



New Eminence Release

How quality in MedTech became a driver of financial performance


Christian Schiel, Sophia Hanau

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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. 





Dr. Christian Schiel

Partner at Deloitte

Industry Lead Life Science & Healthcare - Risk Advisory Germany



Sophia Hanau

Manager at Deloitte

MedTech Practice - Risk Advisory Germany

THE CHALLENGE | Are QA and RA perceived as a performance enablers?



THE CHALLENGE | Are QA and RA perceived as a performance enablers?



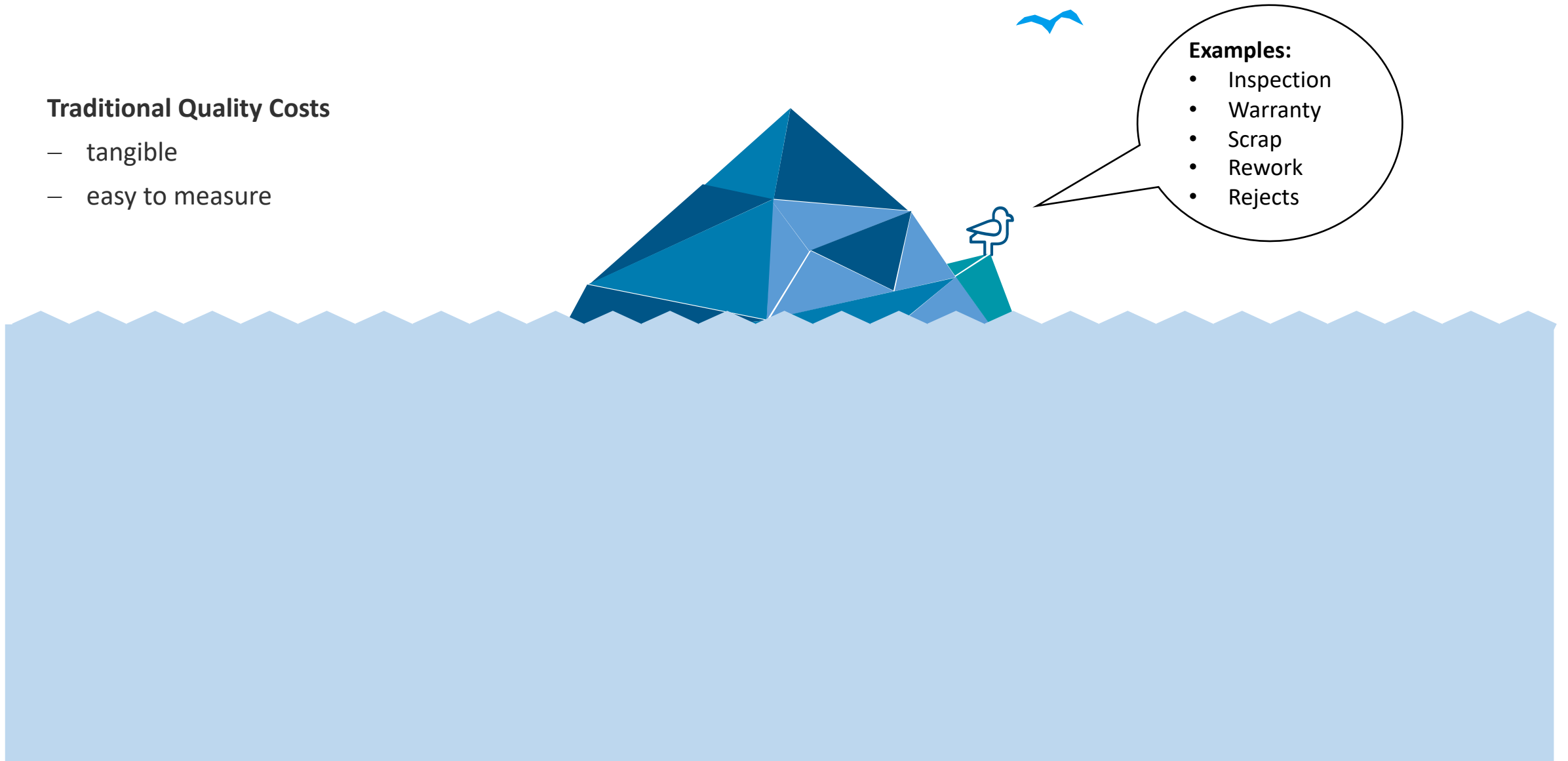
THE CHALLENGE | Cost of poor quality & regulatory compliance

Traditional Quality Costs

- tangible
- easy to measure

Examples:

- Inspection
- Warranty
- Scrap
- Rework
- Rejects



Traditional Quality Costs

- tangible
- easy to measure

Hidden Costs

- intangible
- difficult to measure



The diagram is an iceberg floating in a light blue sea. The visible tip of the iceberg is a dark blue, multi-faceted geometric shape. Inside this tip, the text 'Lost Opportunities & Lost Shareholder Value?' is written in white. The submerged part of the iceberg is a lighter blue. To the right of the tip, a small white seagull is perched on the edge. A speech bubble from the seagull points to the 'Traditional Quality Costs' section. Below the sea, a blue shark is swimming. A speech bubble from the shark points to the 'Hidden Costs' section. Two more seagulls are flying in the sky above the sea.

