DIGITAL TRANSFORMATION IN MEDICAL DEVICES:
It's All About the Mindset!

The medical devices industry needs to challenge their traditional mindset and embrace digital transformation in their product development initiatives.

EXECUTIVE SUMMARY

Medical devices are at the forefront of digital revolution. This revolution is fueling huge investments across the spectrum of medical devices, be it in the form of an accessory, software as a medical device (SaMD) or getting connected to other devices in a given ecosystem and so on. In 2016, MobileHealthNews covered 194 funding deals that totaled about $2.6 billion[1].

While on one side there are investments in billions of dollars, on the other side we see an average increase of 52% in device recalls[2], by FDA, over the last 5 years (2012-2017). Further, the number of 483's issued by FDA in 2017[3] for devices alone was 1030 - the highest among medical categories.

The rise in recalls is the clear indicator that root cause of the issues has yet to be fully identified, addressed and fixed. Since 2011, the FDA's Center for Devices and Radiological Health (CDRH) has been developing the Case for Quality, a program to shift the industry mindset from one of compliance to one of continuous improvement.

"Many within the MedTech industry are comfortable with where their organizations are now. People believe that compliance to the regulations are all that is needed to participate in the marketplace. But that is changing. The days of allowing poor quality products into the market are gone. New companies, smarter companies, are adopting Quality techniques from other industries, and are moving the paradigm from "Compliance Implies Quality" to "Quality beyond Compliance." [4]

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The FDA data highlights striking perspectives. First, the patient safety or risk to life is paramount if device fails to perform as per the regulated guidelines and intended use. Second, organizations need to be well prepared with the right tools and processes for FDA audits and to handle observations and potential warning letters. Third, devices are sold globally and the process for meeting regulatory requirements for different geographies can be challenging if there is no clear understanding of a unified product development process.

Some of the common tactical challenges that we see across the medical devices sector are:

1. Lack of a single view of Bill of Materials (BOM) makes cost unpredictable, eventually making product non-competitive.

2. Disorganized paper-based management of Design History Files (DHFs) and Device Master Records (DMRs) leads to auditing issues and delayed regulatory approvals.

3. Conventional and simple ways of managing information in spreadsheets and local repositories, which create obstacles in auditing.

4. Lack of mindset and maturity of an organization to embrace new technologies for data management, which increases manual overload and dependency.

5. Poor change management and governance for products post-market, prompting recalls and at times litigations as well.

This clearly establishes the need for the product development process to be tightly controlled, audited and governed. At the same time, there exists an opportunity to not only address the challenges but also establish a school of thought to embrace digital transformation to achieve operational excellence and product quality beyond compliance.

However, conversations at strategic levels bring out conventional mindset challenges towards digital transformation. Organizations are struggling to define the true value - a digital product development initiative would add to their bottom line, which translates to safety and efficacy of the product from customer experience.

This view point challenges deep-rooted conventional mindsets and opens the path to tremendous opportunities possible within organizations that are willing to embrace digital transformation.

IT'S ALL ABOUT MINDSET!

In the past five years (2012-2017), FDA's inspection observation summaries have highlighted three major areas viz. Product Design, Manufacturing Process Controls and Supplier Management to be addressed. Especially, in the product design & development, the focus area of this perspective, the average frequency of 483s issued for 21 CFR 820.30 (Design Controls) and for 21 CFR 820.184 (DHF) has been 526 and 156 respectively. This is a large representation of the situation at operational levels of medical device organizations.

Adding to this challenge is the data from Google hits with the search term "medical device risk" for the past five years (2012-2017). The data reflects a 36% increase in the sentiments of the public towards risk.

