INTRODUCTION

Axendia conducted a study focusing on the medical device industry’s (hereafter referred to as Industry) ability to build a “Culture of Innovation and Quality.” The goals of this research were to identify and analyze initiatives organizations are undertaking to proactively manage products across the product lifecycle.

We surveyed 110 medical device professionals and engaged in one-on-one interviews and group discussions with 23 industry executives representing 59 medical device manufacturers from 12 countries. This illustrated guide communicates the outcomes of this research.

KEY TAKE-AWAYS

1. Quality and compliance are often confused. Different roles hold differing viewpoints on how quality is measured, who is responsible, and the role of compliance in ensuring quality.

2. Device makers struggle to close the quality gap. Industry’s approach to quality is changing as organizations work to harmonize business processes across business units.

3. A shift is underway towards closed-loop quality platforms. A closed loop approach not only improves product quality across the total product lifecycle, but also encourages collaboration and visibility.

4. Unifying PLM and QMS improves product quality. Companies who effectively close the loop from quality and compliance processes and feed that information back into manufacturing and engineering systems, will be best situated to meet patient needs.
TAKEAWAY #1

What roles in your organization are responsible for product quality?
(Respondents chose all that applied)

- Everyone
- Quality
- Manufacturing / Operations...
- Executive Management
- Regulatory
- Quality personnel ranked themselves higher and regulatory personnel lower on the responsibility scale. Quality personnel also ranked Quality, Manufacturing / Operations and Executive Management higher.
- Regulatory personnel identified themselves and Quality personnel as primarily responsible for quality.
- Executives placed a higher emphasis on Manufacturing / Operations management. Executives were also the only group that placed a high emphasis on R&D / Product Development as being a key quality driver.

QUALITY AND COMPLIANCE ARE OFTEN CONFUSED.

Who is responsible for Quality? Our analysis reveals that this depends on who you ask.
**What is the role of quality, anyway?**

Across all roles, the vast majority—85% of survey respondents—indicated the primary role of quality is Ensuring Compliance—either with regulatory requirements or with internal policies and procedures. By contrast, only 10% said the primary role of quality is to drive product/process improvement.

Only R&D respondents exhibited a significantly different perspective, with 31% of respondents stating that driving product and process improvements was the primary role of the Quality organization.

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**What is the primary role of the Quality organization at your company?**

(Respondents selected one)

<table>
<thead>
<tr>
<th>Role</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ensure compliance with internal policies and procedures</td>
<td>55%</td>
</tr>
<tr>
<td>Ensure compliance with regulatory requirements</td>
<td>30%</td>
</tr>
<tr>
<td>Drive product/process improvement</td>
<td>10%</td>
</tr>
<tr>
<td>Review records for completeness and accuracy</td>
<td>4%</td>
</tr>
<tr>
<td>Participate in regulatory audits</td>
<td>1%</td>
</tr>
</tbody>
</table>

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What is disrupting the medical manufacturing marketplace?

Regulators were cited as the #1 business disruptor, followed by emerging global markets and new market players.

### RESULTS

#### Which of the following is currently disrupting your business?
(Respondents chose all that applied)

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulatory / government agencies</td>
<td>62%</td>
</tr>
<tr>
<td>Emerging / global markets</td>
<td>42%</td>
</tr>
<tr>
<td>New market players (consumer electronics, mobile apps, tech start-ups)</td>
<td>32%</td>
</tr>
<tr>
<td>Mergers and acquisitions</td>
<td>29%</td>
</tr>
<tr>
<td>Personalized / Precision medicine</td>
<td>12%</td>
</tr>
<tr>
<td>Wearable / Connected devices</td>
<td>10%</td>
</tr>
<tr>
<td>Internet of Things (IoT)</td>
<td>10%</td>
</tr>
<tr>
<td>Other</td>
<td>9%</td>
</tr>
<tr>
<td>3D printing / Additive manufacturing</td>
<td>6%</td>
</tr>
<tr>
<td>Cognitive computing platforms (IBM Watson, Google DeepMind, etc.)</td>
<td>5%</td>
</tr>
<tr>
<td>Augmented Reality (AR) / Virtual Reality (VR)</td>
<td>4%</td>
</tr>
</tbody>
</table>
While quality is valued differently by different sets of stakeholders, quality and compliance are often confused. Different roles hold differing viewpoints on how quality is measured, who is responsible, and the role of compliance in ensuring quality.

Historically, the focus of the relationship between regulators and the medical device industry has been about managing compliance. As a result, Industry has adopted a hyper-focus on compliance. The long shadow cast by regulatory authorities— with Regulators cited as the top business disruptor—is clearly evident here.