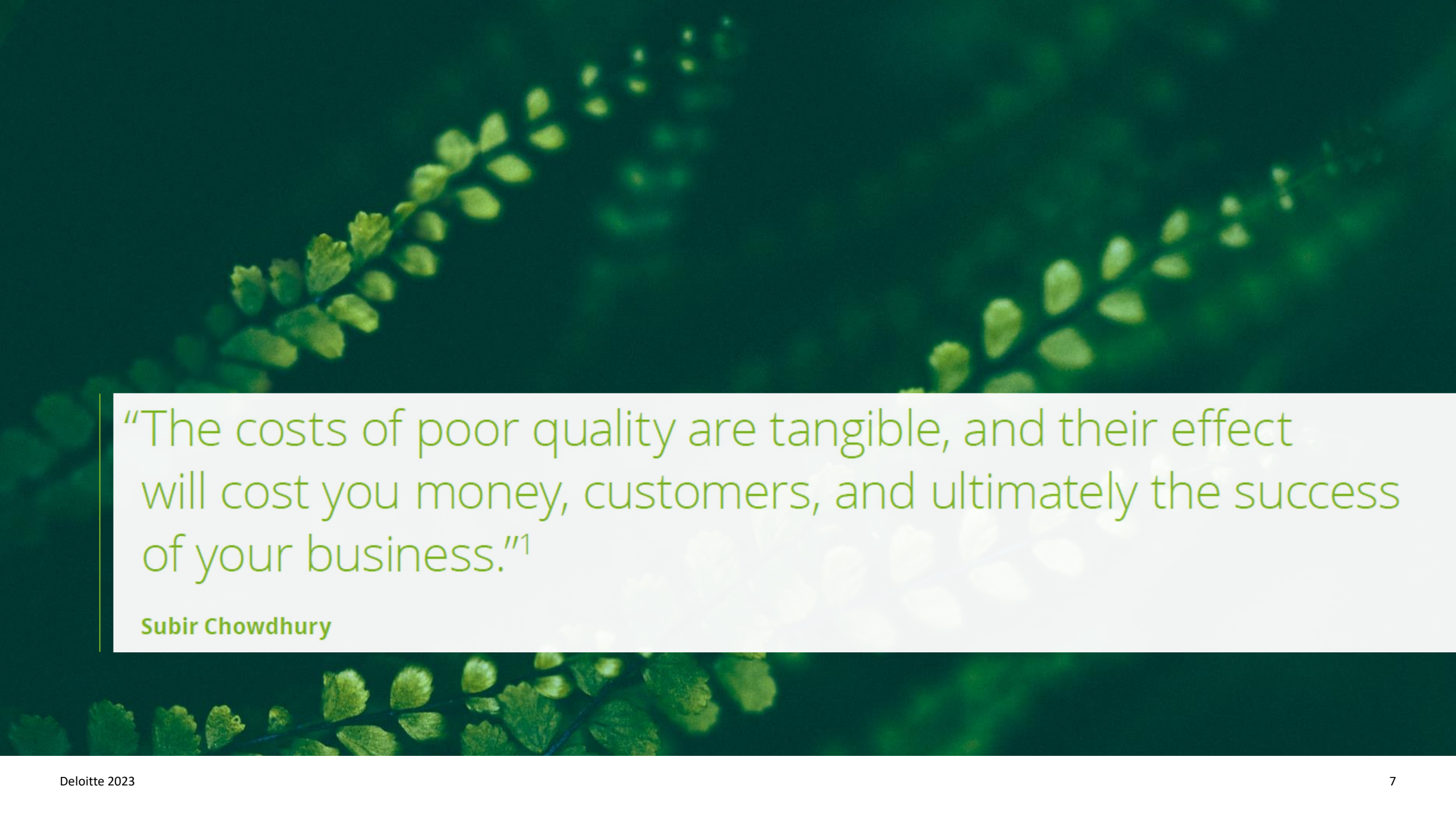
**Lost Opportunities &
Lost Shareholder Value?**

Examples:

- Inspection
- Warranty
- Scrap
- Rework
- Rejects

Examples:

- Lost Sales
- Late Delivery
- Lost Customer Loyalty
- Excess Inventory
- Long Cycle Times