"Med Device Risk" – Google Search Hits
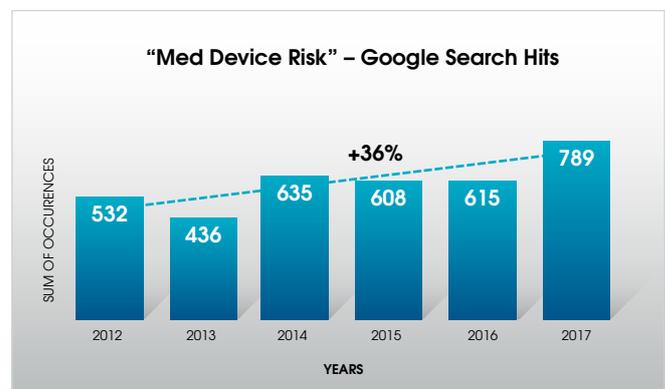
The is an alarming situation! Organizations not only have to deal with their product development approaches to address 483s but now also must address perception issues as well. Hence the mindset change must flow from the top and run across the organization.

MINDSET CHALLENGE 1: Standard Bill of Material (BOM) across business functions is a farfetched statement

A medical device BOM is no different in theory from any other industry. It has two key flavors - eBOM (Engineering BOM) and mBOM (Manufacturing BOM) - which control the product development lifecycle and need to be in sync for the product to be approved. At a high level, the BOM contains detailed level of component breakdown, materials, quantities, manufacturing process, packaging and labelling requirements and so on. Especially in medical devices sector, BOMs are built in line with cGMP (Current Good Manufacturing Practice) and are a critical element in negotiating business with contract manufacturers.

In our experience, managing BOMs in spreadsheets or disconnected systems is still very prevalent. Business functions would frequently use spreadsheet-based BOMs for information exchange with sites. At times, there is a mismatch between BOM version across sites, resulting in manual effort to standardize and fix BOM versions. In other instances, it has been observed that teams prefer to use spreadsheet-based BOMs in team meetings and contract negotiations. However, this process has serious flaws too.

First, maintaining multiple versions of the BOM creates confusion. No one remembers clearly which version was used in what type of discussion. Second, multiple versions are stored in shared folders which do not provide strict mechanisms of security and access controls. At times, multiple teams are editing the last used copy and keep checking it in the shared folder adding to chaos. Third, limited tracking is available to visualize what was changed from previous versions and what is the downstream impact of the change. Lastly, even in organizations where there is some adoption of digital tools, the traditional ways of working still exist. Engineers who download the spreadsheet version of the BOM and start using it for updates and supplier exchange eventually limit the potential benefits of a digital solution.

Standardization of BOM and single view availability enables reporting and analytical capabilities which help manufacturing sites get the right information at the right time. Both adoption and culture change, in addition to implementation of a digital solution, are required to realize benefits from digital capabilities.

MINDSET CHALLENGE 2: One DHF for one product does not exist in real life!

The Design History File (DHF) must represent the entire lifecycle of the finished device from design to commercialization. It is a repository of all documentation generated during the product development process. Across organizations, however, the DHF is created and managed very differently.

First, there are issues in the way DHF is created and managed. Most organizations are still using paper-based or hybrid-based approaches to managing DHF, which often results in serious auditing issues with the FDA. In other words, the 2D drawing may not be a true representation of what engineering has approved for the 3D model. The traceability of the 2D drawing to the approved model may be lost.

