authors provided the respondents with a long list of Lean and Six Sigma tools from which to choose and aid in answering. The top-five tools utilised according to the respondents were (1) 5 Whys, (2) C&E, (3) Brainstorming, (4) 5S and (5) process mapping in order of ranking. The least utilised or recognised tool was Hoshin Kanri. As Hoshin Kanri is a strategic Lean management tool, it is not surprising to see it ranked as least utilised. Lack of leadership and management support for CI seems to be a theme throughout the research and suggests that a CI culture is not embedded fully enough with the management team to deploy Hoshin Kanri. Hoshin Kanri is an important Lean tool for linking CI to strategy and aligning of a CI programme with strategy is an important organisational readiness factor for CI implementation (Antony, 2014; Rodgers and Antony, 2019). A unanimous 100% of respondents (94) stated they had utilised 5 Whys or were

Figure 5.
CFFs of CI in the Irish medical industry

familiar with it. Nearly half of the tools were recognised or utilised by over 50% of respondents suggesting that they are familiar with the tools, that they have been trained in the use of the tools or that the tools are utilised within their organisations. This correlates with the finding in the survey that 94% of respondents use CI methodologies within their organisations (Lean, Lean Systems and Six Sigma) (see Figure 6).

The respondents were next asked, "*Do you feel that a Regulatory Compliance or regulated environment/culture stifles continuous improvement programs in your organisation*?" with an option to answer "*Yes*" or "*No*". Whilst more respondents answered "No" (56%) to the previous question and stated that regulatory compliance or regulated environments did not stifle CI in their organisation, there was still a sizeable "Yes" vote (44%). The fact that there was not an overwhelming majority of "*No*" answers suggests that there is some weight in the argument that a highly regulated environment can be a CFF to CI. This correlates with the FDA's findings in their 2010 report that there was a culture of compliance over quality (Speer, 2018) (see Figure 7).

The "Yes" respondents were asked to answer another question to ascertain why they felt that a regulated environment was a CFF to CI. Issues raised from the literature review research were used to identify some CFFs to include in this question. The "Yes" respondents (44%) to this question had specifically indicated that they felt there were CFFs to CI in highly regulated environments. So the "strongly agree" and "agree" answers to the reasons for CFFs to CI themes within this question were very high, with the "disagree" and "strongly disagree" answers to some of the options were zero or very low. The top-six reasons highlighted in order of the "strongly agree" rankings by those who felt there were CFFs specific to CI in regulated industries were as follows: (1) fear of extra validation activity; (2) a compliance vs quality culture (closing issues/investigations within deadlines to the detriment of investigation); (3) a regulatory culture within the organisation of being "safe"; (4) overdependence on a CI owner to drive the programme; (5) CI changes seen as potentially affecting compliance to regulations and (6) a fear of extra regulatory submission workload.

Of the respondents, 39% strongly agreed and 34% agreed that fear of extra validation activity is a CFF for CI. Validation requirements can be taken as an opportunity to increase

