



Breaking Down the Barriers to Product Innovation

Connecting Product Information and Teams Is Vital to Success in NPD and NPI

WHITE PAPER

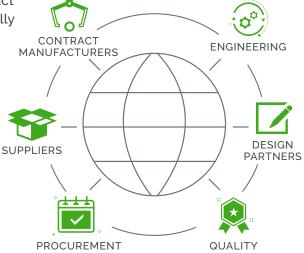




INTRODUCTION

New product development (NPD) and new product introduction (NPI) practices have shifted drastically over the last decade as companies have picked up the pace of innovation to survive and prosper in the face of customer demands for greater performance at a lower price, increased global competition, and more stringent regulatory requirements. Companies developing and launching new products have responded to these demands with smarter and more connected products, lean but highly productive distributed teams that can turn on a dime, and global best-of-breed design and manufacturing partners. Product innovators now

face the challenge of coordinating globally dispersed teams to design, validate, and build ever-more complex products on tighter schedules and budgets than ever before.



This white paper explains how these challenges can be overcome by connecting the entire new product development cycle and the NPI team to the larger product realization process with a system that manages the complete product record as a single source of truth. Such a system keeps internal teams and external supply chain partners synchronized with the latest design and process information, project schedules, regulatory compliance and quality data, and changes. Freed from countless administrative and coordinating tasks, the NPI team can focus on the primary objective of increasing the pace of innovation to speed product launches.

3 SHIFTS IN BUSINESS THAT MATTER TO PRODUCT DEVELOPMENT

- 1. Greater Complexity and Regulations Increase Need for Multidisciplinary Cooperation
- 2. The Changing World of NPD and NPI Means More People on the Team
- 3. Connected Devices Create Challenges Along With Opportunities

Shift 1: Greater Complexity and Regulations Increase Need for Multidisciplinary Cooperation

High-tech electronics product complexity continues to grow as innovators add new features to fend off global competitors and participate in increasingly segmented market niches. Technology and medical products are leveraging Moore's Law coupled with advancements in areas such as sensors, lasers, and displays to add features and functions at a rapid pace. All kinds of products, like Wi-Fi enabled teakettles and Bluetooth door locks, incorporate an increasing amount of electronic and software components.

Software now constitutes a significant amount of the development effort for most electronics product companies and plays an expanding role in many other industries. It is critical for mechanical, electrical, and software engineering teams to collaborate more effectively during early NPD to eliminate quality and functionality issues during NPI. As a case in point, the design of a cell phone enclosure must be closely coordinated with the antenna design to achieve wireless coverage

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requirements while also meeting electromagnetic emissions regulations. Furthermore, ensuring designs can be consistently built to specifications requires paying closer attention to design for manufacturability (DFM) practices.

Medical device electronics manufacturers face even more NPDI (NPD and NPI) challenges due to growing global regulatory and legal compliance burdens. The European Union (EU) recently adopted two new regulations that will force medical device manufacturers to provide substantially more clinical evidence to support claims of safety and performance. And, of course, the EU is just one of an increasing number of issuers of standards and regulations.

Other regulations and directives come from the Food and Drug Administration (FDA), the International Organization for Standardization (ISO), Underwriters Laboratories (UL), CSA Group, the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), the Waste Electrical and Electronic Equipment Directive (WEEE Directive), and Conflict Minerals. Today, managing product development processes while maintaining compliant systems and processes requires greater visibility and sharing of information throughout the product release process than ever before.

Shift 2: The Changing World of NPD and NPI Means More People on the Team

NPD and NPI are sometimes used interchangeably, but they address two different points in the product realization process. NPD focuses on concept generation, the engineering and design process, and commercialization of the new product. NPI begins around the end of the development process and continues through product launch. The later NPI stages require more collaboration with globally dispersed teams to effectively plan, procure, manufacture, and ship products to market. NPD and NPI are complementary processes that overlap and together span the entire concept-to-launch process. With this connected nature of NPD and NPI, we can also refer to these two processes together as new product development and introduction (NPDI).



Overlapping NPD and NPI processes require global product teams to collaborate to deliver high-quality products to market fast.

Thirty years ago, NPD was largely a one-company affair with in-house engineers designing the product and handing off to internal manufacturing resources. Today, the norm for original equipment manufacturers (OEMs) and original design manufacturers (ODMs) involves internal engineering teams around the globe—such as a hardware group in Sunnyvale and a software group in Bangalore—and often includes external design partners.