Second, when a product undergoes a change or is being launched in some other geographies, the DHF must be updated to reflect the requirements for that specific geography. Without a fully digital solution, redundant and potentially outdated documentation is added to the system, making it very difficult to keep the DHF compliant through new product iterations.
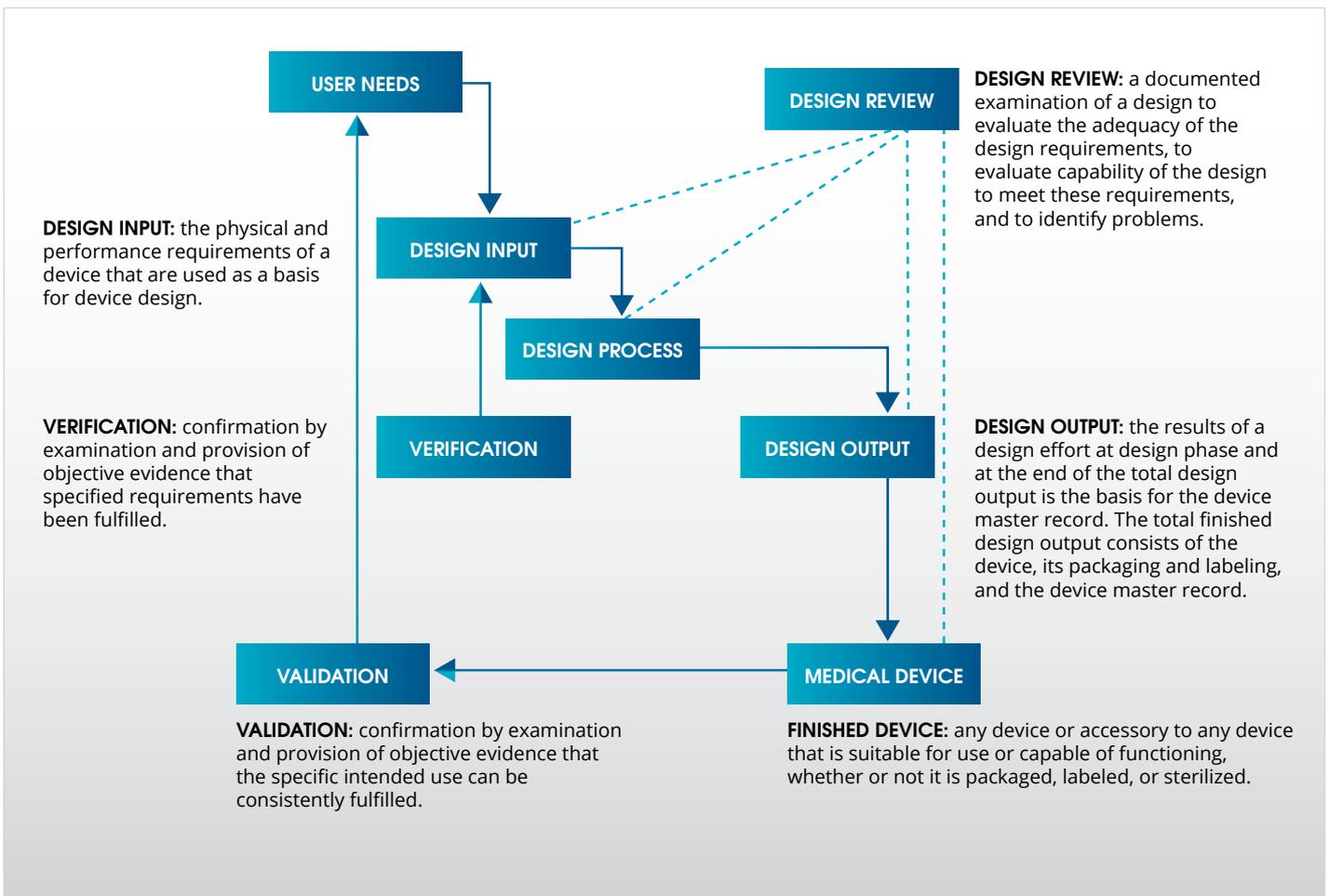
Third, approvals and review signatures for paper-based systems are extremely difficult to maintain when product development is in full swing. It has been observed and experienced that approvals and review signatures have caused tremendous delays in putting product in the market.

Is one digital automated DHF possible? The simple answer - Yes!

Digital solutions today provide comprehensive capabilities to manage DHFs through its entirety and enable regulatory audits. Vigilant companies have started putting efforts to ensure that there aren't multiple versions of DHF for any one specific product on the market. This reduces the burden on engineering by providing quality and regulatory design artifacts required for a fully holistic and comprehensive DHF and DMR.

