

STATE OF MEDICAL DEVICE PRODUCT DEVELOPMENT & QUALITY MANAGEMENT

2020 REPORT HIGHLIGHTS & DATA INSIGHTS

ABOUT THE PRESENTER

Jon D. Speer

Founder and VP of QA/RA of Greenlight Guru



- **20+** years in medical device industry
- Product development engineer, quality manager, regulatory specialist
- **40+** products to market
- Expert at QMS implementations
- Dozens of ISO audits & FDA inspections

Greenlight Guru produces beautifully simple quality, design control and risk management software exclusively for medical device manufacturers.

jon.speer@greenlight.guru

+1 317 960 4280

WHAT WE WILL COVER TODAY

**CHALLENGES, TACTICS,
AND TOOLS IN THE
INDUSTRY**

**THE 8 TRAITS OF
MARKET LEADERS (AND
HOW TO BECOME ONE)**

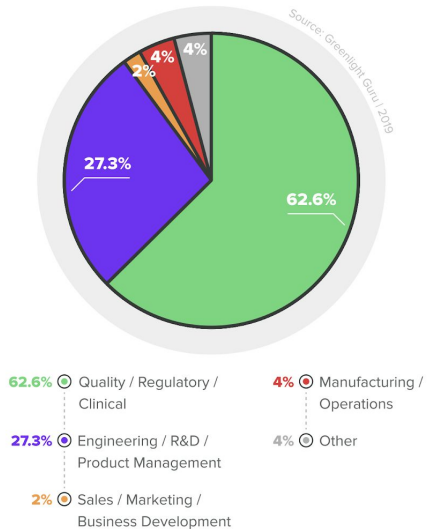
**RX FOR 2020:
5 AREAS TO FOCUS ON
THIS YEAR**

Research Focus

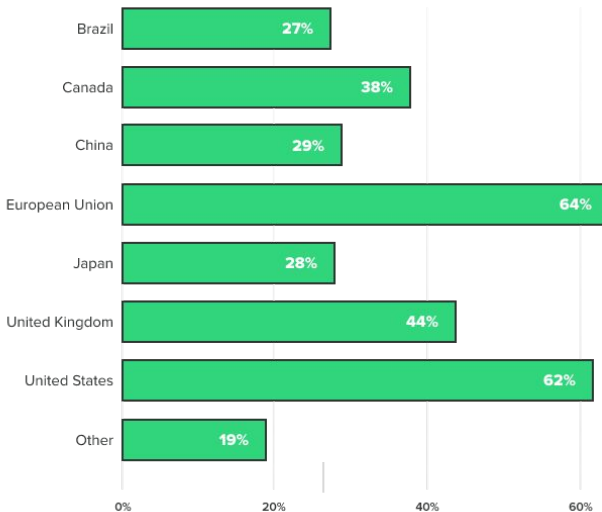
Understanding the strategies, tactics, and technologies around product development and quality management to establish data driven insights on the best practices that differentiate market leading medical device companies.

WHO TOOK THE SURVEY

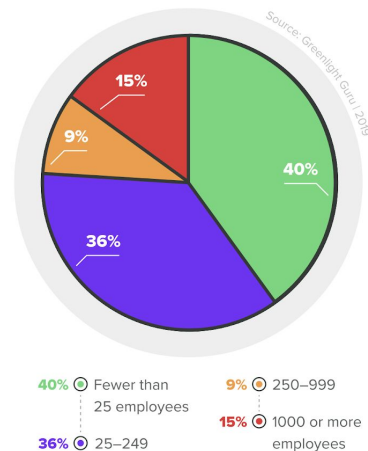
ROLE



CURRENT END MARKETS



COMPANY SIZE



METHODOLOGY: These findings are from an online survey that was fielded between September 11 and 27, 2019 that obtained 524 respondents, all of whom completed the non-weighted survey.

