

PLM for OPERATIONAL EXCELLENCE

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Risk and Disruption Demand Change

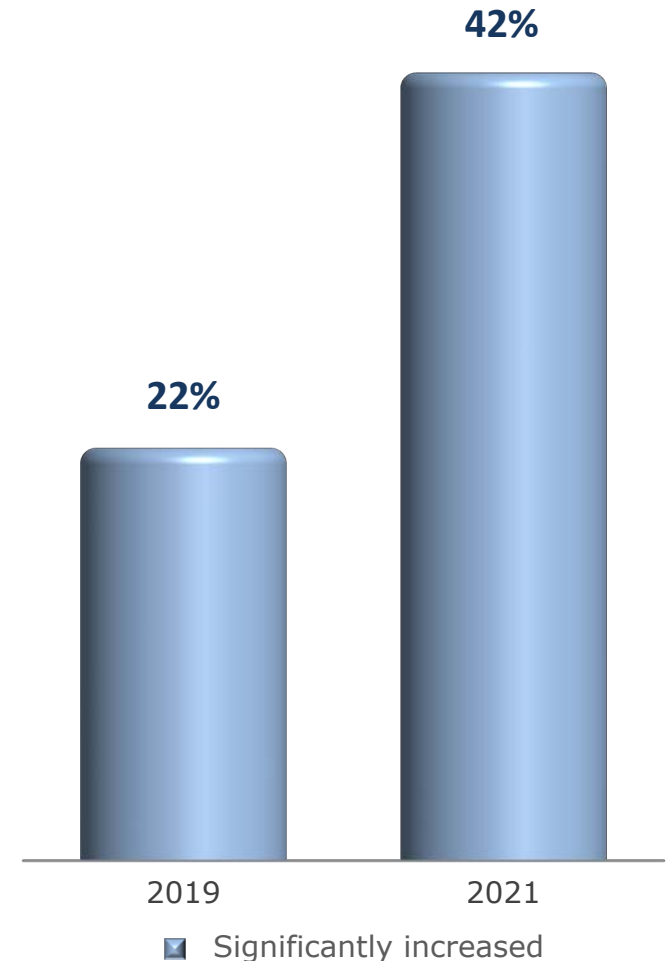
Driving Innovation, Agility, and Operational Excellence

Risk and disruption have skyrocketed over the last few years. Our 2019 survey¹ found that over three-quarters of companies said that business risk and disruption had increased over the prior five years. Further, 22% of respondents said it had increased “significantly.” That number almost doubled in our 2021 survey, rising to 42%.

The COVID-19 pandemic certainly influenced the already challenging business climate. The surveys show other sources as well, however, including the demand for digital transformation, the need to change business models, and calls for greater sustainability. These, and other recent, global disruptions such as tsunamis, earthquakes, volcanoes, and political uncertainty have resulted in supply chain issues and component shortages. This disruptive climate puts pressure on profitability, demanding companies to achieve operational excellence to survive.

Manufacturers need to create agility in their business and processes so they can react and bounce forward better than before the disruptions. To do this, Engineering and product development have to fundamentally change. They have to focus on the big picture, not just engineering, to develop profitable products. How can PLM, traditionally an engineering-centric solution, drive innovation, agility, and operational excellence?

**BUSINESS RISK AND DISRUPTION
OVER THE LAST FIVE YEARS¹**



The Evolution of Engineering

Products Are More Complex

Product capabilities – and complexity – have increased dramatically in recent years. Today, there are more smart, autonomous products than ever. The majority of these products are system-centric, incorporating mechanical, electrical, software, optical, and other types of components.

Product Development Cycle Times are Squeezed

The pace of innovation has also changed. Companies, particularly those in the high-tech and medical device markets, face shorter innovation lifecycles. They must rapidly innovate, launch, improve, and replace products to stay ahead.

