

Improving Global BOM Management for Life Science Companies

Unify Your Product Definition with a Single Enterprise Solution

Executive Summary

Today's life science companies are struggling in their attempt to efficiently design complex products, sometimes adding multiple options in order to meet the requirements of various market segments. These product options represent an increasingly elaborate, interconnected web of hardware and software features. To get these product options right, companies must expend a massive manual effort. For starters, multi-discipline, geographically dispersed product development teams must be constantly coordinated to define these options. At the same time, traceability must be maintained to a consistent set of requirements.

Most current processes and systems have been optimized to support yesterday's less complex requirements. In applying them to today's realities, the results are:

- Blown timelines
- Poor-selling products
- High costs

There is a better way: a revolutionary Product Development System that synchronizes system requirements, multiple design disciplines, and internal systems to provide a single definition of a product – 'a single source of truth' – throughout the product development process. With a Product Development System, companies can greatly improve the quality of their bill-of-material (BOM) information, incorporate more sophisticated product options, and improve their operational efficiency.

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Challenges in Global BOM Development

Life science companies are increasingly turning to the delivery of a wider array of products and product options in order to expand market share and grow revenue. In some cases, customers are demanding greater personalization of the products they buy (i.e., personalized medicine/healthcare). However, determining the right set of designs, features and options to offer isn't just a marketing issue; it's also a major issue for product development. Getting this right is what revolutionizing global BOM development is all about – ensuring that the product meets market requirements efficiently.

Life science companies that struggle with global BOM management typically suffer from the following:

Blown Timelines Due To:

- Lack of visibility throughout the design process
- Lack of current project status
- Late-stage changes due to inability to track product dependencies across disciplines
- Inadequate ability to track or manage changes, leading either to rework or, worse: scope creep
- Lack of an effective means to synchronize the software, hardware and electrical product development processes

Poor-selling Products Due To:

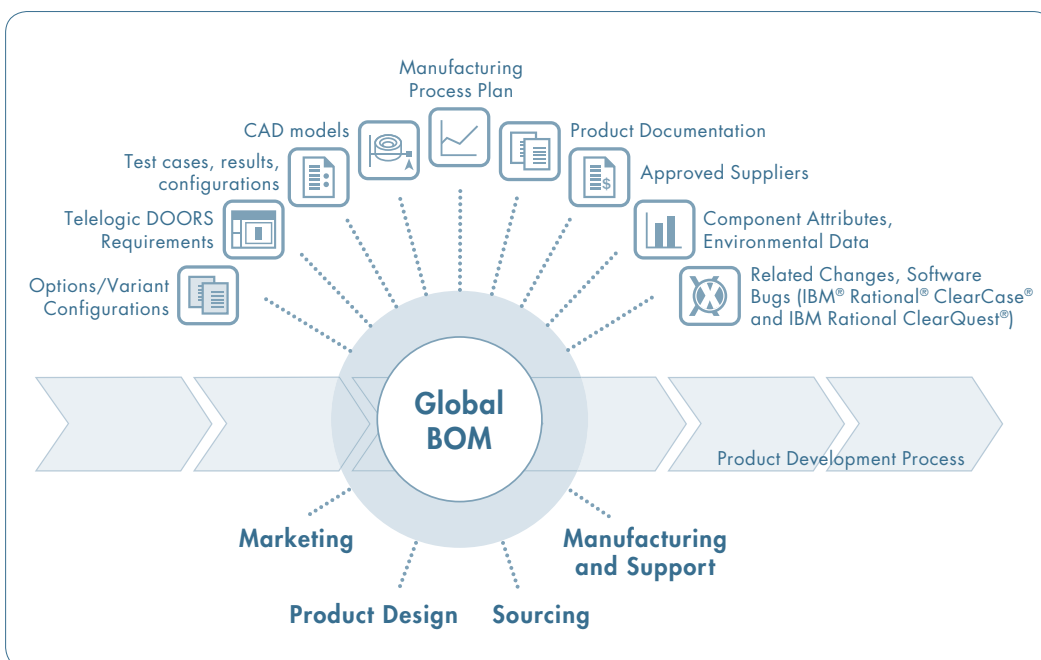
- Missed market delivery dates
- Limited visibility into whether key requirements are addressed
- Requirements specifications don't reflect the real customer/market needs
- Limited ability to offer tailored options and services to customers due to the complexities of managing their design and development

High Costs Due To:

- Ineffective design reuse, especially in software and hardware design
- Inefficient processes
- Inadequate collaboration between manufacturing and key suppliers during the product development process
- Late discovery of missed or inaccurate requirements

As shown in Figure 1, there are many organizations involved in the definition of a product, from Marketing to Engineering to Manufacturing to Sales. In today's life science companies, each of these organizations has their own definition of the product. Marketing has a view that includes requirements and features. Engineering has a view that shows specifications and detailed design configurations. Manufacturing has yet another view. The challenge is that all of these views are highly related, and a change to one can have a significant impact on the other. In most companies, however, those relationships are managed in separate documents or systems, making the management of such traceability almost impossible.

Figure 1: Ideal view of a single definition of a product that spans the entire lifecycle, and connects all disciplines and organizations around a common understanding.



Connecting the different views, and allowing all disciplines and organizations to operate from the same set of data, can have beneficial effects on a company's performance. For example, Procurement has initiatives to reduce the number of suppliers and components. By providing designers with access to the preferred list of suppliers and components, Procurement can enable designers to make better decisions from the beginning of the product development process. As a result, Procurement won't have to 'scrub' the design later to align it with their objectives. In a study of manufacturers conducted by PTC, IBM® and Reed Research, companies that enable early designer access to enterprise and supply chain data achieved 20% higher revenue growth than companies that did not.

