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New Eminence Release

How quality in MedTech became a driver of financial performance

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November 2023

Guest Speakers

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

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THE CHALLENGE | Cost of poor quality & regulatory compliance

Traditional Quality Costs

- tangible
- easy to measure

Examples:

- Inspection
- Warranty
- Scrap
- Rework
- Rejects

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Traditional Quality Costs

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Examples:

- Inspection
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- Rejects

Hidden Costs

- intangible
- difficult to measure

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]

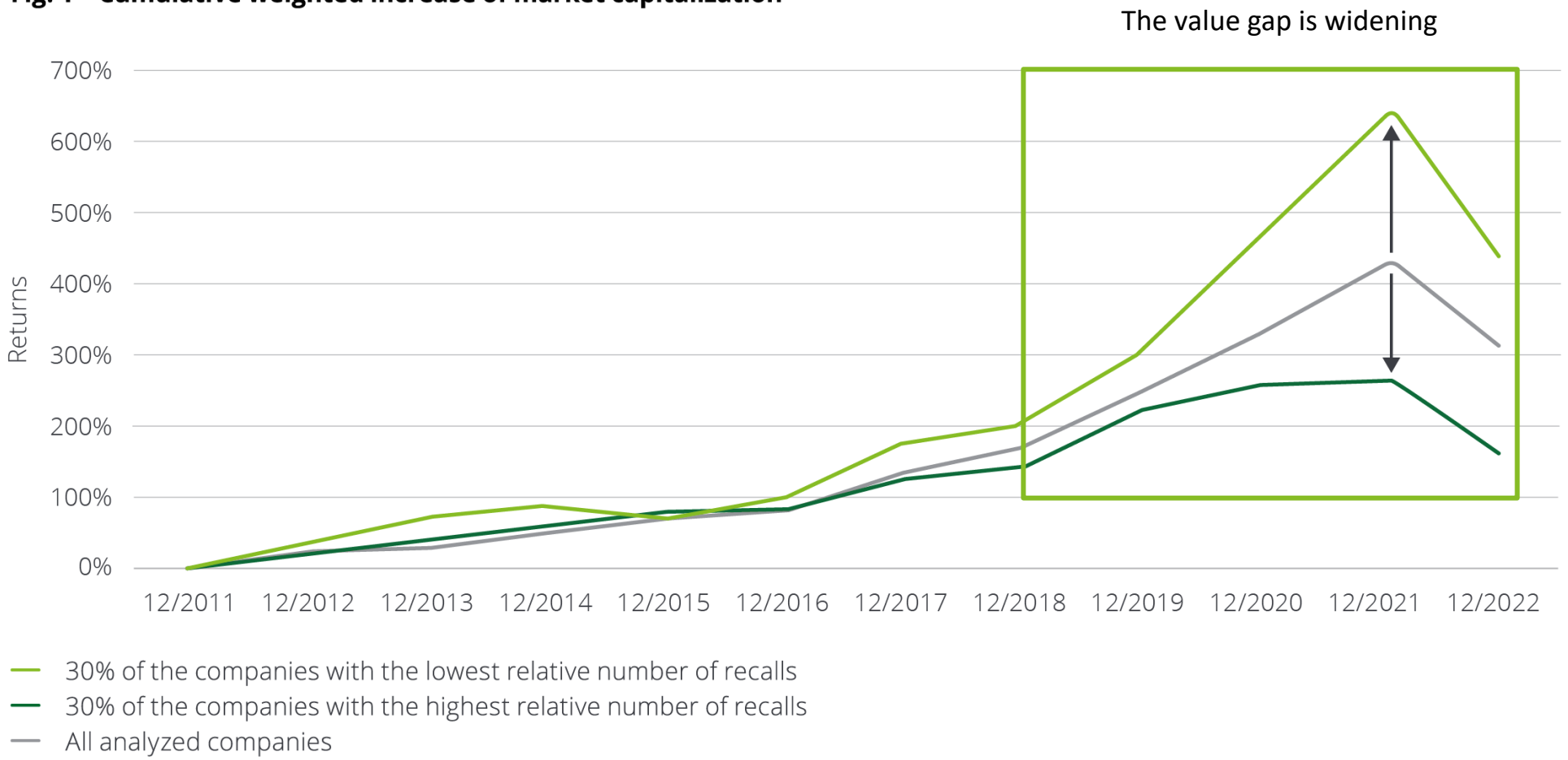
Subir Chowdhury

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.