KEY CHALLENGES

BARRIERS TO IMPROVING PROCESSES

Product Development Processes

- Shortage of resources **(55%)**
- Insufficient budgets **(37%)**
- Lack of management buy-in **(1 in 4)**

Quality Management Processes

- Insufficient budget **(44%)**
- Cost/effort of validating new tools or processes **(34%)**
- Resistance to change efforts **(32%)**

Misallocated resources, insufficient budgets, and misaligned team/management priorities are the most cited, self-inflicted challenges that are holding organizations back from improving processes.

UNIQUE CHALLENGES FOR QUALITY VS. ENGINEERING

Quality professionals are most likely to cite “resistance to change” — and are 44% more likely to say so than those working in product development. And product developers are over 50% more likely than quality/regulatory professionals to cite “confusion about the regulatory environment.”

BIGGEST CHALLENGES RELATED TO IMPROVING QUALITY PROCESSES



PRODUCT DEVELOPMENT INEFFICIENCIES

7%

consider themselves to be **highly efficient** throughout the process of bringing a new device to market.

The most frustrating aspect of the job is the “level of manual operations in collecting quality data.”

212
hours

is the average time it takes to compile a Design History File - equating to **5.5 weeks of work hours**.

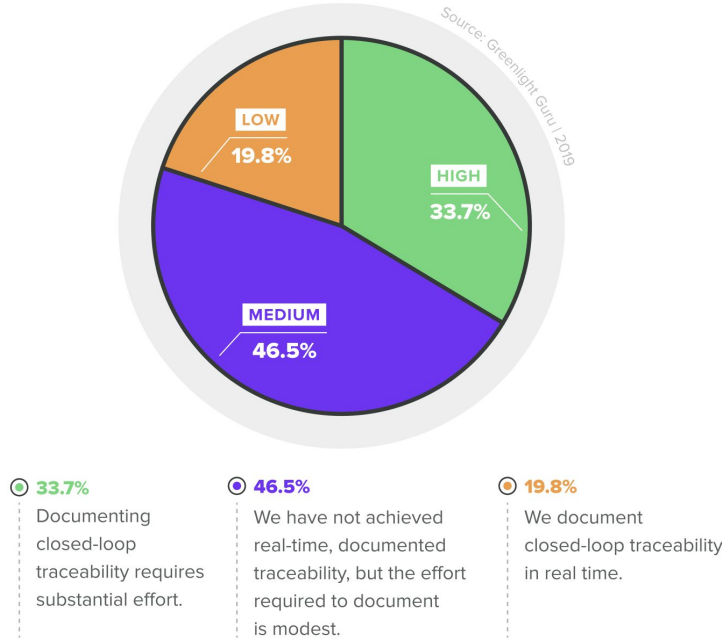
One of the greatest challenges of the job is “the amount of simple tasks that take time and distract from being proactive.”

55%

said that managing a “pile” of documents is a **specific pain point** in documenting and managing design controls.