"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

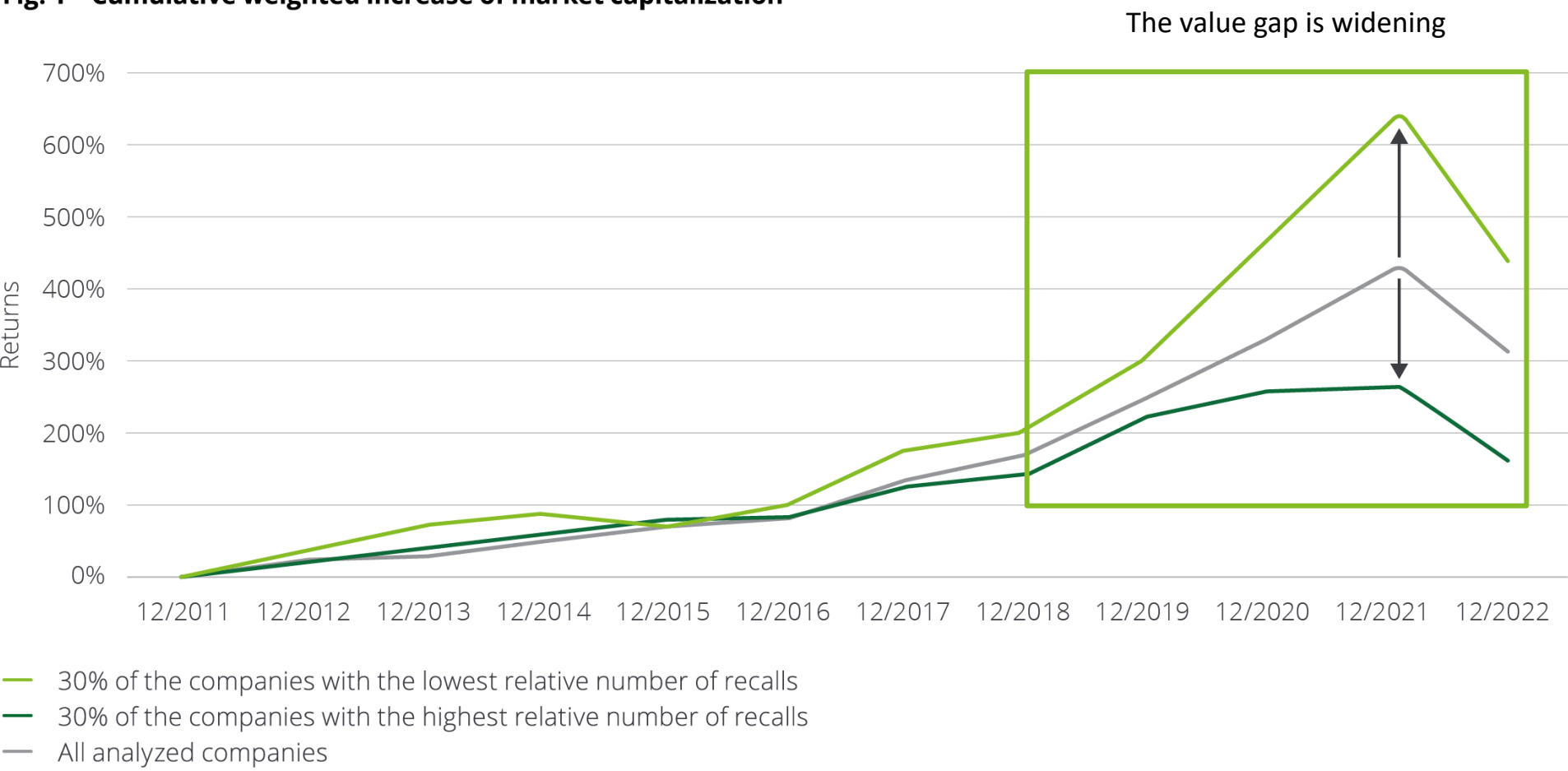
THE STUDY | No evidence for systematic market penalty for poor quality prior to 2018

Fig. 1 – Cumulative weighted increase of market capitalization



THE STUDY | In recent years a value gap has been widening significantly

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. 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. 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’ 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.

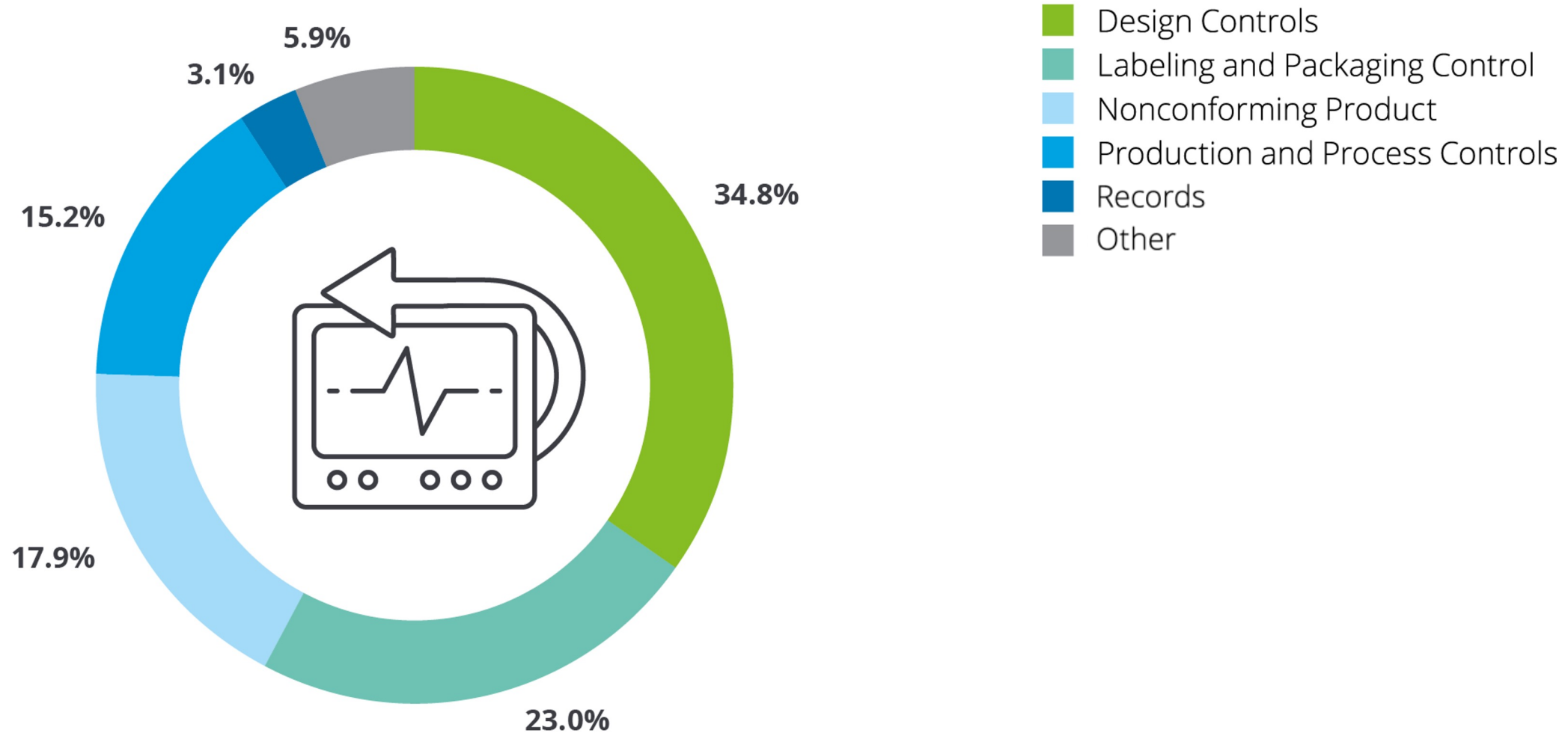
THE STUDY | Speculating about reasons for the widening value gap