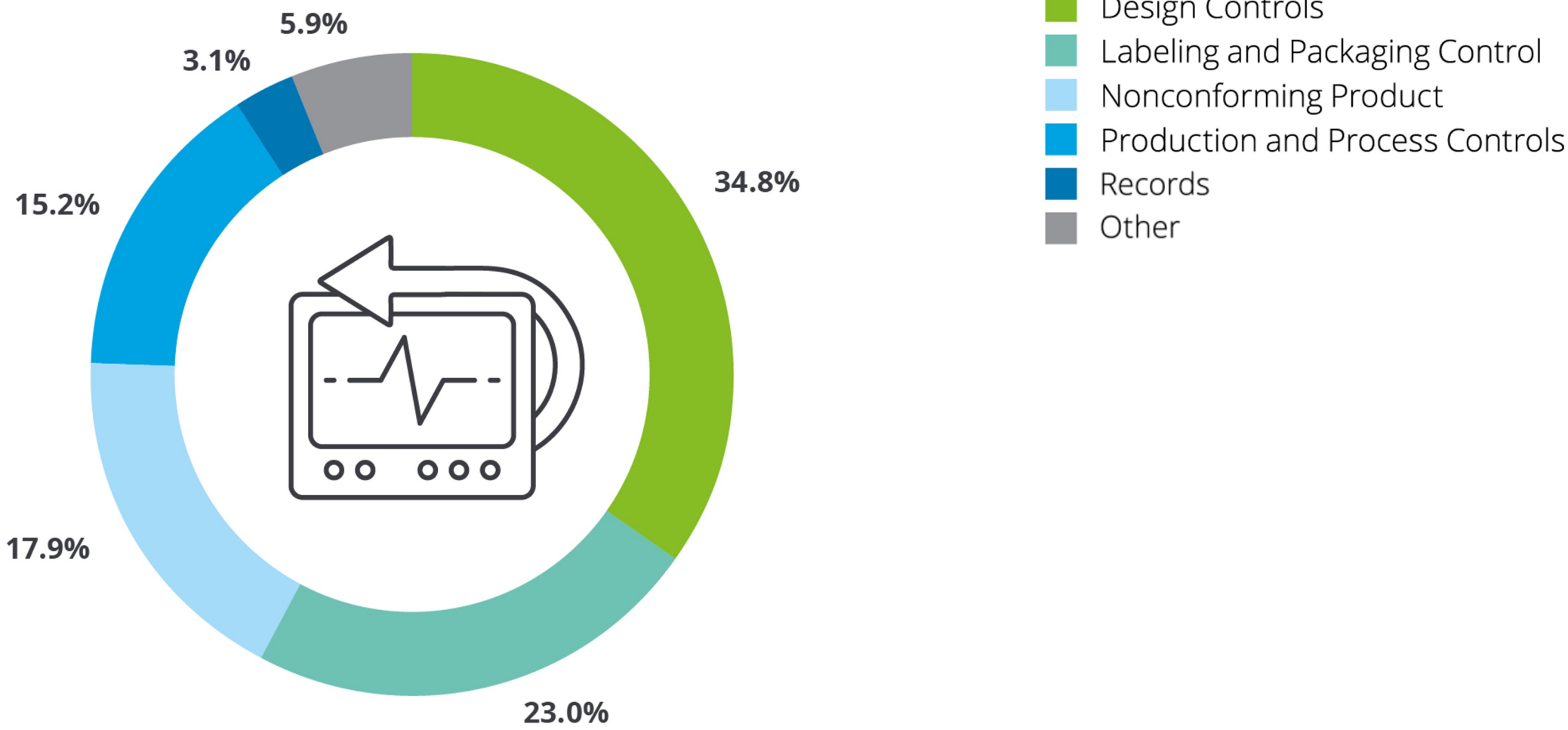
THE STUDY | Speculating about reasons for the widening value gap

- 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.