DEMONSTRATING CLOSED-LOOP TRACEABILITY

EFFORT REQUIRED TO DEMONSTRATE CLT

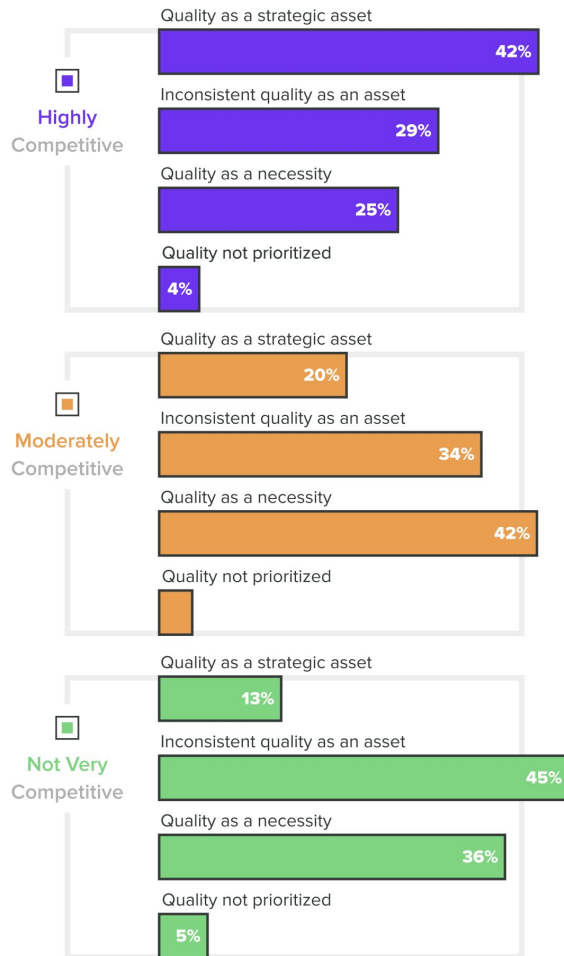


Closed-Loop Traceability (CLT): The ability to connect people, processes and data seamlessly across the value chain.

Nearly half (**45%**) cannot demonstrate CLT today.

Of those that can, **1 in 3** say it takes substantial effort to do so.

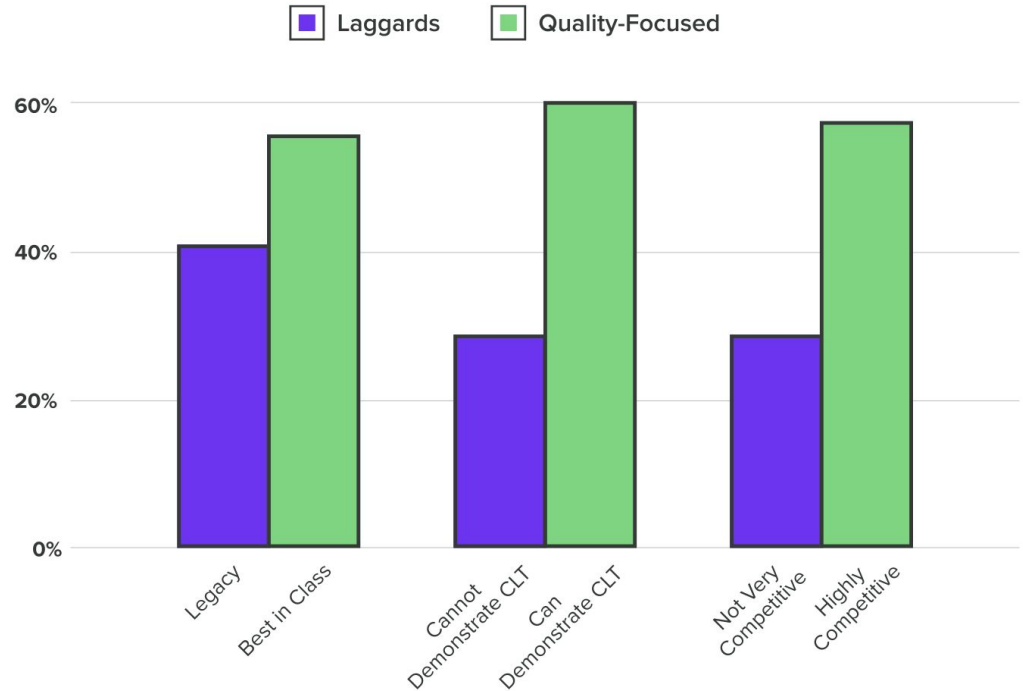
QUALITY AS AN ASSET



QUALITY CULTURE IMPACTS COMPETITIVENESS

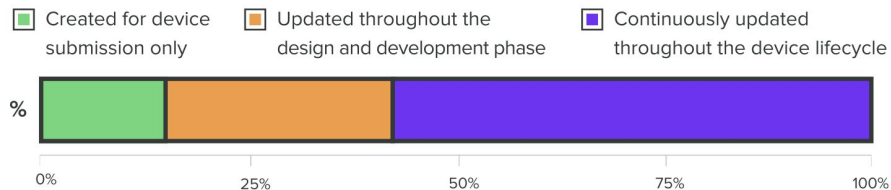
Companies considering themselves **highly competitive** were **over 3x more likely to view quality as an asset.**