High-tech consumer electronics and medical device OEMs and ODMs design complex products; thus, they increasingly rely on outsourcing of production to global contract manufacturers (CMs) and additional first- and sub-tier suppliers. The most common approach is to select best-of-breed CMs in various specialties such as field programmable gate arrays (FPGAs), printed circuit boards (PCBs), injection molding, castings, and final assembly. With so many CMs and suppliers, the need to act as a single virtual company is crucial to successfully introducing high-quality products.

Shift 3: Connected Devices Create Challenges Along With Opportunities

In addition to navigating regulatory and legal compliance, today's product companies may also need to consider how their products integrate with the Internet of Things (IoT). Many consumer and industrial products are already equipped with wireless technologies (e.g., Wi-Fi,



Bluetooth) that serve as a gateway to the Internet of Things (IoT) and make it possible to add new capabilities, including automatically collecting information from products in the field at minimal cost. This field performance data offers the potential to identify design and quality weaknesses and understand customer usage patterns.

IoT-connected devices are generating vast amounts of data used to provide breakthrough functionality, understand the customer experience, track products up and down the supply chain, and help improve product functionality and customer support. NPDI teams are tasked with taking full advantage of this data, while also protecting the privacy of customer information. With this new IoT paradigm, multidisciplinary design and development teams must ensure the seamless operation between one or more ecosystems like Amazon Echo or Google Home devices with voice recognition.

NPDI CHALLENGES

These three business shifts make the demanding process of developing new products even more difficult. While more varied and early input from diverse team perspectives adds considerable value to new product efforts—particularly in the increased product complexity and regulatory world—more teams and more locations does also mean more coordination. In surveys and interviews, complex product companies consistently identify quality as a key challenge in NPDI efforts, highlighting how input from multiple teams is important to deliver high-quality products to market. This



paper explores the following areas in NPDI efforts and how companies can overcome challenges and drive to solutions for healthy NPDI processes and company success.

Key Challenges During NPDI

- Managing the entire BOM
- Collaborating between distributed teams and silos
- Ensuring DFM is considered early
- · Connecting the project plan to product record
- · Streamlining engineering change review processes
- · Enabling regulatory compliance

While it is difficult to definitively rank NPDI challenges in severity, impact, and costs, two areas need to be addressed first: (1) ensuring the full product record (BOM) is managed in one central accessible system and (2) providing flexible, secure collaboration for the entire NPDI team. Teams generally find these first two challenges to be connected. Without the product BOMs in one location, collaboration efforts begin at a deficit.

Managing the Entire Bom

CHALLENGE: Partial BOM Record Visibility Hampers Design Teams

Too often, BOMs managed across multiple systems by engineering and manufacturing teams lead to disconnected NPDI processes resulting in product launch delays, quality issues, manufacturing mistakes, and costly scrap and rework. Many companies manage BOMs in documents (e.g., Microsoft Word, document-centric QMS systems) or spreadsheets, limiting the ability to effectively collaborate across distributed teams and making it more difficult to associate all required documents, drawings, specifications, changes, and quality actions across the entire multilevel assembly.

Some companies use product data management (PDM) or CAD-centric PLM systems geared towards early design and work-in-process (WIP) management processes within engineering workgroups. These systems tend to work well with either mechanical (MCAD) or electrical (EDA) assemblies, but they are not as adept at bringing both electrical and mechanical designs together—let alone software and the complete set of documents, specifications, and drawings required to assemble the final product. PDM and CAD-centric PLM solutions usually provide full functionality only to contributors working with the CAD tool associated with a given PDM or PLM solution, making it difficult to deliver visibility of the entire design to teams outside of engineering.

SOLUTION: Provide Access to the Complete Product Record

As a product realization system, Arena is better suited than point solutions or work team CAD-level systems to aggregate the complete BOM with the entire assembly and all associated components, files, drawings, and specifications required to build the shippable product. This includes the ability to create, import, change, share, compare, and approve new product designs and changes to existing products throughout the entire product lifecycle. Arena is also CAD-agnostic, meaning



your engineering teams can use the PDM or CAD design systems of choice. Arena works equally well with a wide range of internal and external electrical, mechanical, and software design tools, enabling disparate teams to aggregate and share their designs.

Collaboration With the Distributed Teams During NPDI

CHALLENGE: Disconnected Software or Point Solutions Create Silos and Block Collaboration

Ad hoc methods such as spreadsheets and CAD-centric PLM solutions not only result in partial BOM management, they also impair strategic transparency and collaboration with the downstream product teams (e.g., quality, purchasing, manufacturing, CMs, suppliers). With quality issues a leading failure point in NPDI, companies need a complete product information record that is securely accessible by suppliers and partners. Otherwise, quality will suffer as well as team efficiency, time to market, and long-term ability to execute.