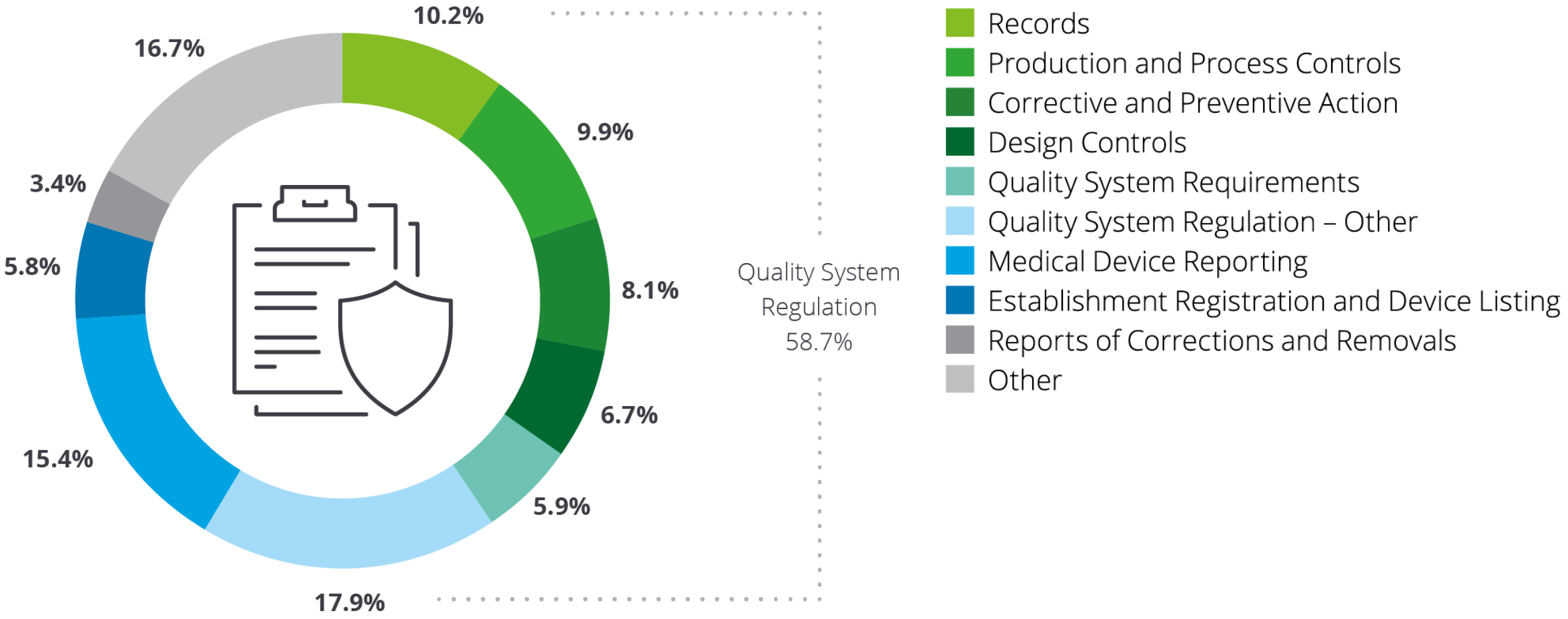
THE STUDY | Design controls and labelling lead the list of root causes for FDA recalls