MINDSET CHALLENGE 3: Design control & change management are separate processes

From FDA: "Design controls are an interrelated set of practices and procedures that are incorporated into the design and development process, i.e., a system of checks and balances. Design controls make systematic assessment of the design an integral part of development. As a result, deficiencies in design input requirements, and discrepancies between the proposed designs and requirements, are made evident and corrected earlier in the development process. Design controls increase the likelihood that the design transferred to production will translate into a device that is appropriate for its intended use."[5]

DESIGN INPUT: the physical and performance requirements of a device that are used as a basis for device design.

VERIFICATION: confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

DESIGN REVIEW: a documented examination of a design to evaluate the adequacy of the design requirements, to evaluate capability of the design to meet these requirements, and to identify problems.

DESIGN OUTPUT: the results of a design effort at design phase and at the end of the total design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.

VALIDATION: confirmation by examination and provision of objective evidence that the specific intended use can be consistently fulfilled.

FINISHED DEVICE: any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized.

Design controls are put in place to ensure that the finished device is safe and meets its intended use before it reaches production and later is launched in market. Patient safety, as mentioned earlier, is of paramount significance when it comes to medical device design and development.

Change management on the other hand has been put in place to ensure design review, verification, validation and approval has taken place whether product or component is in pre-production stage or released in market.

Hence, both design controls and change management are complimentary processes and co-exist in a product's life cycle. Considering them separately would be a grave mistake by enterprises.

However, in our experience the challenges in design control and change management implementation each have their own flavor. Organizations who put in place separate design control and change management processes are seldom able to achieve operational excellence. Most of them embrace these processes in a half-hearted way, viewing them as a never-ending burden put in place by regulatory bodies. The reasons for inefficiency are many. Some of the key ones are:

- There is no focused effort on establishing the traceability, linkages and relationships of design control steps with respect to user needs, design inputs, design process, design output, verification and validation (V&V). The lack of linkages and relationships creates gaps in V&V, eventually increasing employee burden.

- Some organizations interpret FDA design controls as requiring a waterfall approach to design, which is flawed thinking. Due to this misinterpretation, team members tend to postpone reviews and treat critical steps like V&V as end-stage activities. This results in rework and issuances of warning letters and recalls.

- Every change to a device may not need V&V; hence design control procedures may not always apply. Organizations that can clearly document the reasons for not requiring V&V should satisfy regulatory bodies. This process is seldom

followed and non-digital ways of working lead to disparate decision and documentation. Hence, during audits, FDA issues 483s for unavailability of documentation – and at times, even issues product recalls.

Design control traceability and change management hold the keys to product safety and efficacy. They give regulatory authorities the confidence that the right product will be available to the market. Digital solutions provide the essential backbone for these process steps and establish governed workflows as key functionality to ensure the iterative process of design controls is acknowledged.

MINDSET CHALLENGE # 4: Only engineering needs digital data

Medical devices, which typically include mechanical, electrical and software components or any combination of the three, are more complex, with increased usage of IoT sensors populating a growing fleet of smart connected products. Multiple working components need to come together to bring a device to life.

Model-based definition (MBD), commonly referred to as the digital product definition, is the practice of using 3D models (such as solid models, 3D PMI and associated metadata) within 3D CAD software to define and provide specifications for individual components and product assemblies. The types of information stored in the model include geometric dimensioning and tolerancing,

component level materials, assembly level BOMs, engineering configurations, design intent, and other specifications.

In contrast to MBD, traditional design methodologies have historically required the use of 2D engineering drawings to provide these details. MBD enables the production of the "digital thread" and a complete digital product definition within the 3D model, replacing traditional drawings. The usage of MBD conforms to a part-centric approach to Total Product Lifecycle Management and is augmented by all the electronic related product artifacts. The model is treated as another part: a controlled, lifecycle artifact captured in the DHF.