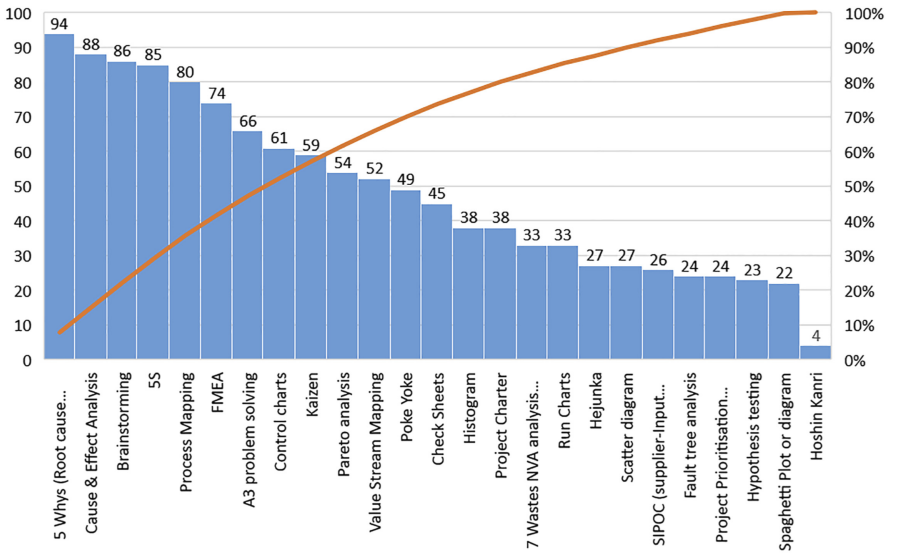

Figure 6.
CI tools most utilised in Irish MedTech

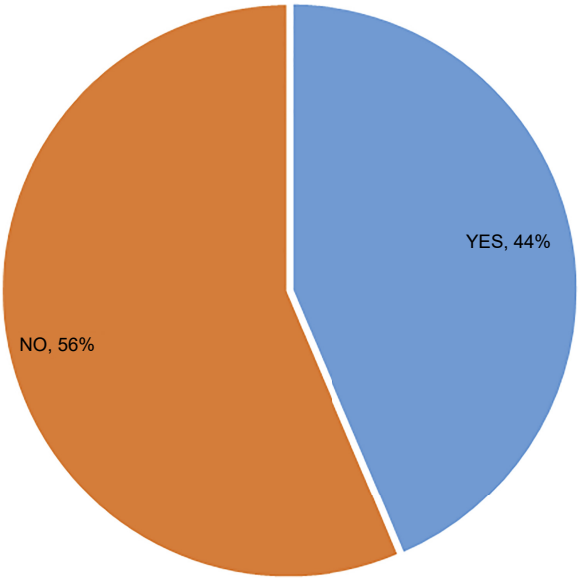

Figure 7.
"Does regulatory compliance or a regulated environment/culture stifle CI programme in your organisation"

process understanding, ensure that processes are operated under optimum conditions, improve quality and reduce costs; they can be seen as time consuming and using resources. This often produces a mindset that simply aspires to have all the relevant documentation completed as soon as possible (Dixon *et al.*, 2006). Any CI programs could potentially lead to product or process changes that require costly, time-consuming and bureaucratic revalidation activities.

"A fear of extra submission workload" as a CFF to CI whilst only having a low "strongly agree" vote at 16% had a 36% "agree" vote that it was a CFF factor for CI. The "CAPA system seen as unwanted extra work" having a low "strongly agree" vote of 11% had the highest "agree" vote as a CFF to CI at 39%.

Heavy external audit schedules by NBs, external regulatory agencies and competent authorities can result in resources being occupied with audit preparedness and audit compliance rather than quality improvement implementation. However, a heavy external audit schedule as a CFF to CI had a very low "strongly agree" vote of 7% as opposed to other barriers offered but had a high 25% of "agree" votes. This contradicts findings by the FDA that audit preparedness is affecting CI in organisations. The FDA is offering reduced surveillance audits as one of the benefits to manufacturers who wish to participate in their Voluntary Manufacturing and Product Quality Programme (CDRH, 2020b).

The recently approved Medical Device Single Audit Programme (MDSAP) is providing some relief from audit preparation and burden. The MDSAP allows an MDSAP-recognised auditing organisation to conduct a single regulatory audit of a MD manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the programme (FDA, 2017).

The CFFs of "Compliance v's Quality" (closing issues/investigations within deadlines) had a strongly agree percentage of 27% and an agree vote of 27%, whilst a regulatory culture of being "safe" had a 20% strongly agree vote and a 20% agree with vote. Essentially, these two CFFs are symptomatic of an overall compliance focus and align with the FDA's findings of compliance vs quality culture and also with the CFF of not wanting to raise a CAPA as it was

seen as extra work. Another CFF identified to CI was that "CI was seen as a Quality department initiative" with a vote of 16% strongly agree and 10% agree. As the CAPA system is controlled and managed by the quality systems department in MedTech organisations and CI was identified as being very strongly integrated into the CAPA system above any other subsystem in this study, this finding is not a surprise. CI is seen more as the responsibility of the quality function.

"CAPA was seen as unwanted extra work" whilst not in the top five "strongly agree" CFFs to CI had an agree vote of 39% that it was a CFF to CI. The FDA, in association with the industry, have recognised that manufacturers are raising and documenting CAPAs for the sake of compliance activity and causing extra workload and not necessarily fostering CI or necessarily solving patient or user safety issues. Medtronic, a global MD manufacturer, stated that they spend "about US$150m on CAPA" – based on "the number of CAPAs that are written and the amount of time it takes to address a CAPA" (Schmitt, 2019). The FDA is recasting CAPA as part of its "Case for Quality" programme to move the CAPA focus from compliance to risk-based CI (MDIC, 2021) (see Table 5).