**WHEN QUALITY IS
WOVEN INTO A
COMPANY'S CULTURE
IT SHOWS.**

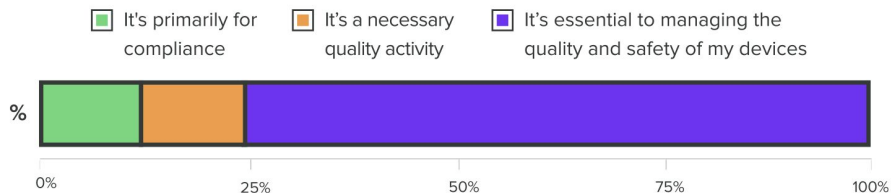


Source: Greenlight Guru | 2019

What is your organization's approach to managing Design Controls and Design History Files (DHF)?



How do you view design control activities?



DESIGN CONTROL ACTIVITIES

Not all organizations that *technically* follow the rules and regulations for quality **truly embrace them.**

MATTER OF PERSPECTIVE

PRIORITIES VARY BY ROLE

Quality professionals stress ***“updating compliance to a new standard or regulation”*** — cited 50% more often than for those in product development (engineering and R&D), while those in product development are much more focused on ***“ensuring compliance to stay audit-ready.”***

TOP QUALITY MANAGEMENT PRIORITIES FOR 2020

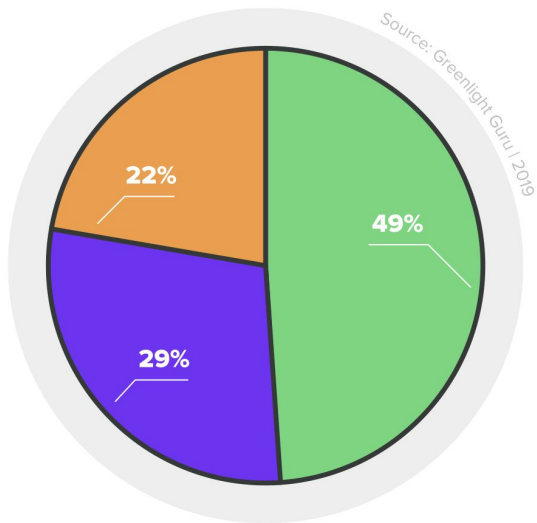


THE RISK CONUNDRUM

TOP CHALLENGES IN MANAGING RISK

1. Having enough information during the design & development process to assess product risk (43%)
2. Lack of clear ownership for risk throughout the product life-cycle (32%)
3. Lack of a strong feedback loop of post-market processes into product risk (31%)
4. Assuring consistent use of risk items across devices or teams (31%)
5. Visibility and traceability of the risk management files (25%)

INTEGRATING RISK MANAGEMENT



● 49%

We fully integrate risk management into our quality management system throughout the product lifecycle.

● 29%

We do not fully integrate risk management into our quality management system, and documenting risk takes modest effort.

● 22%

We do not fully integrate risk management into our quality management system, and documenting risk takes substantial effort.

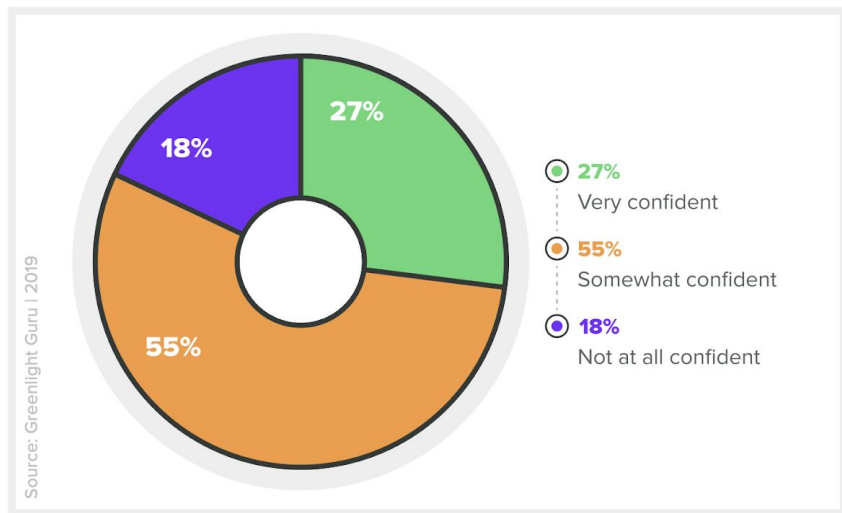
65% of very small businesses (<25 employees) admit they **still use legacy systems** — including paper-based systems — to support quality management and risk processes.