Yet our interviews and work with Industry thought leaders yield a more nuanced view. Quality is experienced and valued differently by different stakeholders within and across the medical device manufacturer ecosystem.

Compliance and quality are not interchangeable.

**Compliance** is the cost of doing business within the industry. Medical device firms are often focused on meeting very discrete or specific regulatory requirements.

**Quality** is focused on assuring that customer needs are being met—which necessarily change depending on the particular customer.

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**The value to a manufacturer** can be reduction of errors, a focus on and increases in customer satisfaction, a drive toward improvement, and/or increasing capacity to innovate.

**Value for FDA** is that it allows the agency to recognize manufacturers who are high performers, or products that are of high quality, which will allow the agency to focus its resources in areas or firms or products that need more attention or intervention.

**A value for the payer** may be transparency on the performance of the product or the performance of the manufacturer.

**Healthcare providers** would appreciate having visibility into the performance of the manufacturers of products that they use and into the quality of those products as they make decisions in the treatment and care of their patients.

**The value for the patients** is it provides common ground: best possible treatment, the best possible outcome.
TAKEAWAY #2

DEVICE MAKERS STRUGGLE TO CLOSE THE QUALITY GAP.

With the growth of mergers and acquisition activity—cited as the #2 business disruptor, only lagging “Regulatory”—it is unsurprising that most organizations struggle with disconnected systems and silo’d, distributed teams.

Other obstacles to delivering high quality products are poor change and configuration control, shrinking product development cycles, and lack of traceability from requirements to parts, as well as test cases and test results.

What are the biggest obstacles to delivering a high-quality product?
(Respondents selected three)

- Complexity of managing multiple, overlapping regulatory requirements: 41%
- Silo’d, distributed teams: 36%
- Errors found too late in the product cycle, when most costly to fix: 36%
- Continuously changing requirements: 35%
- Not enough QA resources: 30%
- Complexity of products: 29%
- Poor change and configuration control: 27%
- Shrinking product development cycles: 24%
- Lack of traceability from requirements to parts, test cases and results: 23%
- Lack of QA automation: 22%
- Lengthy, difficult product integrations: 15%
- Other: 3%
What are the biggest benefits of “closing the loop” between quality processes and rest of the product lifecycle? (Respondents selected three)

- More rapid responses to quality issues: 63%
- Real-time visibility into post-production quality & performance: 61%
- Reduce the cost of poor quality: 54%
- Understand the impact of a change: 30%
- Improve organizational agility: 27%

Less than 40% of survey respondents report closing the loop most of the time and over 60% DON’T close the loop most of the time when addressing a quality event.

Responses varied by role.

- **31% of Executives** said they close the loop most of the time
- **38% of Quality personnel** selected most of the time
- **50% of Regulatory personnel** selected most of the time
How well does your organization currently “close the loop” from quality events to other engineering activities?

An example of a “closed loop” process is a customer complaint that is used to alert engineers of a potential design flaw. (Respondents selected one)
Despite significant advances in medical technology, when it comes to lifecycle quality processes, Industry is still reactive. Errors are found too late in the product life cycle when it’s most costly to fix them. Continuously changing requirements result in an inability to lock down requirements before moving to the next step in the “waterfall” open loop process. Companies still struggle with aligning quality and product development processes in the face of complex products, distributed teams, and shrinking product development cycles.

This points to the need for closed loop systems around the change management process. Companies must focus on closing the loop across the total product life cycle, instead of simply meeting procedural and regulatory requirements.
FDA Perspectives on the Case for Quality

The medical device life cycle begins with identifying a customer need for that technology, whether it’s a patient or a provider, a healthcare provider’s need. Then you launch into product development, design, and whether that is a feasible thing to bring to market. Once you make that decision to move forward, you now need to translate into a production and manufacturing.

But the real learning begins once the actual product is placed in the hands of the user. The real world experience has to feed into a continuous improvement of that product, because you don’t always foresee every risk. You don’t always foresee every potential use or benefit of that technology until it gets into the ecosystem.

When I think about some of the key principles of Case for Quality, and that we’re really looking to recognize firms that see a need to focus on continuous improvement and meeting customer and stakeholder needs, that’s where this fits in.

Capt. Sean Boyd
Deputy Director, CDRH Office of Compliance, FDA

1 FDANews Webinar – March 1, 2017
“Driving a Culture of Quality for Device Makers”
TAKEAWAY #3

A SHIFT IS UNDERWAY TOWARDS CLOSED-LOOP QUALITY PLATFORMS.