Compared to document-centric workflows, MBD can have dramatic impact on the pace of new product innovation while lowering the Cost of Poor Quality. That's because the empowered model, along with all its associated design artifacts, serves as the single source of truth for the intended use of the medical device. For example, a single source of dimensional and tolerance information completely avoids the all-too-common issue of approved drawings not matching models released for manufacturing. In effect, what is captured in the DHFs and DMRs will always be current and compliant. Companies that embrace a MBD approach to design control reduce time spent on engineering documentation, improve downstream V&V, and reduce manufacturing errors and scrap.

Industry is familiar and comfortable with 2D drawings, which have been used to define the finished product for decades. For CFR 820 compliance, incorporating the 2D drawing in to the DHF has been sufficient in the past. This design control practice has built a wall of compliance between engineering and quality in how these 2D drawings are incorporated into the DHF. In some cases, the existence of multiple, redundant data required to define a manufactured part has led to deviations in the final 3D form.

The use of 2D drawings for communicating downstream production requirements adds an unnecessary burden to the product development cycle. A simple change in the product definition

not only requires updated 3D digital data, but also necessitates numerous engineering changes to all 2D documentation associated with the product. Since it takes time to maintain this documentation, the lifecycle for implementing a product change grows with the extent of its associated 2D data.

Although MBD is best practice for design control, for those companies that are not ready to make the complete switch to MBD, a walk-run-sprint approach to model-based design can be achieved with Limited Dimension Drawing (LDD), sometimes referred to as Reduced Dimension Drawing. These 2D drawings that only contain critical information, noting that all missing information is to be taken from an associated 3D model. For companies in transition to full MBD from traditional 2D documentation, LDD allows for referencing 3D geometry while retaining a 2D drawing that can be used in existent corporate procedures.
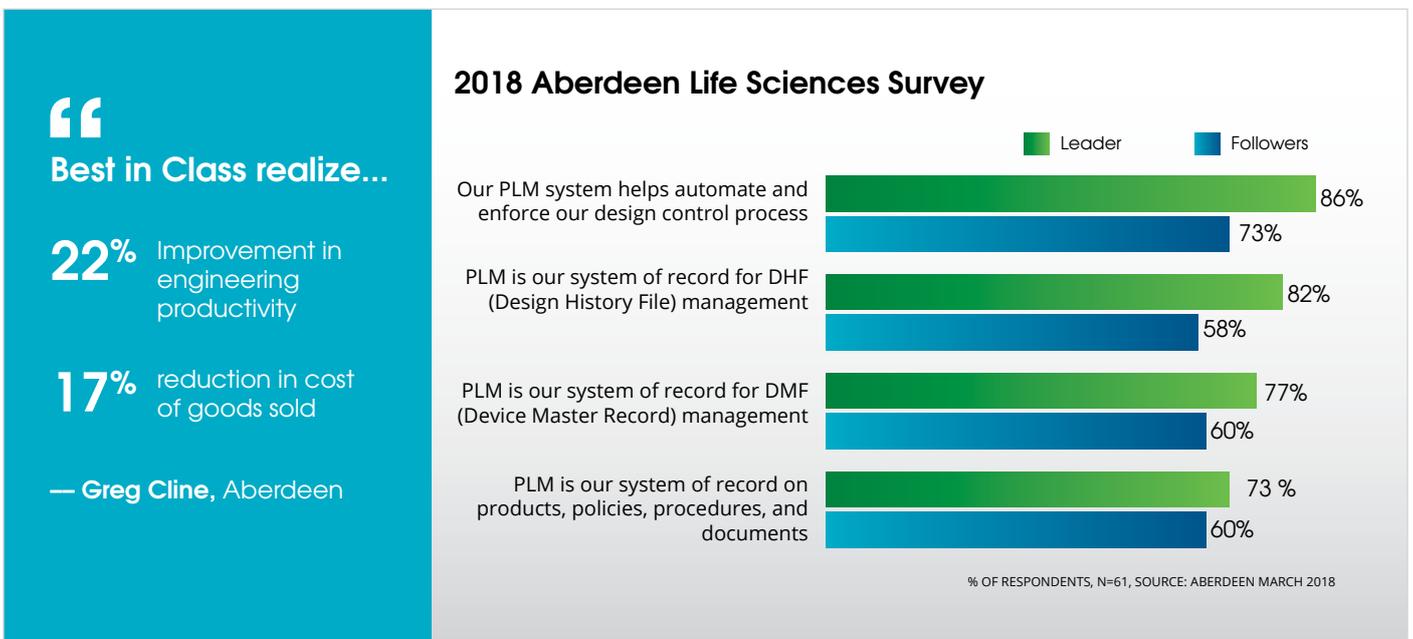
MINDSET CHALLENGE # 5: Regulatory compliance is best managed as a standalone process