1 in 3 say product level risk management is minimally or not at all integrated with post-market quality processes.

STATE OF (UN)PREPAREDNESS

AUDIT READINESS

If a government agency or notified body showed up for an unannounced audit tomorrow, how confident are you that you could demonstrate total produce lifecycle traceability?



1 IN 4

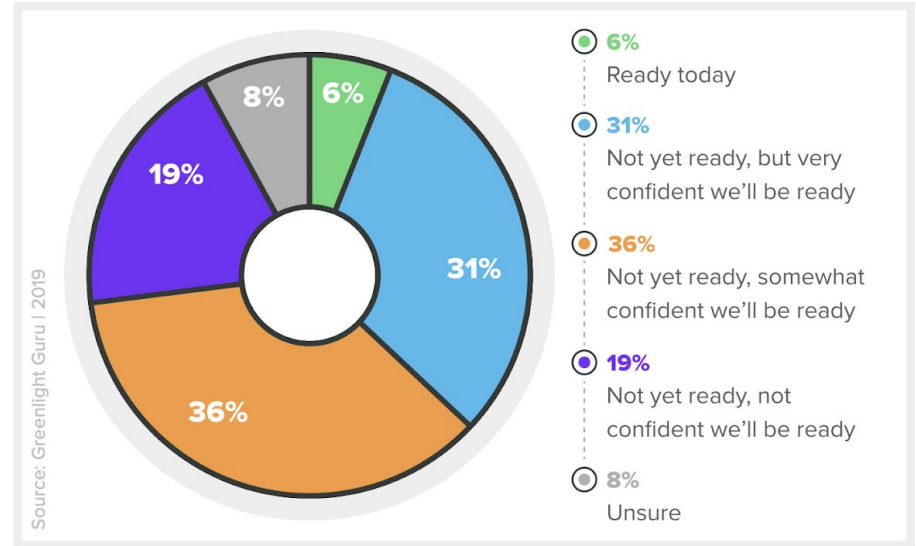
are “very confident” in demonstrating traceability in an unannounced audit

Competitive organizations are 2x as likely to *need less than a day to prepare for an audit*

EU MDR READINESS

OVER HALF
of respondents indicated they
are not very confident they'll
be ready for EU MDR by the
implementation deadline

Estimate your company's readiness to meet the EU MDR implementation date in May 2020:

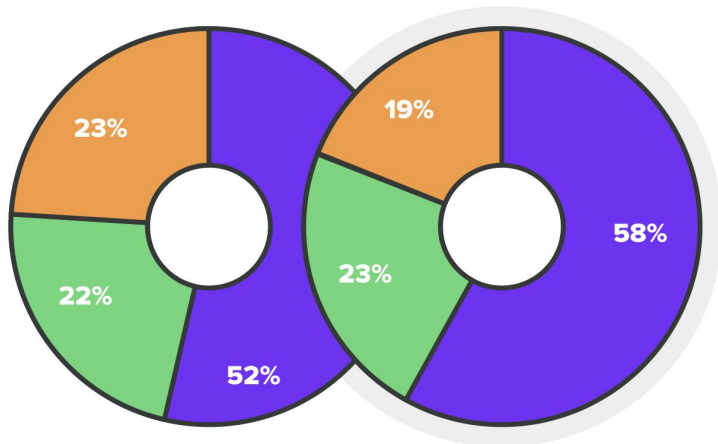


TECHNOLOGY & AGILITY

TECHNOLOGY: SOLUTIONS BEING USED TODAY

Design controls & risk
management technology

Quality management
processes technology



52%

We use legacy tools

22%

Use more specialized
tools, but not best-in-class

23%

Use best-in-class tools

58%

We use legacy tools

23%

Use more specialized
tools, but not best-in-class

19%

Use best-in-class tools

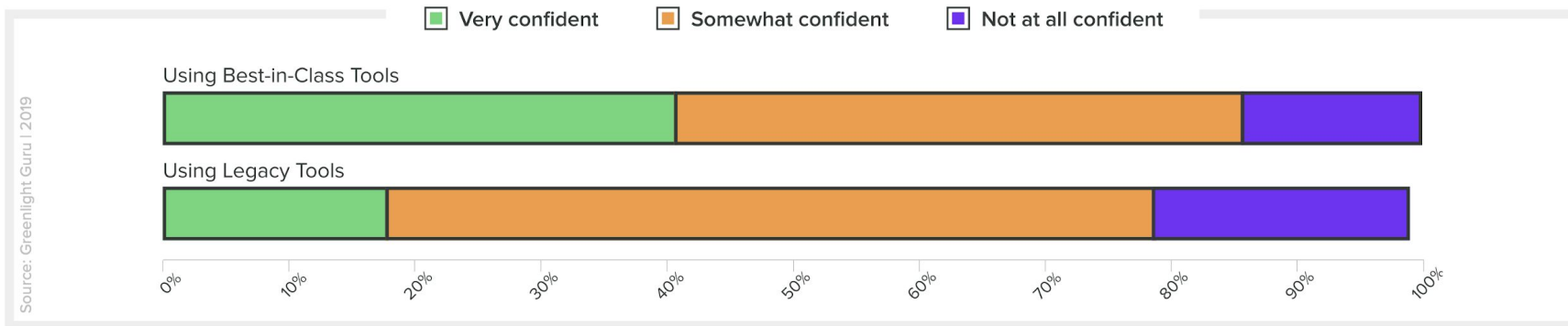
While they may be perceived as helping save money short term, long term these legacy and ad-hoc systems create tremendous **(and costly) inefficiencies**, as well as introducing both **patient and business risks**.

TECHNOLOGY: LEGACY VS. BEST-IN-CLASS

Organizations that have embraced CLT have generally **invested in all-around better tools.**

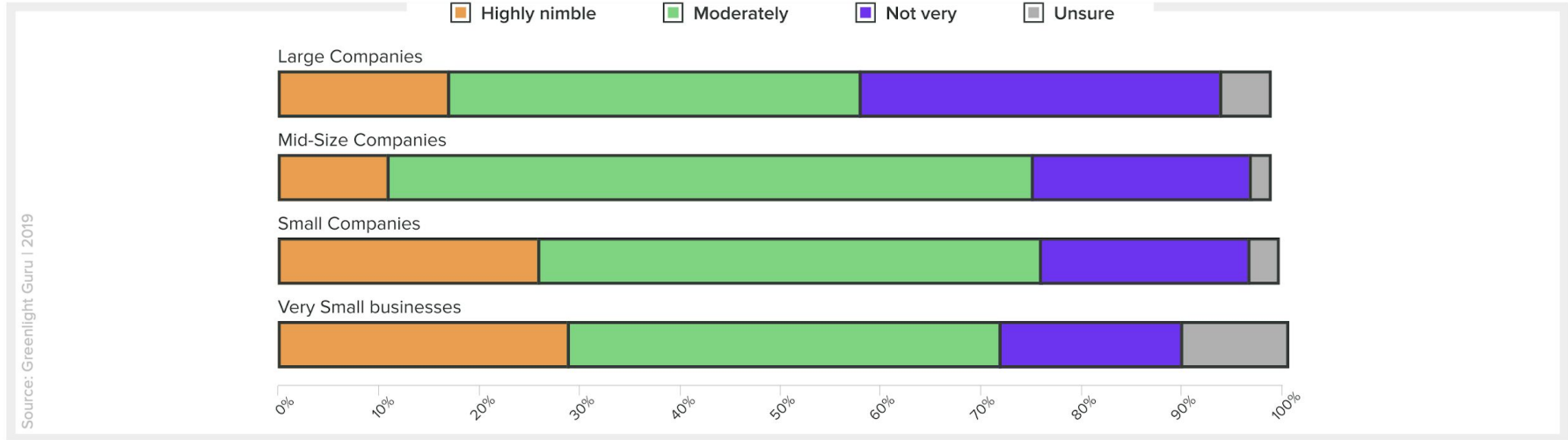
These tools allow them to **move away** from time-consuming activities and focus their efforts on improving other processes, ultimately impacting their **audit confidence.**