Fig. 2 – Root causes for FDA recalls



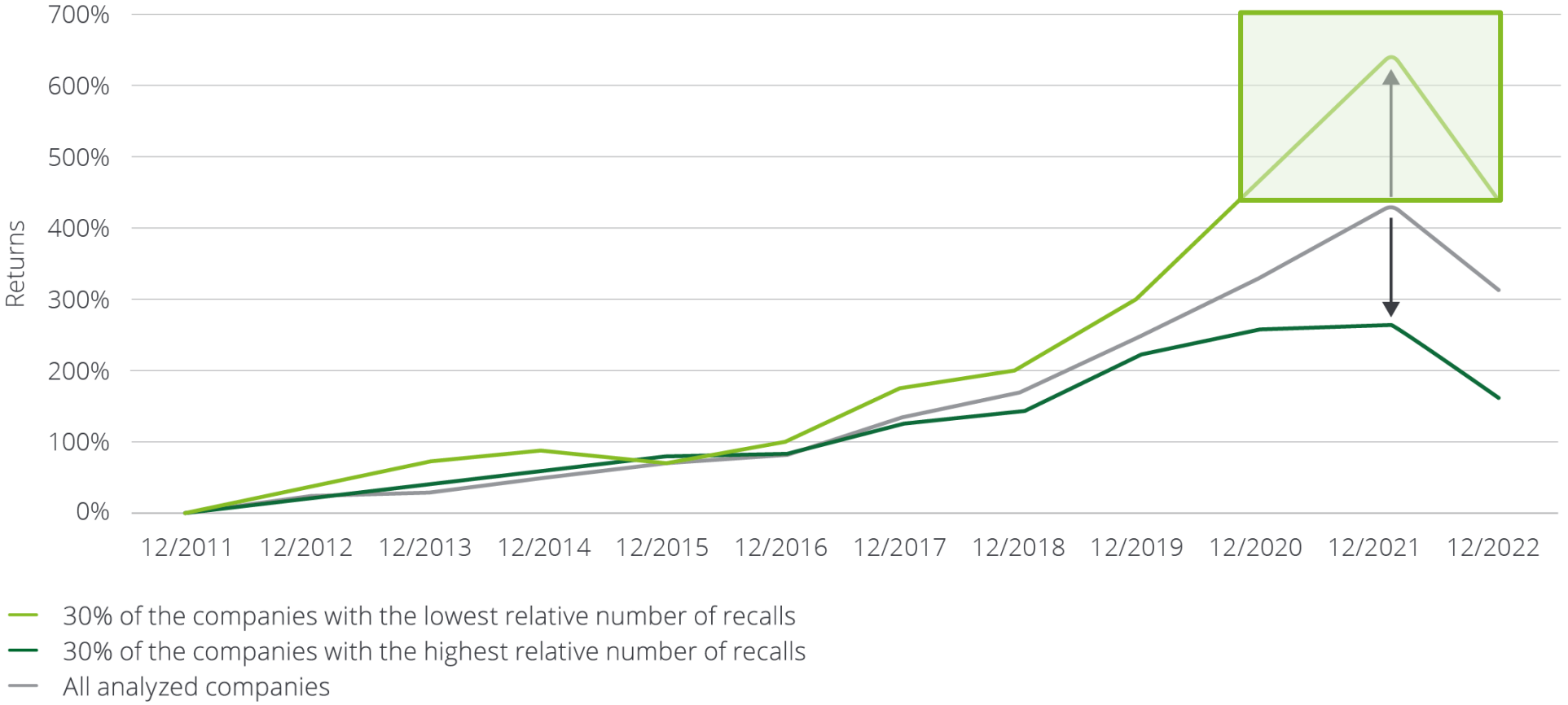
THE STUDY | Quality is a critical factor explaining systemic weaknesses