- Changing **regulatory environment** in the MedTech industry (EU MDR, IVDR, UDI, serialization, ISO 13485 and more)
 - Increased **public awareness and media coverage** of adverse events, product safety concerns and lacking supply chain traceability
 - Increasing **product complexity and interconnectivity** combined with growing pressure to achieve a rapid market launch
 - **Cybersecurity vulnerability associated with** innovative device categories (e.g. SaMDs)
 - **Globalization of design requirements** – companies have to incorporate requirements from more and more markets into the design and manage changes continuously.
 - **M&A activity** in the sector may lead to increasingly fragmented and siloed management systems, IT architectures and data landscapes
 - **Portfolio effects:** ‘firms with [...] broader product portfolios have a higher likelihood of device recalls’.
- A company’s ability to consistently meet quality and regulatory requirements has clearly become a strategic differentiator in the MedTech sector.



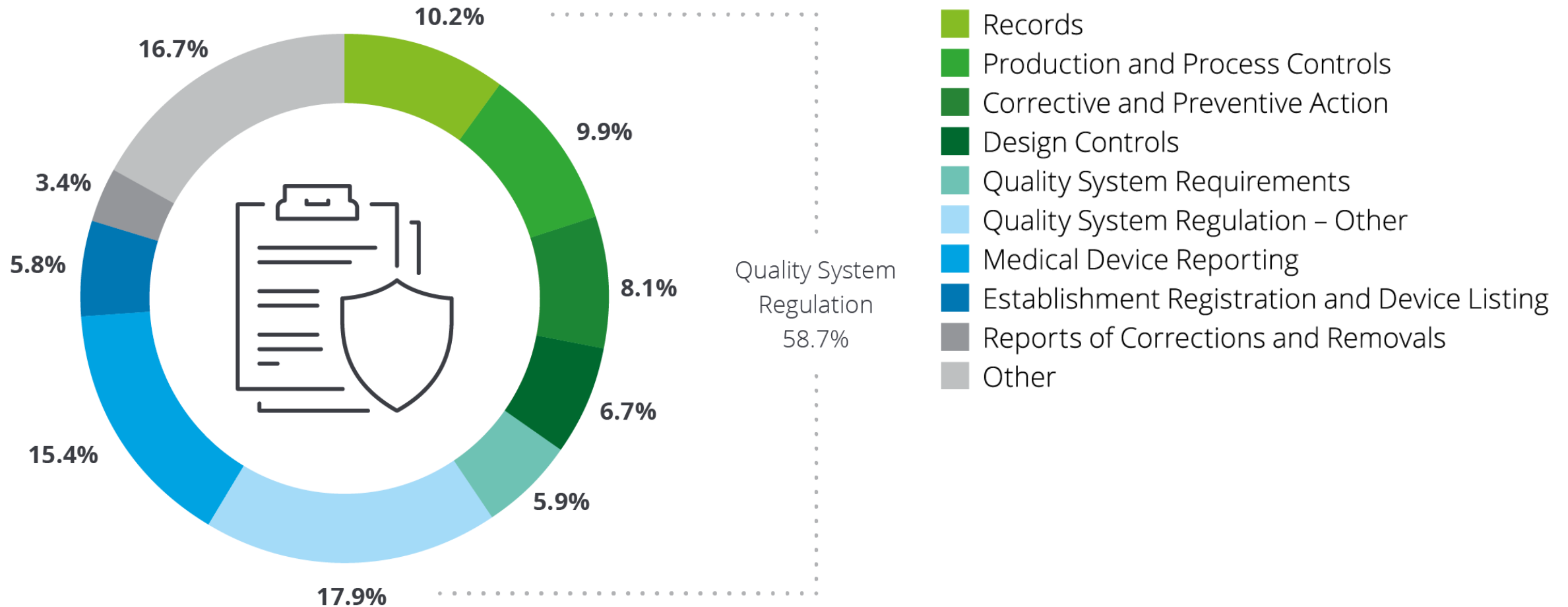
THE STUDY | Design controls and labelling lead the list of root causes for FDA recalls