Supply Chain are More Dynamic

Market dynamics have also evolved rapidly over the last decade. Many companies that relied on vertical integration and internal innovation have adopted more supply-chain-centric strategies. They now rely on the innovation and engineering prowess of their suppliers. This has led to more fluid value chain

partnerships. In fact, our research³ finds that the majority (56%) of manufacturers say that supply chain volatility has increased over the last five years.

The Impact on Engineering

The factors above have led to significant changes in the job of engineering and developing products. Beyond meeting performance specs, engineers must make the right decisions to develop a product that is designed for supply, cost, quality, compliance, and more. This is what it takes to develop a profitable product in today's business environment.

PLM Needs Have Changed

In the same way, systems that support product innovation must enable this broader perspective and new ways of working. The result is that companies looking for PLM now have to find a solution that goes beyond Engineering and supports continuous improvement and drive operational excellence.

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Excellence means meeting physician, patient, and practice needs. We have to do it in a way that's efficient so you make money and meet regulations. That means sustaining quality in all operations to achieve company goals in the least burdensome approach while making sure we meet standards and regulations.

— **Scott King**, Director,
IRIDEX CORPORATION

Choosing PLM

Moving Beyond Engineering Efficiency

Let's start with the end in mind, product profitability. Many Engineering process and systems improvements have focused primarily on engineering productivity. Engineering efficiency is important, but doesn't dramatically change the P&L statement. To impact earnings companies must also focus on their profit margins and efficient use of assets. This can be achieved through increased innovation, continuous improvement, operational excellence, and reducing product development cycle times.

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With PLM you can see the whole picture, solve problems, and access data and make use of it.

— **Scott King**, Director,
IRIDEX CORPORATION

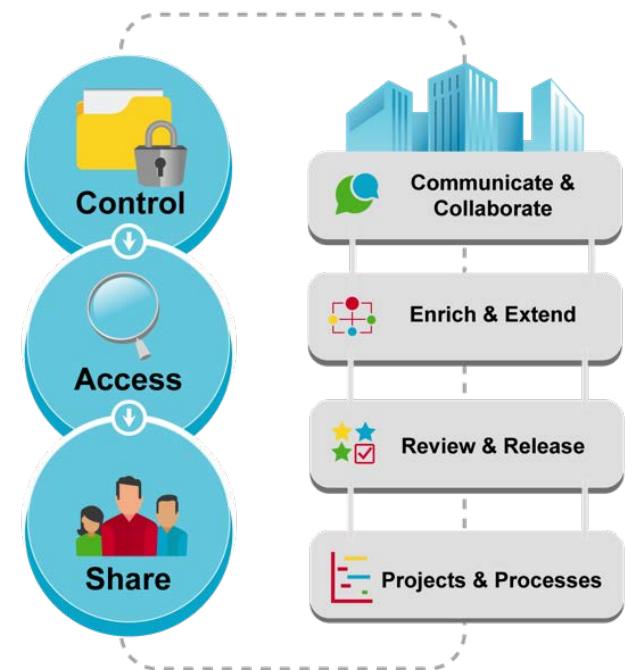
The Role of PLM

Product Lifecycle Management (PLM) has promised to deliver these business benefits, but many solutions and implementations have limited their focus to the basics. PLM value expands significantly beyond basic engineering data management. Because of this, selection and deployment of a PLM solution should be led by an operations-oriented, cross-functional team representing all product related functions.

PLM Requirements for Operational Excellence

We've tracked the way PLM value expands in four dimensions. These factors include supporting the whole product, including more people/departments, extending to more facets of the product lifecycle, and improving a broader range of processes. These are what deliver the real potential value of PLM. We'll discuss each of these four dimensions, how it impacts operational excellence, and what to look for in a PLM solution to support it.