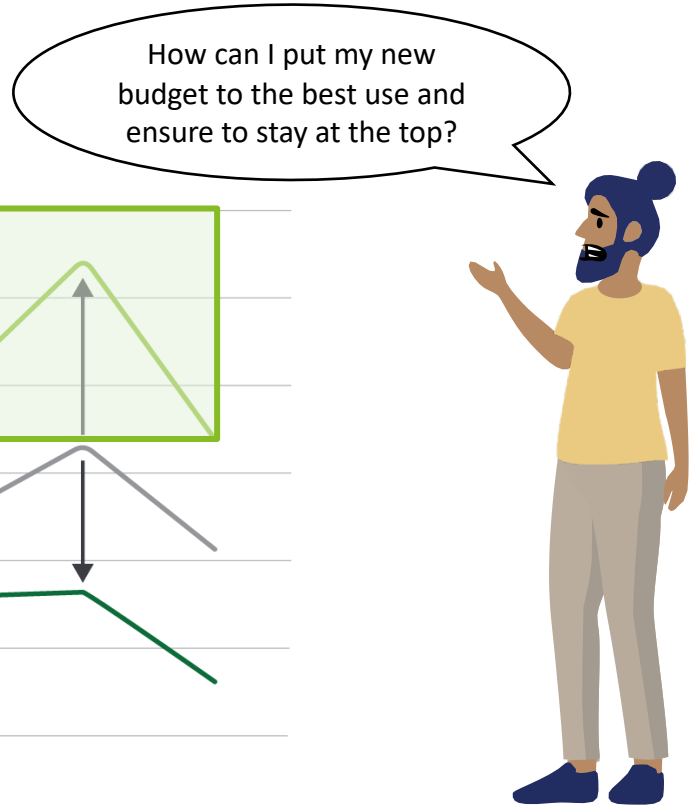
Fig. 3 – CFR citations of 'device' related FDA warning letters



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

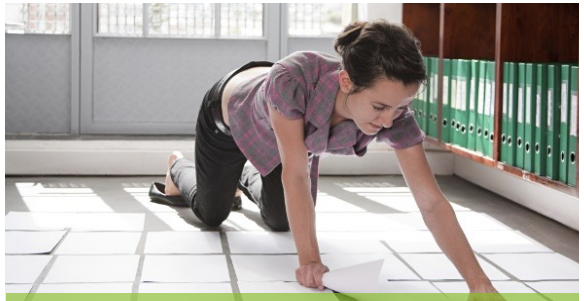
Fig. 1 – Cumulative weighted increase of market capitalization





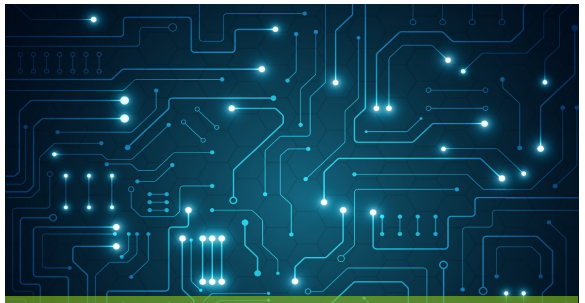
THE CHALLENGE | How to invest in ‘good quality’?

From documents to data and automated workflows



Moving from reactive to preventive quality

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



Ensuring efficiency and compliance in modern agile engineering

Risk-based approach and Quality by Design

Balancing Local and Global Governance

Increasing the agility and speed of controlled changes

Providing on-demand guidance for employees

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

THE STUDY | The study is available for download

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.

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

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

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Strategy	Operations	Implementation	Outsourcing
• GxP Strategy • Quality by Design • Cultural Transformation • Organizational Strategy • Risk-based approach • Vendor strategy • Cloud GxP strategy • GxP Data Strategy • GenAI in GxP processes • …	• Business Process Analysis & Improvement • Governance, Roles & Responsibilities • Employee Qualification • Risks & Controls • Data Governance, Privacy and Security • Regulatory Intelligence • M&A related restructuring of GxP processes • …	• Solution Design • Configuration • Systems Integration • Data Migration • Testing & Validation (CSV) • Training • Change & Communications • …	• Application Managed Services • Managed infrastructure technical services • Testing & Validation as a service • Legal Managed Services • Service Provider Monitoring • …

Quality Assurance	**Regulatory Affairs**	**Medical Affairs**
Quality Control	**IT Quality**	**Safety**

Examples of how we add strategic value

- Warning Letter Remediation
- Regulatory Intelligence
- Trustworthy AI
- QA/RA Complexity Reduction
- Predictive Quality Analytics
- Quality by Design

Let’s talk!