Fig. 2 – Root causes for FDA recalls



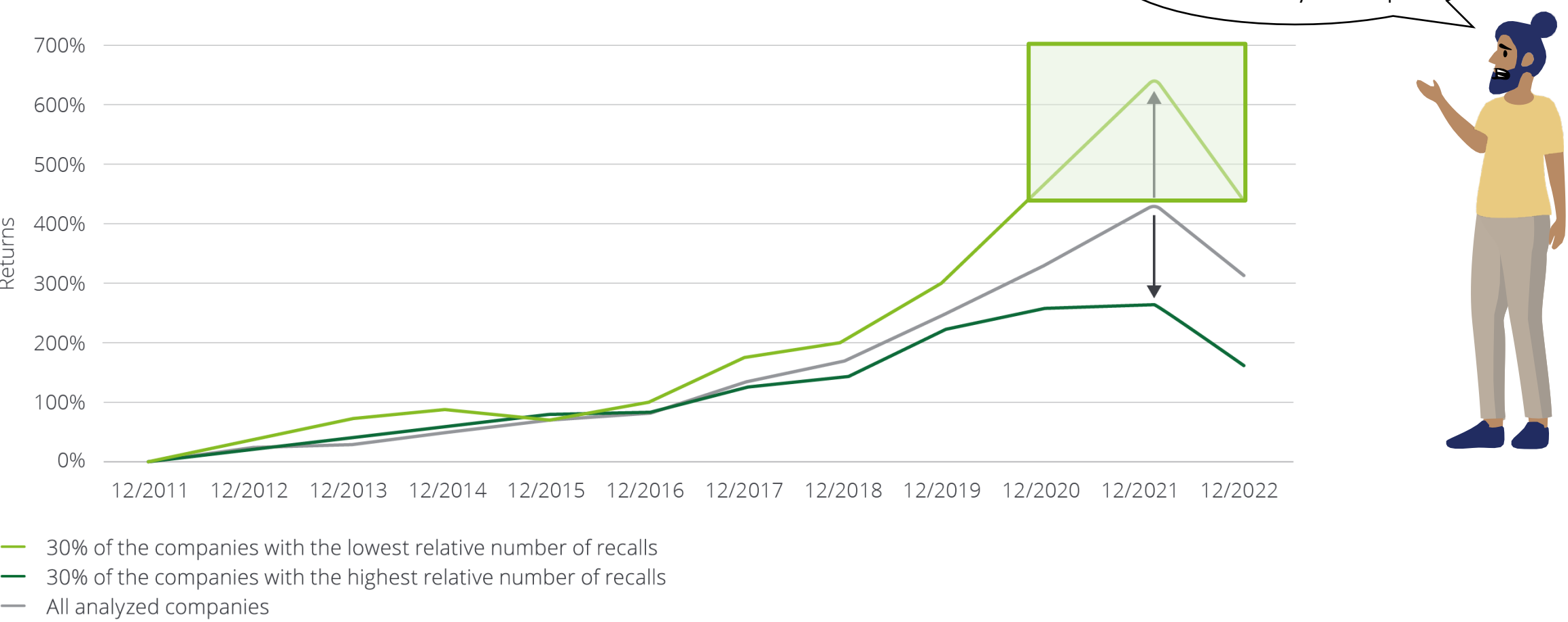
THE STUDY | Quality is a critical factor explaining systemic weaknesses

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



THE CHALLENGE | How to smartly invest in quality & regulatory compliance?

Fig. 1 – Cumulative weighted increase of market capitalization



THE CHALLENGE | How to invest in 'good quality'?



THE STUDY | The study is available for download

Deloitte.



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. 1



Scan the QR Code below:



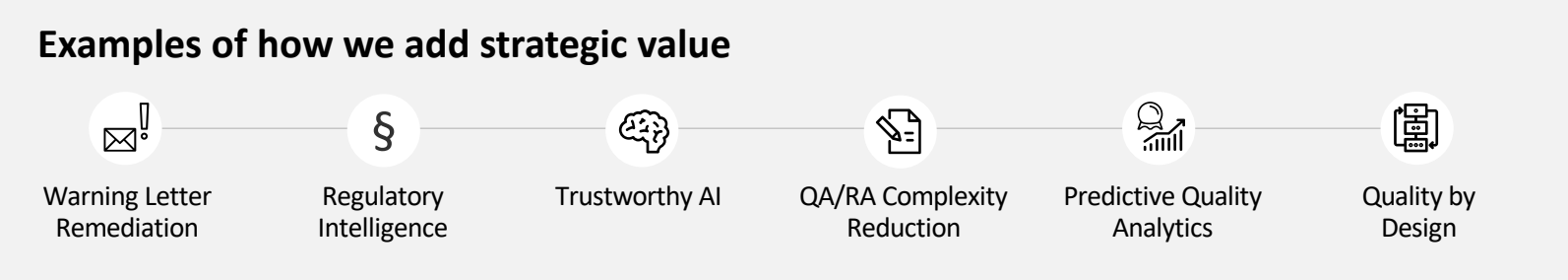
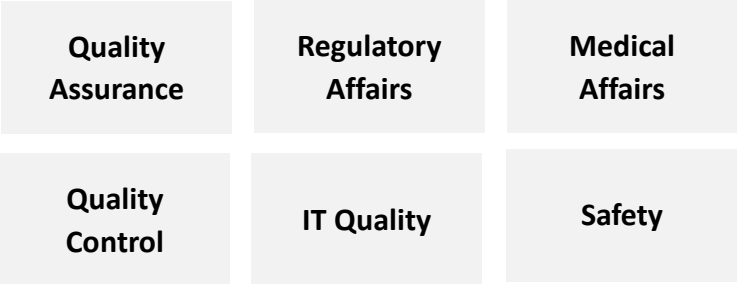
DELOITTE | We deliver end-to-end business transformations in the GxP regulated space