EXPANDED ROLE OF PLM



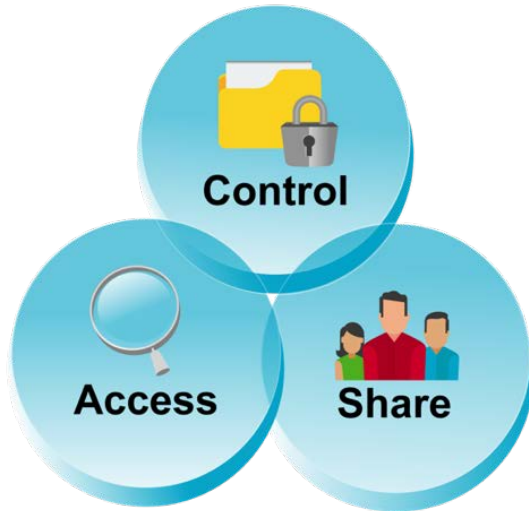
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We were getting feedback from customers that our control methods weren't good enough, and we realized we weren't as efficient as we could. PLM is part of our organizational upgrade to improve our business. It's allowing us to apply a level of automation to standards through software to meet Mil standards and FDA requirements.

— **John Baumann**, CEO,
THINGAP, INC.

The Basics

THE BASICS OF ENGINEERING DATA MANAGEMENT



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PLM is critical to the business. It offers control and process formality. It's a centralized, organized, systematic approach so we can capture critical data, circulate it through the organization efficiently, and make sure the right people see and approve it.

— **John Baumann**, CEO,
THINGAP, INC.

The Importance of Basic Capabilities

While basic engineering data management capabilities may not be enough to drive real innovation and agility, they are still important. Engineering and product development processes must be organized and under control. This ensures efficiency and traceability. It also prevents errors and resulting rework. We describe the basic PLM needs as the ability to control product data, provide access to it, and share it with others.

Controlling Product Details

Product definitions must be managed in context. This means that relationships between mechanical, electrical, and software designs must be managed holistically. The same is true for component and supply chain information. The comprehensive product record has to be maintained and change controlled.

Accessing Product Data

Engineers have to be able to quickly find and view product data in full context. This requires fast search capabilities that span the full breadth and interrelationships of the product record. Data and documents of all types should be viewable regardless of the authoring tool.

Sharing Product Information

The value of product data expands as it is shared beyond Engineering. Others in the enterprise and the value chain should be able to access information easily in a self-service fashion. This access, of course, must be selective based on IP protection rules.

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Managing paper is the way of the past.

— **Scott King**, Director,
IRIDEX CORPORATION

Expanding PLM for Operational Excellence

The Four Dimensions of PLM Expansion

PLM implementations must go beyond the basics to support operational excellence. We'll discuss four important ways that PLM has expanded in order to support operational excellence:

- **Process:** Improving processes beyond basic revision control and release to manufacturing
- **People:** Including more people and departments beyond Engineering, including partners, the supply chain, and customers
- **Lifecycle:** Supporting upstream and downstream capabilities beyond design
- **Product:** Expanding beyond product design to a full product definition

Each of these expands the value of PLM, supports more mature product innovation practices and helps make better use of product information throughout the enterprise. Together, they support the pursuit of operational excellence.

THE FOUR DIMENSIONS OF PLM EXPANSION



Expanding Communication with PLM

Another valuable dimension of PLM expansion is by supporting broader communication and collaboration between Engineering and the rest of the business. This can be looked at in two directions:

- **Inbound:** Enabling engineers to better use information coming out of other business areas such as Procurement, Quality, Manufacturing, and others to design for operational excellence
- **Outbound:** Making better use of information coming out of Engineering in other areas of business such as Marketing, Sales, Service, and more to support broader product innovation, development, manufacturing, and support process to drive operational efficiency

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To start, PLM supports document management, design control, and training. That sets the foundation for product development process compliance. Then, you can build on that to support operational needs like NCMR, suppliers, CAPA, change control, and complaint handling as you go to the commercial phase.

— **Scott King**, Director,
IRIDEX CORPORATION

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We started with ECOs, took some small bites, then expanded it more broadly by implementing it with supply chain, customers, drawings, orders, contract tracking, and source tracking. They lend themselves perfectly to PLM.