Most CAD-centric PLM systems were introduced as on-premises applications installed on desktops and servers inside an OEM's or ODM's firewall. This makes them hard to access without granting trusted access via virtual private networks (VPNs) to external design, contract manufacturing, and supplier partners. Even with technical access, many systems do not handle the provisioning and proper data security access and history tracking that companies will want for supply chain partners. Spreadsheets, even in online repositories, may be shareable, but have similar security and audit concerns along with lack of formal change control and disconnection from the greater context of product efforts.

Understandably, many product companies have refrained from sharing product development information with external partners due to these inherent risks and complexity burden. With these capability and process gaps, it is difficult to collaborate and stay on the same page with cross-functional product teams from early design through volume production.

SOLUTION: Single System Improves Visibility, Control, and Access

Connecting NPDI teams requires a secure approach that can work with even the least technologically advanced partners anywhere in the world. Arena's cloud solution closes the gap between internal teams, design partners, and CMs—encouraging collaboration and sharing throughout the value chain. External partners have permission-based access to the latest design files and product information without cumbersome and complex firewall access processes. Automated change control processes also ensure all product and process data and documents are maintained under revision control. With direct access to product information, supply chain partners are empowered to provide feedback, prevent errors, and suggest cost-saving alternatives.

For design for manufacturing (DFM) best practices, connecting all product, quality, purchasing, and manufacturing teams ensures improved design and earlier detection of possible design flaws or quality issues. Aggregating all the mechanical, electrical, and software designs into a single system eliminates design errors and quality issues. Enabling a CAD and ERP agnostic approach allows engineering teams to design in the design solutions of their choice, and production teams to do the same with their chosen production systems.

Disconnected data silos' impact on distributed teams

- Engineers must spend considerable time compiling information for the downstream supply chain
- Suppliers have difficulty accessing the latest product information, and can't contribute effectively during the NPDI process
- CMs lack visibility, making it hard to provide useful feedback on the manufacturability of the product

NPD teams need to collaborate closely with NPI teams to ensure:

- Key stakeholders work on the right design at every stage
- Requirements are captured, prioritized, and tracked effectively
- Designs created by different engineering teams work well together
- Impacted teams have cross-functional visibility to drive project deliverables through product launch
- Regulatory requirements are factored into design and sourcing decisions
- Supply chain partners have access to the information required to source or build their portion of the product

Meeting Product Requirements

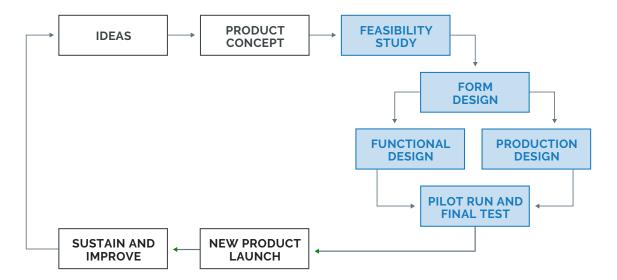
CHALLENGE: Failure to Achieve Design Specifications

The inability to overcome technical challenges during the early NPD stage can result in failure to deliver products on time and on budget. It's not uncommon for a product to reach the prototype phase—with substantial funds invested for detailed design, documentation, prototyping, and testing—only to discover it fails to meet core functionality, performance, or cost objectives.

SOLUTION: Technical Feasibility Studies During Early NPD

Performing technical feasibility studies on major product capabilities as early as possible in the development process is key to avoiding issues during NPD. Michael Keer, CEO of Product Realization Group (PRG), a company specializing in delivering outsourced NPDI consulting services, speaks about the importance of these studies. Keer notes: "Instead of saying: 'we think this will work,' PRG recommends that OEMs and ODMs design an experiment that will evaluate the concept against the product requirements to objectively determine whether it will work." He adds that these types of feasibility studies can be performed quickly and often inexpensively. For electronics, the breadboard has been the accepted feasibility method for decades. With intelligent 3D CAD modeling and inexpensive 3D printing, mechanical engineering has similar options while software teams can utilize feasibility reports.

In all cases, the best practice for feasibility studies as part of overall requirements management is to cover various aspects of the capabilities—technical, operational, financial, legal, security—and identify risks and alternatives. Besides building confidence that the design concept meets the product requirements, feasibility studies often identify suitable materials technology and production processes to ensure the concept design can be manufactured and tested to meet projected volume and cost targets. This helps overcome production issues while ramping volume to meet customer demand for new product launches.