Deloitte is the largest professional services firm in the world and a leading transformation advisor for GxP regulated management systems in Life Sciences.



Dr. **Christian** Schiel
Partner and Risk Advisory
Industry Lead for Life
Science & Healthcare

“We build smart GxP solutions for our clients to navigate regulatory complexity.”



Let's talk!

Author



Christian Schiel

Life Science & Healthcare Leader
Risk Advisory Germany
cschiel@deloitte.de

Global Contacts

Global MedTech Lead

Glenn Snyder
gsnyder@deloitte.com

EMEA MedTech Lead

Michael Dohrmann
mdohrmann@deloitte.de

Belgium

Michel de Ridder
mideridder@deloitte.com

Central Europe

Pavel Nevicky
pnevicky@deloittece.com

Germany MedTech Cyber

Carsten Heil
cheil@deloitte.de

India

Muthukumarasamy Karuppiah
mkaruppiah@deloitte.com

Italy

Tommaso Stranieri
tstranieri@deloitte.it

Japan

Tetsuyuki Tatsuoka
ttatsuoka@tohatsu.co.jp

Switzerland

Doug McKinnell
dmmckinnell@deloitte.ch

The Netherlands

Aida Demneri
ademneri@deloitte.nl

UK

Andrew Flockhart
aflockhart@deloitte.co.uk

United States

Oliver Steck
osteck@deloitte.com



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Meet Your Presenters:



Presenter

Taylor Holcomb
*Solutions
Engineer*



Moderator

Chris Rush
*Solutions
Engineer*

Quality is the best business plan.

61% of industry professionals still only focus quality management efforts on ensuring compliance over establishing **quality as a strategic advantage**.

Quality's Impact to the Bottom Line



Save

Drive operational efficiencies throughout your organization



Scale

Get started quickly and grow faster with a quality system that allows you to scale and navigate different international markets



Mitigate Risk

Improve the quality of regulatory submissions, be audit-ready, and achieve peace of mind knowing your quality system can stay ahead of compliance changes

62%

Of QA/RA professionals consider ensuring compliance to a regulatory body as a top objective for 2023

1 in 3

corporate executives see upgrading systems and processes as a top priority



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Embracing Technology for Better Quality

Only 30%

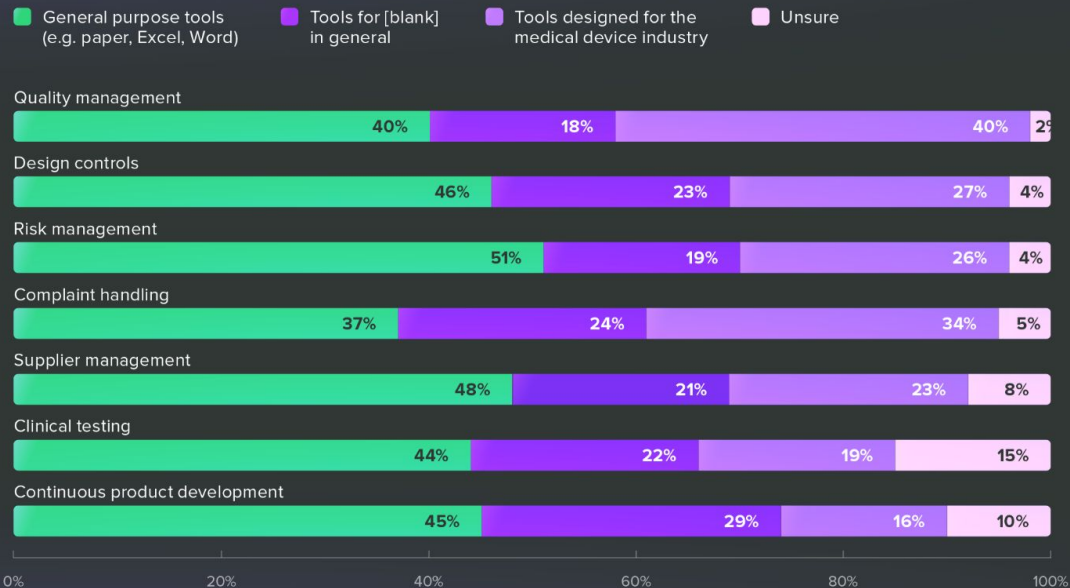
of pre-market companies say they are “very confident” their current quality system can handle projected growth over the next 12 months

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Out with the old

General purpose tools versus purpose-built solutions for companies with product(s) on the market

Q What system/tool do you use for
the following:



Showing responses for
pre-market companies only

In with the new

Comparing companies that use general purpose tools vs. those that use purpose-built solutions:

Quality management

- ✓ 50% more likely to say they'll meet their quality objectives in 2023.
- ✓ 2x more likely to say documentation of design controls is "excellent".
- ✓ Nearly 2x more likely to say they'll meet their product development objectives in 2023.