TECHNOLOGY INVESTMENTS IMPACT AUDIT CONFIDENCE



Company Size AND Tools Impact Company Agility

COMPANY NIMBLENESS BY SIZE



Overall, **smaller companies** are **more nimble**.

Large companies struggle to be as agile as their small-business competitors. They also struggle to move away from legacy technologies - with only **19% of organizations with more than 1000 employees able to say they've adopted best-in-class systems**.

HOW DO I USE THESE INSIGHTS?

8 TRAITS OF BEING A **MARKET LEADER**

1. USE BEST-IN-CLASS TOOLS

Those using best-in-class systems are...

- **3x more likely** to consider themselves as *highly efficient*.
- **2x as likely** to admit they are *very confident* about demonstrating CLT in an unannounced audit.
- **Significantly** more likely to be ready for regulatory shifts - like EU MDR.

2. HAVE RELIABLE DATA

Half of organizations that consider themselves to be *highly competitive* say their data is **consistently reliable** - with another **45%** saying their data is **somewhat reliable**.

3. EMBRACE CLOSED-LOOP TRACEABILITY

- Far more likely to consider themselves **highly competitive**
- Run more **efficiently**
- **Save** time and money
- **Boost** job satisfaction and morale

4. QUALITY IS WOVEN INTO COMPANY CULTURE

Well **over half** (58%) of organizations that say they're **highly competitive** also agree that **quality is woven into their culture.**

Over half (just over 51%) of them also say that senior leadership within their company **sees quality as a strategic asset.**

5. INVEST IN QUALITY

Market-leading organizations **invest in technology** to get their quality processes to the next level.

Organizations that describe themselves as competitive are the **least likely** to cite under-investment in technology as an obstacle, and **over half** of them (53%) say they anticipate **spending more on technology next year**.

6. ARE AUDIT CONFIDENT

Over half of competitive organizations say it would take them **less than a week** to prepare for an inspection.

Almost half (47%) saying they are either **ready today** or **very confident** they will be ready for EU MDR before the May 2020 deadline.

7. ARE MORE NIMBLE

Running an agile business is key to success.

36% of **highly competitive** organizations calling themselves **highly nimble**, compared to the average of 19% of non-competitive companies.

8. LOVE WHAT THEY DO

Those working for **highly competitive** organizations are generally **highly satisfied** with their jobs — just **over 75%** of these respondents said they were either “very satisfied” or “satisfied” with their current job.

WHAT TO DO IN 2020

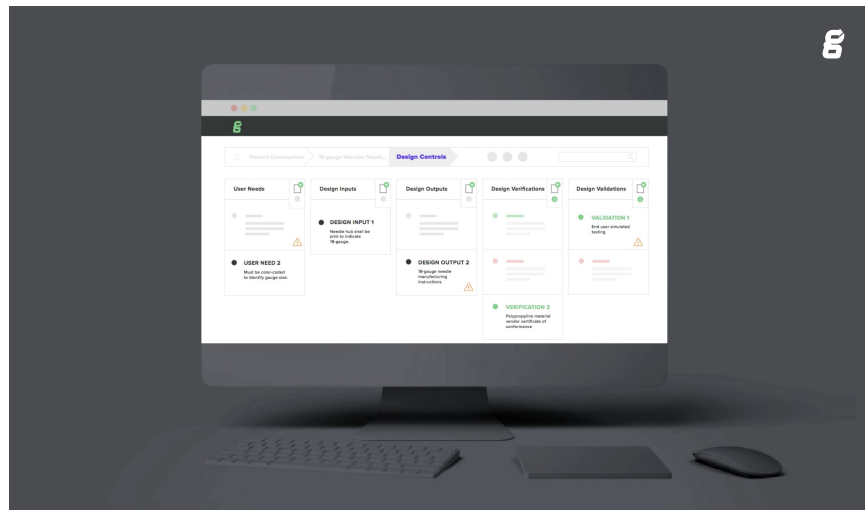
2020 TO-DO's:

- ☐ **INVEST IN THE RIGHT SOLUTIONS**
- ☐ **GET THE RIGHT (STRUCTURED) DATA**
- ☐ **FOCUS ON BUILDING A QUALITY CULTURE**
- ☐ **WORK TOWARDS NEAR REAL-TIME AUDIT READINESS**
- ☐ **GET USED TO HEARING THINGS YOU DO NOT WANT TO**



INVEST IN THE RIGHT TOOLS

GREENLIGHT GURU'S MEDICAL DEVICE QMS SOFTWARE



SCHEDULE YOUR DEMO →

MDQMS PLATFORM CAPABILITIES

Built-in controls that align with 21 CFR Part 820 and ISO 13485:2016

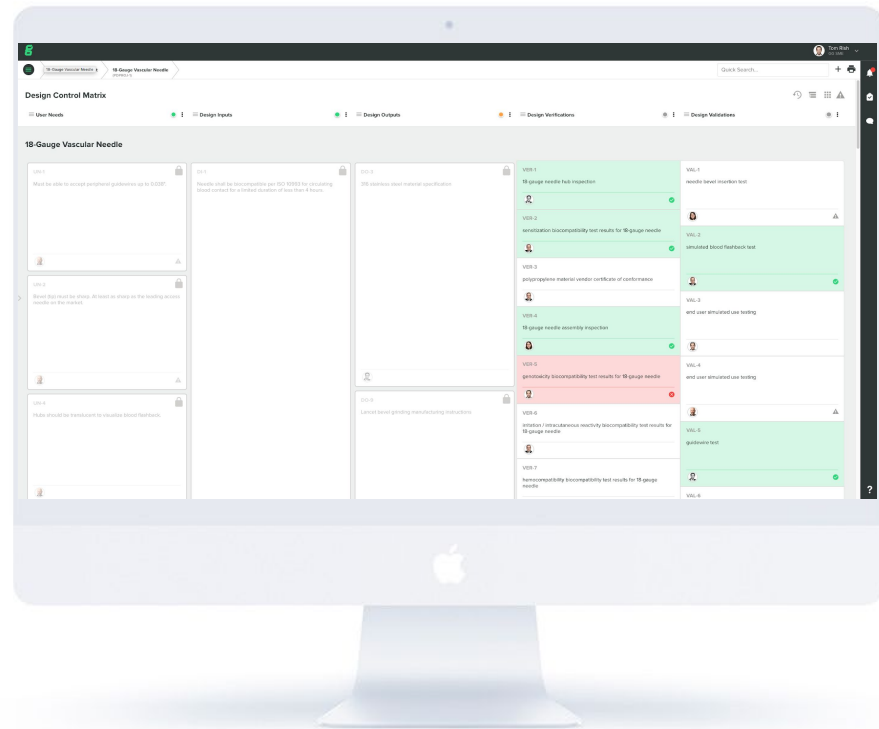
Flexible review & approval workflows with Part 11 compliant e-Signatures

Fully integrated risk aligned to ISO 14971

LinkAnything drives full lifecycle traceability

Zero effort system validation

Drive collaboration with task management, comments, and notifications



DON'T GET STUCK IN THE OLD WAYS OF MANAGING PRODUCT DEVELOPMENT AND QUALITY PROCESSES



**INVEST IN THE RIGHT TOOLS AND
TECHNOLOGIES THAT ENABLE YOUR
TEAM TO BECOME A MARKET-LEADING
ORGANIZATION**



CONNECTED

QUESTIONS?



JON SPEER

jon.speer@greenlight.guru