— **John Baumann**, CEO,
THINGAP, INC.

Expanding PLM – Process

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PLM allows you to sustain your business processes in a way that's compliant and provides data that shows how well you're doing. It gives you the tools to measure so you know how well you're doing and know what to focus improvement efforts on.

— **Scott King**, Director,
IRIDEX CORPORATION

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PLM is logical and stands on its own merits in terms of operational efficiency. We have to standardize and automate processes and methods. It would be like not being ISO certified. It would fail immediately if we didn't have a method and a platform that dictates how things are approved, tracked, and stored.

— **John Baumann**, CEO,
THINGAP, INC.

Driving Operational Excellence

We'll start with process expansion and look at each of the dimensions of PLM expansion and discuss how it drives operational excellence and the impact it has on selecting the right PLM system. Business processes and operational excellence are a natural combination. Operational excellence demands consistent application of well-managed, leading practices. Following best practice processes reduces variability, improves efficiency, enables automation, and allows continuous process improvement.

Impact on PLM Selection

Companies should look for basic processes like engineering change and release management. But they should also expect more advanced processes supporting Approved Supplier List (ASL), Approved Manufacturer List (AML), Corrective Action and Preventive Action (CAPA), Non-Conforming Materials Report (NCMR), program management, continuous improvement, supplier assessment, audits, equipment calibration, certifications, and more. Revision control and engineering change management are no longer enough.

PLM solutions should provide standard practices out of the box, but must also be easily adaptable and extendible to support improved or unique processes. This flexibility is increasingly important as companies look to support new needs arising from disruption and digital transformation. The workflow engine should be able to be configured to change pre-configured processes or add new ones without the need for time-consuming and costly programming.

Expanding PLM – People

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Don't forget about adoption. If it's too hard to use, people aren't going to use it.

— **Scott King**, Director,
IRIDEX CORPORATION

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Our PLM is used about 50% in Engineering, 30% in Operations, and 20% everybody else. The whole organization, more than expected, saw the value.

— **John Baumann**,
CEO of **THINGAP, INC.**



Driving Operational Excellence

Profitability demands breaking down the barriers between departments and improving collaboration. Getting more people and departments using PLM encourages early feedback on design decisions that have a big impact downstream, allowing optimized decisions for sourcing, production, and service early to prevent rework. It also encourages holistic innovation so companies can more quickly incorporate advances such as new manufacturing methods.

Expanding PLM to more people also helps enable concurrent engineering to support faster, better product development where downstream departments can get the information they need sooner. This enables them to get a jump start on sourcing, manufacturing planning, and other decision-making to reduce product launch cycles.

Impact on PLM Selection

To expand PLM to more people, the solution must support the processes and capabilities these other people need. This goes beyond simple engineering collaboration to incorporate quality, procurement, and manufacturing processes. It should also support people-centric processes, such as training and skills certifications for people in various functions to ensure they are qualified for the activities they perform.

It's also important to recognize that expanding PLM requires solutions that are simpler to use. This is important because other departments have less technical users who may use PLM less frequently. It must also be easy to quickly make new people and partners productive on the system. Companies should focus their attention on ease-of-use and user experience in order to support and encourage expanded use across departments.

Expanding PLM – Lifecycle

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PLM ties it all together and provides tremendous advantages. You have traceability and visibility to everything including CAPA, non-conformance, and change history.

— **Scott King**, Director,
IRIDEX CORPORATION

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We have contract checklists, flow downs, scorecards reviews, training, RMA tracking, customer complaints, and work instructions all in PLM and under ECO.

— **John Baumann**,
CEO of **THINGAP, INC.**

Driving Operational Excellence

Covering more of the product lifecycle also adds great value and drives operational excellence. It's important to have all product information in one place and create an integrated view of the product from requirements through fulfillment. This complete digital thread provides traceability and supports compliance, but also helps eliminate disconnects and mistakes. Managing data relationships in PLM allows decision-makers to understand the impact of their actions upstream and downstream so they can make better, more holistic decisions.