Life sciences companies operate in a regulated, safety critical environment. All aspects of the product development lifecycle–including contributing mechanics, electronics, software, and hardware–must be governed in accordance with regulatory bodies around the globe (in U.S.by the Food and Drug Administration (FDA) and in Europe by the EU, author of the European Union Medical Device Regulation (EU MDR). Indeed, in a 2018 survey conducted by health care consultancy Axendia, Regulatory / Government Agencies were cited as the top industry disruptor.

Life sciences innovators are planning for a wave of regulatory submissions due to the EU MDR. Those companies that have embraced common PLM processes for the creation and management of their digital product definition will establish a foundation that is future-proof vis-à-vis continuously evolving regulatory requirements.

When design control best practices center around MBD, life science innovators can reference actual products, parts and detailed design information throughout the product development lifecycle – from initial concept through design, submission, release to manufacturing and ongoing post-market surveillance. This digital management model can also be extended to include other product related data such as post-market surveillance and regulatory information management.

There is multiple advantage of a unified product lifecycle management framework that spans multiple processes and teams. Key benefits include: quality and compliance records that are always in sync– because they are controlled against the same digital definition of the product. Improved collaboration and cross- team visibility, as all teams share the context-rich information. In addition, shared quality intelligence enables faster, more agile response to design problems, supply chain problems, and other quality issues.

> "
> ### Best in Class realize...
>
> **22%** Improvement in engineering productivity
>
> **17%** reduction in cost of goods sold
>
> — **Greg Cline,** Aberdeen

2018 Aberdeen Life Sciences Survey

Legend: ■ Leader ■ Followers

Our PLM system helps automate and enforce our design control process
- Leader: 86%
- Followers: 73%

PLM is our system of record for DHF (Design History File) management
- Leader: 82%
- Followers: 58%

PLM is our system of record for DMF (Device Master Record) management
- Leader: 77%
- Followers: 60%

PLM is our system of record on products, policies, procedures, and documents
- Leader: 73 %
- Followers: 60%

% OF RESPONDENTS, N=61, SOURCE: ABERDEEN MARCH 2018

THE DIGITAL THREAD – Challenges Accepted!

Companies facing the many challenges outlined in this article can meet these head-on by digitalizing their product data and creating a digital thread. The digital thread is a communication vehicle that enables connected digital product data flow across engineering, manufacturing and supply chain. It provides an integrated view of the product data throughout its lifecycle across traditionally siloed organizations. **The digital thread delivers "the right product information to the right place at the right time."**

A best in class company has created and managed the digital thread throughout the lifecycle of the product. They've built best practice design control incorporating proper change management and quality design review to innovate new products faster and with better quality. The outcome of their design control process is a holistic digital product definition and always compliant design history file.