5. Discussion and implications

It is evident that CI methodologies are integrated into Irish MedTech organisations, with CI methods being utilised and deployed in 94% of manufacturers. The top-five tools utilised for CI according to the respondents were (1) 5 Whys, (2) C&E, (3) Brainstorming, (4) 5S and (5) process mapping in order of ranking. However, these tools are very basic and non-statistical and suggest a lack of embracing and understanding of CI tools and techniques within the industry. The fact that Hoshin Kanri was the least utilised or recognised tool as cited by respondents in the industry suggests that management could be doing more to align CI with their organisational strategy.

However, despite MedTech's industry regulatory authorities endeavouring to drive a patient/user-product safety focus, productivity and financial factors were seen to be the

Reasons for CI barriers in regulated environments	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Fear of extra validation activity	39%	34%	11%	7%	0%
Compliance vs quality (closing issues/ investigations within deadlines)	27%	27%	9%	7%	0%
Regulatory culture of being "safe"	20%	20%	18%	9%	0%
Overdependence on a continuous improvement owner/department to drive program	20%	14%	25%	9%	0%
Changes seen as potentially affecting compliance to regulations	18%	32%	11%	11%	0%
Fear of extra regulatory submission workload	16%	36%	9%	11%	0%
CI seen as a quality department. initiative	16%	11%	16%	16%	7%
Lack of training	11%	34%	16%	11%	0%
CAPA seen as unwanted extra work	11%	39%	11%	7%	0%
Regulatory department do not see benefits	9%	25%	14%	7%	18%
Lack of management support	7%	25%	25%	11%	2%
Heavy external audit schedule limits time for CI	7%	25%	11%	2%	0%

Table 5.
Reasons for CI CFFs in regulated environments

main drivers of CI in Irish MedTech. In terms of the benefits of CI to their organisations, the respondents ranked the following in order of preference (1) improved product quality, (2) improved productivity, (3) improved standardisation of processes/procedures, (4) reduced defect rates in processes and (5) achieved greater cost savings. Within Irish MedTech, CI was seen as least integrated into the complaints/PMS, design process and management review process. This may be explained by the lack of focus on CI within ISO 13485:2016 but customer focus and voice of the customer is an important part of any organisations success irrespective of the standards they certify to (Gunasekaran *et al.*, 2006; Zrymiak, 2017).

Manville *et al.* (2012) put forward CSFs for the implementation of CI methods such as LSS to be: senior management commitment, support and enthusiasm; linking LSS to business strategy; linking LSS to the customer; understanding the tools and techniques; project selection and prioritisation and training and education. The findings of this research aligned somewhat with the top CFFs to CI were seen as (1) poor communication about CI from senior management, (2) lack of training and education, (3) resistance to culture change, (4) lack of resources (financial, technical, human etc.) and (5) lack of awareness of the need for LSS and its benefits. Of the respondents, 56% stated that regulatory compliance or regulated environments did not stifle CI in their organisation, but there was still a sizeable 44% who strongly agreed that it did. The top-six reasons highlighted in order of the "strongly agree" rankings by those who felt there were CFFs to CI in regulated industries were as follows: (1) fear of extra validation activity, (2) a compliance vs quality culture (closing issues/investigations within deadlines to the detriment of investigation), (3) a regulatory culture within the organisation of being "safe", (4) overdependence on a CI owner to drive the programme, (5) CI changes seen as potentially affecting compliance to regulations and (6) a fear of extra regulatory submission workload.

Leadership's involvement or lack thereof in CI was a recurring theme where poor communication, lack of resources was seen as top CFFs to CI. A culture of regulatory compliance vs a culture of CI and quality was indicated as a barrier to CI in Irish MedTech. Fear of extra validation activity and CAPA projects (which are basically quality improvement projects utilising CI methods) being deemed extra work coupled with a culture of being "safe" in terms of ensuring continuing regulatory compliance all contribute to CI deployment being not as successful in regulated industries as in other industries.