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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

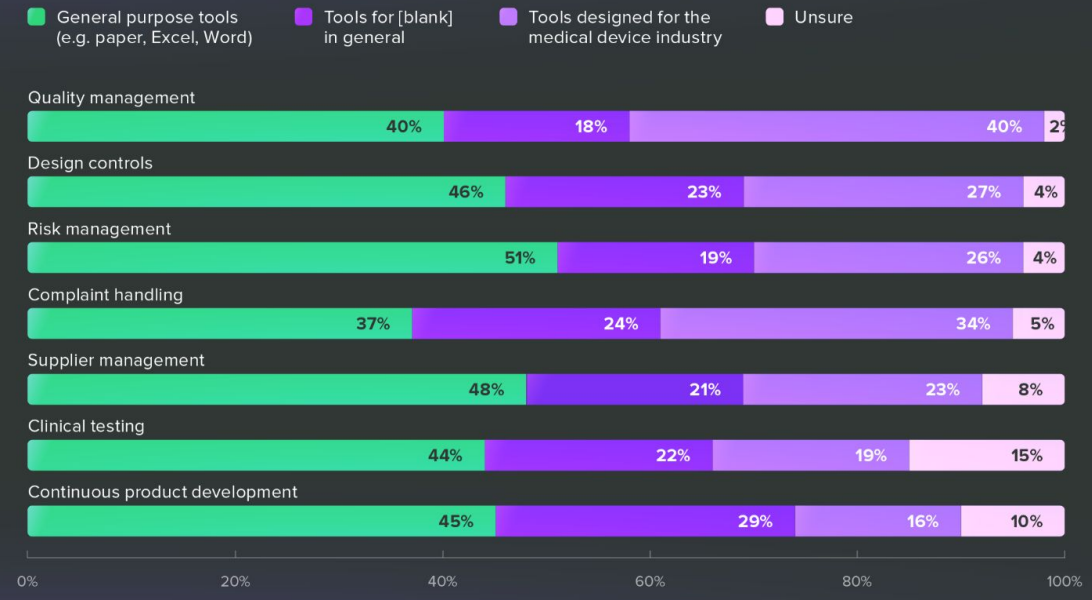
Only 30%

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

Out with the old

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

What system/tool do you use for the following:



Showing responses for pre-market companies only

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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. · HUMA · Milliken · SPARK BIOMEDICAL · Avenda Health

Cardiologs · 4DMedical · carlsmed · PhotoniCare · CREO MEDICAL · eli

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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.

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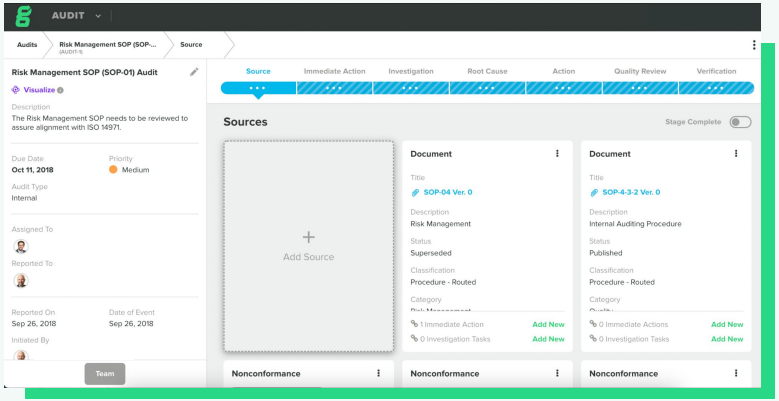
From documents to data and automated workflows