Medical device makers are actively seeking solutions to address existing quality and innovation gaps. 51% of respondents are harmonizing business processes across business units; a little over 36% of respondents report that their companies are investing in quality systems.
Quality, regulatory and executive personnel have varying opinions when it comes to prioritizing quality system investments.

- **Quality personnel** cited electronic reporting, PLM, and training. CAPA and nonconformance also rank highly.

- **Regulatory personnel** focused primarily on management review, quality management and document management.

- **Executive management** is interested primarily in investing in manufacturing operations, design controls and complaint management.

This provides further evidence that harmonizing and streamlining business processes across business units would have a positive impact on the cultural shift from Compliance to Quality.

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**TAKEAWAY # 3: A SHIFT IS UNDERWAY TOWARDS CLOSED-LOOP QUALITY PLATFORMS**

**RESULTS**

Which quality systems will you invest in over the next three years? (Respondents chose all that applied)

<table>
<thead>
<tr>
<th>Quality Systems</th>
<th>Executive Management</th>
<th>Quality</th>
<th>Regulatory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design Control</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Electronic Reporting</td>
<td></td>
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<tr>
<td>Nonconformance / CAPA</td>
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<td></td>
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<tr>
<td>Complaint Management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Manufacturing / Operations</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Quality (QMS)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>PLM</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Training</td>
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Cross-tab analysis also shows a big difference in the investment profiles of open loop and closed loop companies.

Companies that say that they never close the loop, or are unable to do closed loop analysis of quality and compliance, are focusing their investments in manufacturing operations and quality management, as well as document control and training. Companies who have no closed loop analysis of quality or compliance events are not investing in CAPA, design control or electronic reporting. These companies run the risk of continuing to lack visibility throughout the total product lifecycle.

By contrast, companies who close the loop 75% of the time or more exhibit a more strategic view of investments. They are investing in, and place high value on, a broad range of quality systems. Given this, we infer that closed-loop companies view quality system investments more holistically and are contemplating a platform approach across the entire organization.

### Takeaway #3: A Shift is Underway Towards Closed-Loop Quality Platforms

**Which quality systems will you invest in over the next three years?**

(Respondents chose all that applied)

<table>
<thead>
<tr>
<th>OPEN-LOOP COMPANIES</th>
<th>CLOSE-LOOP COMPANIES</th>
</tr>
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<tbody>
<tr>
<td>Design Control</td>
<td></td>
</tr>
<tr>
<td>Document Control</td>
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<tr>
<td>Electronic Reporting</td>
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<tr>
<td>Nonconformance / CAPA</td>
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<tr>
<td>Complaint Management</td>
<td></td>
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<tr>
<td>Management Review</td>
<td></td>
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<tr>
<td>Manufacturing / Operations</td>
<td></td>
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<tr>
<td>Quality (QMS)</td>
<td></td>
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<tr>
<td>PLM</td>
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<td>Training</td>
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</table>

Closed-loop companies view quality system investments more holistically and are contemplating a platform approach across the entire organization.
Investments in technology in support of quality systems is continuing. Leading technology providers are working closely with their existing customers to offer a single source of truth for quality events. Both the results of our survey and our thought leader interviews support a trend Axendia has witnessed in the medical device industry: the continuing shift from point solutions to platforms.

In our view, the shift from point solutions to modern, closed loop, product development platforms is long overdue. A closed loop approach not only encourages collaboration and visibility; it also improves product quality across the total product lifecycle.

Companies who effectively close the loop from quality and compliance processes and feed that information back in to manufacturing and engineering systems will be best situated to meet patient needs.
TAKEAWAY #4

UNIFYING PLM AND QMS IMPROVES PRODUCT QUALITY.

PLM plays a crucial role in enabling product quality. 8 out of 10 respondents recommended unifying PLM and QA process through a common platform.

Do you recommend unifying PLM and QA processes through a common technology platform?

Yet the medical device industry seems to be slow to adopt PLM solutions. Over half of medium sized companies surveyed don’t use a PLM system or are still relying on paper systems; 2 out of 3 midsized companies do not use an off-the-shelf PLM. 67% of small companies use homegrown systems.

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Of those companies who don’t use PLM, the number one obstacle cited in bringing a high quality product to market is a lack of QA resources.

The other challenges these companies face are more business driven:

- The complexity of managing multiple, overlapping regulatory requirements
- Errors found too late in the product life cycle when it’s most costly to fix them
- Changing product requirements

These are the kinds of issues that a product life cycle management solution can address. Locking down requirements at an early stage prevents problems from occurring and lowers the cost of poor quality.

In fact, PLM can address many of the obstacles cited by those who don’t use them. Nearly 50% of the respondents who indicated they are able to close the loop most of the time, reported using a commercial PLM solution. 21% used a home-grown system, and another 21% noted that they use either a paper system or they don’t use a PLM system.