Product development

- ✓ Over 2x more likely to say they include supply chain partners in design change discussions.
- ✓ Almost 3x more likely to say employee training oversight is fully automated (i.e., automated notifications rather than tracking via spreadsheets and searching for people who need additional training).

Risk management

- ✓ 2x more likely to say their team's ability to view/ access real-time data for cross-functional collaboration is "very good" or "excellent".

Clinical data capture

- ✓ 1.8x more likely to say employees have "high visibility" to access data and details about quality problems.

Source: Greenlight Guru's 2023 Medical Industry Benchmark Study

Greenlight Guru enables medical device companies to bring products to market faster, more efficiently, and with less risk.

1200+ of the world's leading MedTech companies trust Greenlight Guru

frida baby

contraline

Fearsome

ORBIS
DIAGNOSTICS

Astrego[®]
Diagnostics

KYTOPEN

TENACORE.

H U M A

Milliken

SPARK
BIOMEDICAL

Avenda Health

Cardiologs[®]

4DMedical[™]

carlsmed[™]

PhotoniCare

CREO
MEDICAL

eli

Capterra
4.5

Fastest
Implementation
Mid-Market
SUMMER
2023

Leader
Europe
SUMMER
2023

Best
Results
SUMMER
2023

Leader
SUMMER
2023

Best
Est. ROI
Mid-Market
SUMMER
2023

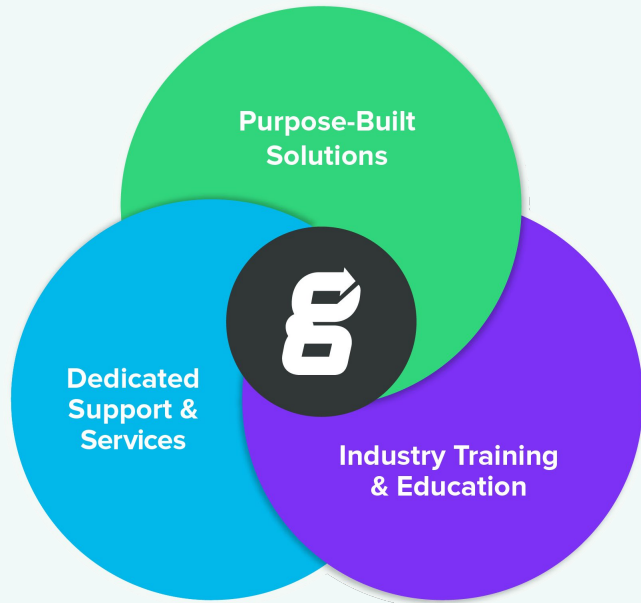
Momentum
Leader
SUMMER
2023

Best
Relationship
SUMMER
2023

2023
QUALITY
MANAGEMENT
SOFTWARE
MARKET LEADER

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Partnering with an Industry-Specific QMS



- **Purpose-Built for MedTech** companies with validated workflows compliant with industry-specific regulations and requirements.
- An **out-of-the-box** system intuitively designed to get teams into a better system, faster.
- A **single source of truth** that breaks down information silos and drives alignment across your team
- **End-to-end traceability** that empowers teams and drives visibility that scales with you through each stage of your product lifecycle.

Achieve Peace of Mind Navigating Industry Regulations

Streamline compliance and gain peace of mind knowing that your workflows and systems are validated and compliant with industry-specific regulations and requirements.



Balancing Local and Global Governance

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From documents to data and automated workflows

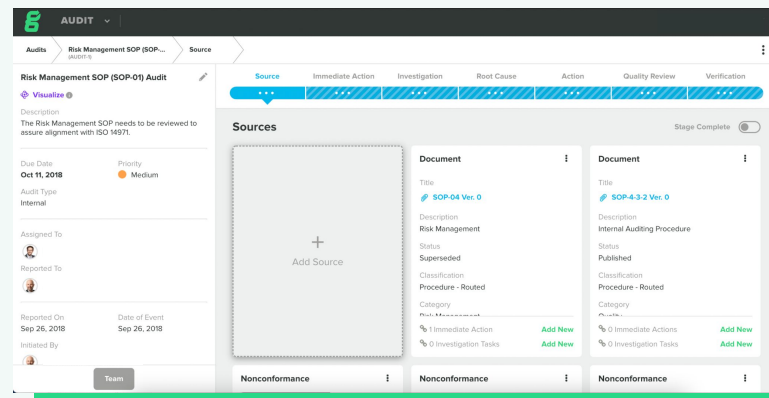


Risk-based approach and Quality by Design

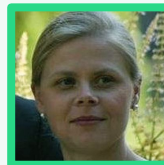
For Quality Teams: Manage risk-based quality processes in a connected ecosystem that unites internal and external stakeholders

1. Automate your quality event workflows
2. Assure your team's documentation is up-to-date and audit ready
3. Stay ahead of compliance changes
4. Drive end-to-end traceability - from design controls to post market surveillance

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"I highly recommend Greenlight Guru. They have taken a complex industry and made it into a product that is simple to use."