CI can only be driven from within a company; but within regulated industries, there are more external CFFs to CI deployment and culture driven by regulations. The regulatory authorities globally are making progress in order to reduce the regulatory burden on manufacturers. From a strategic regulatory point of view, regulatory authorities working with the International Medical Device Regulators Forum (IMDRF) are trying to harmonise regulatory requirements globally and reduce manufacturers having to conform to different regulatory requirements in different jurisdictions. The IMDRF-instigated MDSAP has already started to reduce the number of regulatory audits on manufacturers by those countries participating in the program. As a partner within the MDSAP program, the FDA has announced it will transition (was expected in 2021) from its existing QSR to ISO 13485:2016 instead of 21 CFR part 820 going forward (Schmitt, 2020). This will save global MedTech manufacturers from having to meet the requirements of both if they export into the USA. This should reduce resources that are engaged in ensuring compliance to both.

Having just one QMS to conform to will mean that ISO 13485:2016 is the only standard for a QMS in MD manufacturing globally. Whilst ISO 13485:2016 does not focus on CI within its clauses, the FDA, for example, is trying to drive CI, operational excellence, reduced audit surveillance, expedited change submission review times and reduced CAPA workload through its highly successful "Case for Quality" initiative. Conversely, the EU, whilst acting as an observer of MDSAP within the IMDRF have not very adopted it. The EU is introducing

the new MDR, which will drive increasing regulatory reporting, documentation, testing, clinical trial data, PMS tracking and a reduced number of NBs to support its implementation. This new EU legislation may not improve the perceived and actual regulatory barriers to CI within Irish MedTech organisations.

In terms of the implications of this study, this work is very important for CI professionals in the Irish and global MedTech industry but in particular for senior management and leadership teams. Aside from the main findings on the CFFs to CI in MedTech, there is some strong evidence that a regulate environment can be a further CFF to CI. Senior management teams should use this research to analyse their own organisations and assess the culture of regulatory compliance vs quality. Within the academic community, this study is one of the first focussing on the barriers to CI within a regulated environment and should aid further study, research and understanding of CI in regulated environments.

6. Conclusion, limitations and directions for further research

This research shares several managerial implications for CI programmes and for the MD industry in general. Regulatory compliance is seen as a partial CFF to CI in Irish MedTech organisations. There have not been many studies demonstrating CI deployment in the MedTech industry, and this study demonstrates that there are factors associate with a highlight regulated environment that can affect CI deployment and culture. This study particularly highlights aspects of a regulatory environment that managers must take into account when deploying CI which previous studies have not captured. It is also one of the first quantitative studies studying the CSFs and CFFs of deploying CI in the Medtech industry. The CFFs in relation to regulatory environments can be studied by senior management teams and focussed on to improve organisational readiness for CI programmes and help determine CSFs for deployment.

Finally, this study has some limitations that must be noted. First, the study was carried out within the Irish MedTech industry. The authors plan to expand the study to other global countries. The pharmaceutical industry is perhaps more highly regulated than the MD industry, and it will be interesting to carry out comparative studies.

The response rate could possibly limit the generalisability of the findings and the robustness of the conclusions. It is worth testing and comparing the validity of the results in companies operating in different countries worldwide. The authors are keen to investigate and learn about the perceived differences in the findings of the study within different countries and regulatory jurisdictions. In particular, the authors would like to conduct the study after the new European MDR and in-vitro diagnostic regulation have been in place for a period of time to assess the impact of the new regulations on workload in the industry. Also, the efforts by the FDA to incorporate an operational excellence focus into its regulatory oversight will potentially improve the focus on CI across the industry.

Finally, the authors are planning to pursue more in-depth exploratory research in the form of semi-structured interviews or focus groups involving a number of leading quality practitioners in the field to obtain further insights into the topic of interest.

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Appendix
Survey questions

(1) How many years of experience have you within the MedTech industry?

(2) What functional area do you work in?

(3) What type of quality standard or system is your organisation certified to or in compliance with?

(4) Which CI methodologies are you utilising within the organisation in which you work?

(5) What are the internal drivers of CI in your organisation in terms of productivity, customer/patient focus, quality, regulatory and safety drivers?

(6) What are the benefits of CI in your organisation?

(7) Which of the following tools have you utilised in your current organisation as part of CI initiatives or are you aware of as being utilised (please tick all that applies to your organisation)?

(8) Do you feel that a regulatory environment is a CFF for CI?

(9) Which of the following factors do you feel contributes to regulatory environment being a CFF for CI?

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