In an ever-increasing competitive landscape, those companies that embark on their digital transformation journey will increase market share, innovate new products faster, and improve positive patient outcomes more quickly.
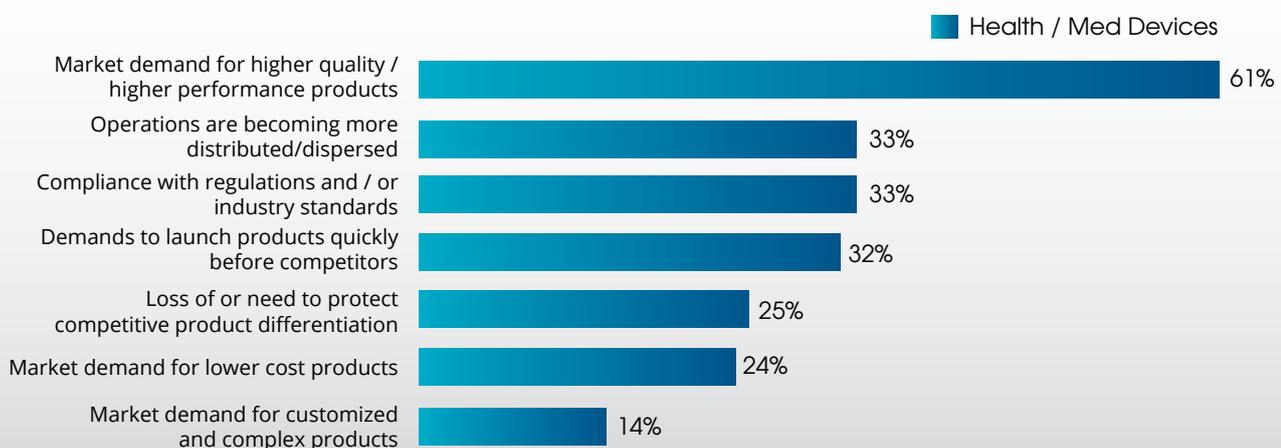
SUMMARY

A recent Aberdeen study from March of 2018 outlined the top market pressures driving decisions related to PLM. This study shows that companies that embrace PLM are motivated by a common desire to innovate, collaborate, and compete in the marketplace of ideas.

Leaders who rely on their PLM processes and systems as the foundation for design control reduce the time it takes to bring these new products to market. Quality and Regulatory teams can leverage the same digital thread to create packages necessary for new product submissions to regulatory bodies.

A recent Aberdeen Life Science survey showed that best in class medical device leaders who utilize PLM as the backbone of their digital backbone outperform their competitors. These leaders realized a 22% improvement in engineering productivity and a 17% reduction in Cost of Goods Sold, when compared to life sciences companies that did not utilize a PLM system.

In an increasingly smart, connected world, digital transformation is a requirement to compete now and in the future.

Top Market Pressures Driving Decisions Related to PLM

■ Health / Med Devices

Market pressure	%
Market demand for higher quality / higher performance products	61%
Operations are becoming more distributed/dispersed	33%
Compliance with regulations and / or industry standards	33%
Demands to launch products quickly before competitors	32%
Loss of or need to protect competitive product differentiation	25%
Market demand for lower cost products	24%
Market demand for customized and complex products	14%

% OF RESPONDENTS, N=64, SOURCE: ABERDEEN MARCH 2018

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Footnotes

1. "All the digital health funding MobiHealthNews covered in 2016", MobileHealthNews, Dec'26,2016.
   https://www.mobihealthnews.com/content/all-digital-health-funding-mobihealthnews-covered-2016

2. https://datadashboard.fda.gov/ora/cd/recalls.htm

3. FY 2017 Inspectional Observation Summaries, https://www.fda.gov/ICECI/Inspections/ucm589892.htm#Devices

4. Value of Quality - Good Quality is Good Business - November 2016

5. "Design Control Guidance for Medical Device Manufacturers" March 11, 1997

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