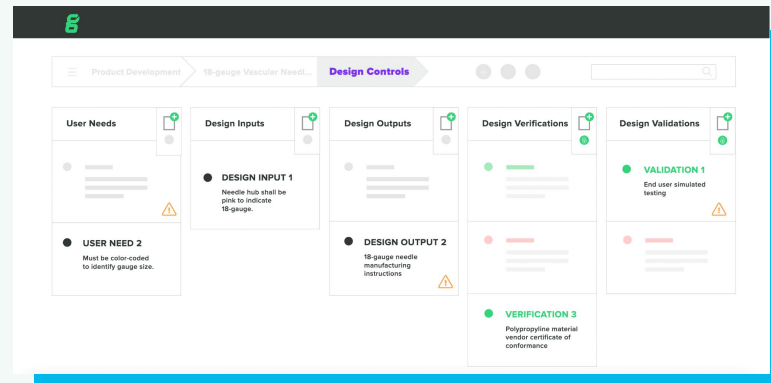
Tonia Bryant
Director of Quality/Regulatory
Lucerno Dynamics



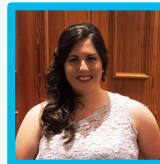
For Product Teams: Accelerate product development with a QMS that drives traceability throughout the entire product life cycle.

1. Automatically maintain end-to-end traceability of your total product lifecycle
2. Auto-compile key design and risk documentation
3. Demonstrate a risk-based approach to design
4. Enhance collaboration to accelerate device development timelines

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“Streamlining our agile development and design reviews with Greenlight Guru allowed us to create a compliant DHF and attain 510(k) clearance in 2 months - while ultimately saving team resources.”



Victoria Enjamio
VP of Operations
BIOREP TECHNOLOGIES, INC.

Real Results from Real Customers

75%

*reduction in time
needed to set up a
QMS*

40%

*reduction in number of
audit findings*

50%

*reduction in time spent
on development &
design documentation*

35%

*reduction in time to
market*

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Migrates from paper and overcomes failed eQMS implementation to scale into new markets and maintain compliance in global markets with Greenlight Guru

The logo for ZYRIS, featuring the word "ZYRIS" in a bold, dark grey sans-serif font. A small red dot is positioned above the letter "i". A thin purple horizontal line is located directly beneath the text.

Company Size: 51-200 employees

Device Type/Class: Class I

Selling into: USA, Canada, Europe, Australia, Japan

*“Partnering with Greenlight Guru provides you with a team that’s on your side, who are **all medical device industry pros** and understand what companies like ours go through.”*

- Morris Sherwood, Person Responsible for Regulatory Compliance, Zyris

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Streamlined quality and compliance efforts while accelerating product development timelines by 50% for their second-gen product.



Company Size: 11-50 employees

Device Type/Class: Class II

Selling into: USA (FDA)

*"Greenlight Guru's software is **expensive on day one, and dirt cheap on day two**. This is a year's worth of someone's salary already done, implemented, and ready to go."*

- Daniel Powell, CEO, Spark Biomedical

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***Implemented an audit-ready QMS in just 3 months
and successfully navigated 6 audits over the course
of a year.***



Company Size: 11-50 employees

Device Type/Class: Class I

Selling into: USA

*The easy-to-follow onboarding and implementation process at Greenlight Guru allowed us to **scale our business** while implementing our new eQMS.”*

- Amanda Feddersen, QA Manager, MTI

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Make Quality Your Strategic Advantage.

We Can Help.

The screenshot displays the Greenlight Guru CAPA Management interface. On the left, a sidebar shows the CAPA record details for 'CAPA Management 1'. The main area shows the 'Quality Review' workflow, which includes a timeline from 'Draft' to 'Published'. A 'Reviewers' table lists reviewers and their status. A 'Version History' table is also visible.

CAPA Management 1

Description: This CAPA will be opened to investigate and determine if any corrective actions are needed.

Due Date: Aug 21, 2022 | Priority: Urgent

CAPA Type: Corrective

Assigned To: Marcus Mueller

Reported To: Janice Jones

Reported On: Mar 20, 2021 | Date of Event: Mar 10, 2021

Initiated By: Marcus Mueller

External ID: AC-85

Quality Review

Start Date: Mar 21, 2022 | End Date: Aug 21, 2022

Workflow: Draft → Routing → Approved → Published

Reviewers

Reviewer	Review Days	Review Status	Status
Marcus Mueller			Complete
Diya Singh			Reviewing

Version History

Author	Effective Date	Ver.	Status

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<https://www.greenlight.guru/bonus>

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522k

podcast listeners

200k+

look to us for the latest in MedTech

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510(k) clearances & CE marked devices

2000+

ISO 13485 certifications

1100+

I-III/SaMD/IVD

MedTech companies worldwide in all device classes and types

500+

clinical trials



"Best QMS I have ever used..."

"User-friendly EDC and responsive support team"

"This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry."

"The whole experience of using Greenlight Guru Clinical is accessible and user-friendly"

"Makes your QMS Simple and Effective"



Thank you | Q&A