What system do you currently use to manage PLM processes? (Respondents selected one)

- 46% Off-the-shelf software and Other, combined
- 34% No system used
- 15% Homegrown system
- 13% Unsure
- 12% Other
When asked to design the ideal technology suite, respondents identified Quality Management, Product Lifecycle Management, CAPA, Document Management and MDR/Adverse Event Reporting as the top five applications that support visibility / quality through the product life cycle.

This preferred functionality falls into distinct groupings. The first segment targets quality management. The next segment of over 50% focuses the product lifecycle (manufacturing execution and manufacturing operations management, service life cycle management, customer relationship management, and enterprise resource planning).

**An interesting observation:** The top five applications address the immediate needs or the immediate challenges of an organization followed by the more long term value of MES, SLM or CRM.

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**An ideal Enterprise Medical Device Technology Suite would be comprised of the following applications and be capable of supporting visibility / quality throughout the total product lifecycle:** (Respondents chose all applications that would apply)

- Quality Management System (QMS) 95%
- Product Lifecycle Management (PLM) 87%
- CAPA 86%
- Document Management System (DMS) 85%
- MDR Adverse Event Reporting 67%
- Manufacturing Execution System (MES) 57%
- Service Lifecycle Management (SLM) 57%
- Customer Relationship Management (CRM) 54%
- Enterprise Resource Planning (ERP) 53%
- Business Analytics 43%
- Application Lifecycle Management (ALM) 32%
- Enterprise Asset Management (EAM) 23%
- Internet of Things (IoT) 17%
- Simulation / Digital Twin 7%
- Augmented Reality (AR) / Virtual Reality (VR) 4%
Engaging PLM and QMS early in the design-to-release process drives down the cost of quality through early issue detection and resolution. Executives, quality and regulatory personnel overwhelmingly recommend unifying PLM and QA processes through a common technology platform. Axendia encourages this approach.

Our analysis shows a striking correlation between the ability to close the loop and the use of a product life cycle management solution or process. Every respondent who reported that they can’t or they don’t close the loop also reported that they either don’t use a technology solution or that they use only a paper-based system.

Medical device organizations are continuing to sharpen their focus on developing high quality medical devices aimed at improving patient outcomes. However, industry’s hyper-focus on compliance often becomes an obstacle to improving quality and innovation. In our survey, most organizations continue to identify the primary role of QA is compliance—ensuring documentation and adherence to regulatory requirements and with internal policies and procedures. However, the true focus of QA should be on improving product quality. Closing the loop between PLM and QMS systems makes this possible because it allows quality and compliance events to influence the product engineering cycle in a timely fashion.

To compete in today’s global markets, medical device companies must shift to modern, closed loop, product development approaches. They must also change their approach from simply meeting compliance requirements, to managing critical to quality data with visibility across the total product lifecycle. A unified approach to PLM and Quality process can help medical device makers make this crucial shift by enabling better collaboration, visibility, and product quality across the total lifecycle.

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Axendia conducted a study, sponsored by PTC, focusing on assessing the industry’s culture of quality and innovation.

This report is based on a survey of 110 individuals in the medical device industry as well as insight from PTC’s customer panel. Additionally Axendia conducted in-depth interviews with “Industry thought leaders” to validate, distill, and refine our analysis. The survey served as the quantitative sample of Industry Executives across a range of products, organizational size, and scope of responsibility across.

The analyses, charts, and figures presented in this research are based on the data from survey respondents and interviewees.
In which markets does your company sell / market products?
(Respondents chose all that applied)

- North America: 91%
- Europe: 76%
- Asia: 57%
- South America: 53%
- Australia: 48%
- Africa: 35%

Please describe your company’s product(s)?
(Respondents chose all that applied)

- Single-Use: 57%
- Electro-Mechanical: 37%
- Reusable Mechanical: 32%
- Combination Product: 26%
- Diagnostic Device: 26%
- Software Driven Device: 24%
- Other: 13%
- Software ONLY Device: 11%
- Smart, Connected: 11%
- Additive Manufactured: 4%
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Axendia, Inc. is a leading trusted advisor to the Life-Science and Healthcare industries. We provide trusted counsel to industry stakeholders on Business, Regulatory and Technology issues. We are honored to be recognized by CIOReview as one of the 20 Most Promising Life Sciences Technology and Services providers.

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Published 2018

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**Definitions**

Throughout this illustrated guide, the following definitions were used:

**Closed Loop System:** a system in which the desired output depends on the input signal and feedback elements.

**Open Loop System:** a system in which the desired output depends on only the input signals.