Streamlining Engineering Change Processes

CHALLENGE: Manual NPDI Change Processes Take Too Long

Manual change processes make it hard to track and approve changes quickly, leading to delays in getting products designed under cost and delivery targets. Manual or paper-based engineering change request/order (ECR/ECO) processes also do not support parallel team reviews unless you meet physically as a change control review board (CCB). With distributed teams, physical meetings are no longer practical. With manual serial review processes, companies struggle to track, review, and collaborate effectively around the latest design. Slower and siloed review processes delay product launches and result in issues ranging from increased scrap and rework to higher product development costs.

SOLUTION: Automating Change Approvals

Arena helps streamline the ECO approval process with automated routings and review cycles based on specified criteria like change types, priorities, and product lines. All internal and external reviewers are notified through automated email and application notifications. All edits are made to a single, shared version visible to all impacted groups. Impacted teams collaborate around the latest change information and can view cycletime performance, while monitoring change progress across multiple product lines. External supply chain partners can easily participate in the ECO process with read only, edit, and/or approval rights based on the access policies assigned. Automated reviews accelerate early NPD and provide better collaboration with production teams during NPI.

Proactive NPDI Project Management

CHALLENGE: Project Management Separated From Product Record

Introducing new products to market requires the completion of many different tasks by people throughout the internal organization and many partners with the end goal of meeting the product requirements. Delivering the product on time and on budget requires that these tasks be completed in a specific sequence at specific points in time. One of the greatest difficulties in keeping NPDI on schedule is that the project management tools used to track task completion and scheduling are usually separated from the product record and often available only to a limited number of managers within the organization.

Additionally, teams typically capture and track requirements in disparate formats. Traditional project management is focused on a manager creating a schedule, sharing it with the team, updating the schedule based on the team's feedback, sharing the file back out to the team, collecting the inevitable comments for updates and adjustments, and then continuing the sharing process again. This approach requires considerable time and effort on the part of the entire team in communicating task status and updating the project management tool. It is particularly prone to difficulties when changes occur. A more modern, yet still challenging, project management method includes shared Google, Box, or Dropbox spreadsheets. While these are more accessible and sharable, these files tend to be disconnected from the NPDI product deliverables surrounding BOMs, requirements, and quality issues, so shared spreadsheets are prone to get out of sync with related product and quality records.

SOLUTION: Connected Product Management

With Arena, the product record is connected to the project management schedule and all impacted teams have access. This approach aligns better with the nature of distributed teams today, allowing every stakeholder increased visibility, access, and ability to update and share comments or changes with the entire NPDI team. Engineering, design partners, purchasing, manufacturing, CMs, and external suppliers can view the phases, tasks, and milestones in context with the product record throughout the product lifecycle. Team members are freed from most of the coordination and communications tasks involved in traditional project management. Instead of meeting with or calling other team members, they can simply bring up the current project status on their screen.

This more connected project management approach ensures components, BOMs, documentation, design requirements, and even defects can be linked—giving impacted teams full context and added visibility to accelerate the NPDI process.

Enabling NPDI Regulatory Compliance

CHALLENGE: Managing Compliance With Ever-Changing Regulations

In addition to managing effective projects, many companies are faced with everincreasing regulatory compliance requirements. Failure to successfully oversee regulatory compliance issues can not only delay or derail product launches, it can result in warnings, fines, and even company shutdowns. For example, the widely publicized problems at Theranos can be attributed to the fundamental inability of the company's products to comply with FDA regulations. Even minor regulatory issues can create serious delays getting products to market. PRG's Mike Keer explains one example where a company recently designed a product it thought would have no difficulty passing UL and FCC emissions. However, the product failed the emissions tests three times. Each failure required a redesign of several weeks, including engineering time and building a new prototype. The issues were not major, but they still set the product launch back three months, which significantly reduced the revenues generated by the product.

SOLUTION: Embedded Compliance

Ensuring your product meets applicable regulations is often the responsibility of quality assurance and regulatory assurance teams with expertise in monitoring and complying with constantly evolving regulations and standards. These teams drive the validation process to guarantee that products and development processes meet regulatory requirements. Arena helps simplify and expedite both regulatory (e.g., FDA, ISO) and environmental compliance (e.g., RoHS, REACH, WEEE, Conflict Minerals) by managing the required product, training, compliance, and quality records in a single system.