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



"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

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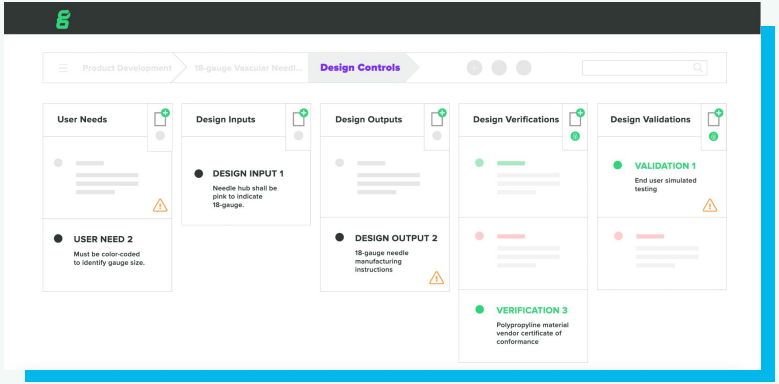
Increasing the agility and speed of controlled changes

Ensuring efficiency and compliance in modern agile engineering

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



"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.

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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

ZYRIS™

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.

SPARK BIOMEDICAL

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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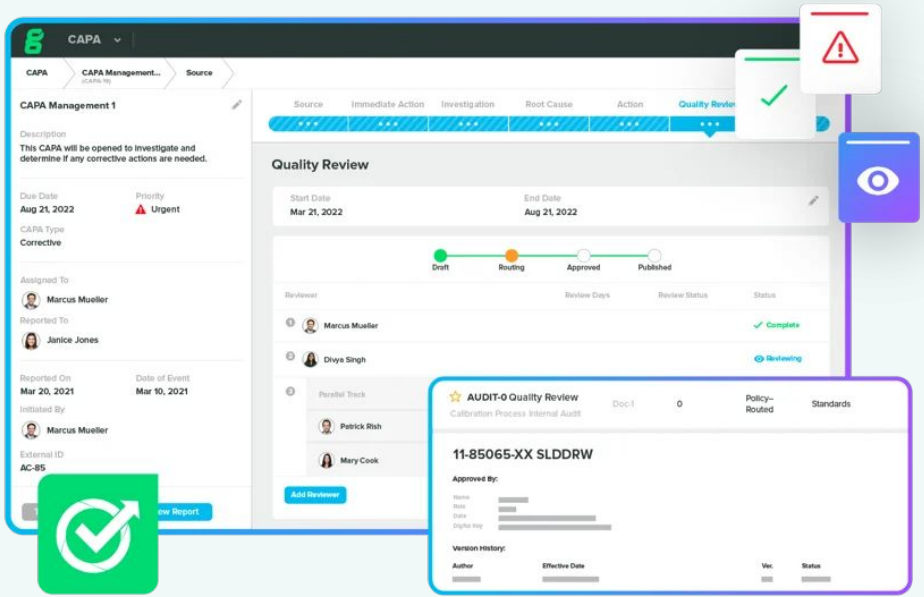
Make Quality Your Strategic Advantage.
We Can Help.



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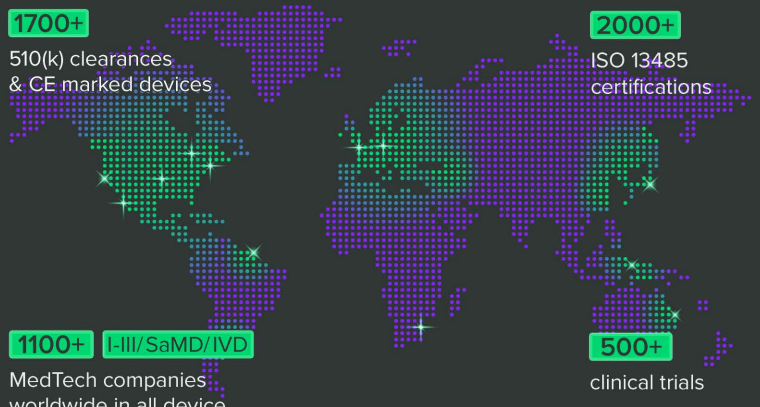

"Best QMS I have ever used..."

"User-friendly EDC and esponsive 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