Impact on PLM Selection

PLM should provide a comprehensive data model that spans from product requirements through product obsolescence. It should not only support design data, but also cover component information including preferred suppliers and costs, manufacturing data like work instructions, fixtures, tooling, and manufacturing specs, quality information like incoming part inspections and test specs, and service information such as service BOMs and service instructions.



Expanding PLM – Product

Driving Operational Excellence

Supporting a comprehensive product model is critical, and clearly overlaps needs in the other dimensions of PLM expansion. No CAD system has all of the information required to define a product, so PLM must support complex products with a holistic definition. The system should manage and connect designs and documents of all kinds. It must support engineers who are asked to make more decisions about sourced components that significantly impact cost, compliance, sourcing risk, supply chain resilience, and other profitability drivers. A comprehensive, integrated product model also allows confidence when making decisions or making engineering changes with broad impact on the enterprise and the supply chain.

Impact on PLM Selection

PLM needs to do more than help engineers design parts. It has to have a strong parts library and component data to help engineers properly select the right components that will be operationally efficient over the long term. It must also support a full array of product details including mechanical, electrical, and software components. The product model should extend beyond design specs to include sourcing and supplier information, manufacturing procedures, validation and verification processes, packaging details, shipping instructions, and more. Further PLM should manage and incorporate designs and documents of all kinds to create a single, trusted source of product information.

SAMPLE PRODUCT RELATIONSHIP MODEL



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We can check on a part, revise it, and see the whole history. We can look at the supplier, CAPAs, and NCMRs. In an audit, I can access that information quickly and show the linkages between them.

— **Scott King**, Director,
IRIDEX CORPORATION

Conclusions and Next Steps

Moving Toward Operational Excellence

Manufacturers have to recognize the need for innovation, agility, and operational improvement. Business risk and disruption are threatening profitability and survival for many businesses. Products and markets have changed, demanding more.

Recognize the New Role of the Engineer

To support more supply-chain centric, operationally-focused product development processes the role of engineers has changed. They must be able to access a wider array of information in order to make broader product-related decisions. This, in turn, changes the requirements for the PLM systems that support them.

Choose the Right PLM Solution to Drive Operational Excellence

The four dimensions of PLM expansion provide a framework to understand what's needed to drive operational excellence. Traditional, Engineering-centric PLM systems are not sufficient for fast-moving industries like high-tech and medical devices. Companies in these industries need a PLM solution built for the enterprise and the supply chain.

Lastly, manufacturers must get a solution that *delivers* on the promise of PLM. Systems selections and implementations should be driven by cross-functional teams that represent all aspects that impact product profitability. Selection requirements should span the enterprise and focus on how the systems supports the new role of engineers and product developers. This is the way that companies can ensure that they select the right PLM systems to drive operational excellence.

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Operational excellence with PLM brings down turnaround times for complaints, product releases, and audits. It provides traceability so auditors can get what they need quickly and leave happy because we can show them that we're in control.

— **Scott King**, Director,
IRIDEX CORPORATION

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PLM is like CRM for engineers, or like how email and a website. You really need one. I can't imagine in a modern day how you would support the customers and markets we serve without one.

— **John Baumann**,
CEO, **THINGAP, INC.**

Acknowledgments



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About the Author

Jim Brown founded Tech-Clarity in 2002 and has over 30 years of experience in the manufacturing and software industries. Jim is an experienced researcher, author, and speaker and enjoys engaging with people with a passion to improve business performance through digital enterprise strategies and supporting software technology.

Jim is actively researching the impact of digital transformation and technology convergence in the manufacturing industries.



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Tech-Clarity is an independent research firm dedicated to making the business value of technology clear. We analyze how companies improve innovation, product development, design, engineering, manufacturing, and service performance through the use of digital transformation, best practices, software technology, industrial automation, and IT services.

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