MATCHED PART	DESCRIPTION	MARKET AVAILABILITY	STATUS	RISK	DATASHEET	ROHS	REACH	CONFLICT MINERALS	PCN
68000-406HLF Amphenol ICC	Conn Unshrouded Header HDR 6 POS 2.54mm Solder ST Top Entry Thru-Hole BergStik® Bulk	26,391	Active	•	Datasheet	RoHS	REACH	Conflict	PCN
SN74HCT540N Texas Instruments	Buffer/Line Driver 8-CH Inverting 3-ST CMOS 20-Pin PDIP Tube	33,628	Active	0	Datasheet	RoHS	REACH		PCN
Lookup is disabled for this Supplier.									
293D106X9010A2TE3 Vishay	Cap Tant Solid 10uF 10V A CASE 10% (3.2 X 1.6 X 1.6mm) Inward L SMD 3216-18 3.4 Ohm 125°C T/R	1,880,590	Active		Datasheet	RoHS	REACH		
LTST-C191TBKT Lite-On Technology	LED Low-Power Uni-Color Blue 468nm 2-Pin Chip LED T/R	822,036	Active		Datasheet	RoHS	REACH	Conflict	PCN
RC0402FR-0712K1L Yageo	Res Thick Film 0402 12.1K Ohm 1% 0.063W(1/16W) ±100ppm/°C Pad SMD T/R	6,234,781	Active		Datasheet	RoHS	REACH	Conflict	PCN
RC0402FR-071K5L Yageo	Res Thick Film 0402 1.5K Ohm 1% 0.063W(1/16W) ±100ppm/°C Pad SMD T/R	10M+	Active		Datasheet	RoHS	REACH	Conflict	PCN
RC0402FR-071ML Yageo	Res Thick Film 0402 1M Ohm 1% 0.063W(1/16W) ±100ppm/°C Pad SMD T/R	663,381	Active		Datasheet	RoHS	REACH	Conflict	PCN
08056G106ZAT2A KYOCERA AVX Components Corporation	Cap Ceramic 10uF 6.3V Y5V -20% to 80% Pad SMD 0805 85°C T/R	8,611	Unconfirmed		Datasheet	RoHS	REACH	Conflict	
C2012Y5V1A106Z TDK	Cap Ceramic 10uF 10V Y5V -20% to 80% Pad SMD 0805 85°C	n/a	Obsolete	0	Datasheet	RoHS	REACH		PCN

Arena's Supplier Item Lookup provides regulatory and material availability information to eliminate risks to ensure compliant parts can be sourced when needed.

Arena also electronically tracks and maintains requirements, test details, and electronic approvals linked to the appropriate part of the product record. Arena tracks design control elements and deliverables for the impacted product, quality, and production teams. This simplifies regulatory compliance and ensures responsible team members are always aware of key action items and project deliverables. Maintaining regulatory information in context with the product record makes it easy to respond to and pass audits, ultimately speeding product launches. Furthermore, for medical device manufacturers, Arena manages device master records (DMRs), design history files (DHFs), and validation maintenance services to simplify FDA compliance and software validation. This ensures quality processes meet intended uses per FDA Title 21 CFR Part 820 (i).

CONCLUSION

Today's innovators are continually increasing design and configuration complexity and compressing product launch cycles to drive growth in the face of intense global competition. The convergence of mechanical, electrical, and software design, along with the advent of the IoT, means it's crucial for multiple disciplines to freely share information. Hence, NPDI processes require distributed teams to collaborate in real time to deliver high-quality products to market fast.

The modern way to speed product launches involves using a single cloud-based system that will empower teams to collaborate throughout NPDI and beyond. Providing cross-functional teams with a single product realization solution to aggregate the entire product record provides better visibility to all teams, ensuring faster and more successful product launches.

Arena enables the product realization process, enabling seamless sharing of product information with connections to change, quality, training, and related product processes. This connected single system Arena's product realization solution bridges NPD and NPI processes with connections to:

- Complete product record including hierarchical BOMs
- Quality and corrective action preventive action (CAPA) processes
- Project management information
- Product requirements and issue tracking
- Component lifecycle and compliance information
- Product and quality analytics
- Employee training records
- Upstream and downstream systems

accelerates NPDI processes throughout the product lifecycle. Real-time collaboration is further enhanced by Arena's cloud-based platform to enable dispersed product teams to collaborate securely and effectively. The result is OEMs, ODMs, and supply chain teams are empowered to create innovative products with breakthrough capabilities and unparalleled levels of performance, while meeting regulatory, scheduling, and budget constraints.

REFERENCES

i https://www.investopedia.com/terms/m/mooreslaw.asp