Similar value is seen by connecting Manufacturing and Design. Most companies are trying to develop their manufacturing process plans and work instructions earlier in the product development process to speed the transition to volume manufacturing. As a result, Design and Manufacturing engineers face daily challenges of ensuring that the current version of manufacturing data accurately reflects the correct engineering model. In fact, 94% of the respondents to a recent PTC survey claimed that their number one product development concern is "coordination between Engineering and Manufacturing BOM's." By allowing both Design and Manufacturing to operate off a common-definition or 'global' BOM, dependencies and impacts can be more readily identified.

In addition, a trend in the life science industry is to use software, rather than hardware, to enable product options. While this is a valuable and quite often necessary approach, it also serves to complicate an already complex process. In most companies, software development organizations operate separately and have limited day-to-day interaction with their related hardware design disciplines. As the global development and delivery of products has increased, silos of information have grown up around these organizational divides. In fact, while software developers should be intimately tied to other development and implementation teams, collaboration between these organizations has proven to be an increasingly challenging task.

All organizations involved in product specifications, design, development and manufacturing struggle to work from the 'same page'; what they all seek is 'one version of the truth'. From the start, a consistent view of the requirements for the product is highly desirable. Requirements may impact electrical, mechanical, electronic and software components of the product, and place dependencies on the manufacturing process. The ability to track how those requirements are satisfied by product features and components could enable thorough impact analyses should the requirements change.

These problems are widespread. A survey conducted by Manufacturing Business Technology Magazine demonstrates the impact of improperly coordinated cross-discipline design. The survey results show that, due to poor synchronization between the various design disciplines, 64% of surveyed manufacturers experienced late-stage changes at their companies, 57% suffered delayed product launches, and 40% cited blown budgets.

To better understand why these issues occur, it is useful to consider a day in the life of a product development organization.

A Day in the Life of a Product Development Organization

In this example, a fictitious life science company, MedCo, plans to introduce a new medical device: an extremely small, wireless camera that captures images from inside the human body which can then be sent wirelessly to a computer. This product would eliminate the hassle of connecting cumbersome cords and installing software on a computer in order to download photographs.

Creating this product requires a complex combination of multiple design disciplines that are geographically distributed between the US, India and Taiwan. Multiple mechanical, electrical and software design teams are required to develop numerous mechanisms in the camera, including microelectronics, advanced software, miniature printed circuit boards (PCBs) and wireless capabilities. To further complicate the product development process, 25% of the software development is being outsourced to a third party in India, and the layout of the PCBs is being outsourced to a design house that specializes in miniature PCBs.

Given these factors, here are some of the key product development challenges facing MedCo:

Challenge: Understanding the Latest Project Status

MedCo has assigned a Program Manager to manage the entire product development program to design and launch the new camera. The Program Manager is responsible for making sure the project meets the agreed upon market requirements, as well as the internal requirements, including budget and time-to-market. In order to accomplish these goals, the Program Manager must collaborate with the Project Managers responsible for the development projects required to get the product out the door.

The Program Manager calls a meeting to review and understand the current program status across the multiple projects governing the development of the camera. The Project Manager for the image capture device needs to collect information from several different development managers prior to this meeting. The development managers communicate their status to the Project Manager via email. This proves to be an ineffective way to collaborate, as the Project Manager finds it difficult to get a comprehensive view of the project's status from the emails. He finds that it's nearly impossible to determine the impact of any problems that may exist at any given time. For example, electrical and software teams are working together on the image capture device, but are they in synch? Do dependencies exist between the teams that are not being tracked?

The Project Manager has a hard time even finding the latest design status because each design team has their own silo of information. For example, electrical data is stored on a file server, while software-related data is stored in IBM® Rational® ClearCase® and ClearQuest® servers. No single product definition exists that would provide complete visibility into the design process, since the definition information is scattered throughout the enterprise. As a result, the Project Manager is not able to provide completely accurate data to the Program Manager during their meeting. Both managers privately fear that potential problems may be hidden. Unforeseen risks may be lurking, which may only be discovered late in the product development process.

Challenge: Understanding If the Design Meets the Requirements

As the project proceeds, several changes have been made to the camera since the original specification was developed, particularly to the user interface and hardware components. MedCo does not have an integrated system in place that can track and manage the potential impact these changes may have on the overall requirements document. As a result, it is difficult to assess whether the current design still meets the requirements. It is left to the Project Manager or Development Manager to perform a manual check. Because the product specification is not linked to the original requirements document or to the product design as it unfolds, traceability between the requirements and design is lost.

The process of determining if the product requirements are met by the design is often called “requirements traceability”. Figure 2 shows all of the relationships that need to be maintained and managed during this process, which is clearly very difficult using a manual approach. As in MedCo’s case, the result is a significant number of errors that eventually lead to delivering a product that does not meet all of the key requirements. Since project schedules are tight, it is both difficult and costly to accommodate either a re-spin, software fixes, or other needed changes this late in the process.

Challenge: Maximizing Design and Software Reuse

When MedCo software engineers begin creating code for the LCD device driver, the first thing they do is find existing code that can be used as a starting point. However, MedCo’s software data is stored in disparate systems and isn’t associated with a product or project. As a result, it is extremely difficult to search for and find appropriate code that can be reused, even though such code exists. The software engineers must then start from scratch, thus duplicating effort and increasing software costs. Product quality also suffers because when designers reuse existing software, they benefit from the previous designer’s having retested the same code over and over again, which improves the product’s quality over time. MedCo now has a higher volume of software to develop, integrate, test, debug and certify. The result: additional costs and wasted time are incurred.

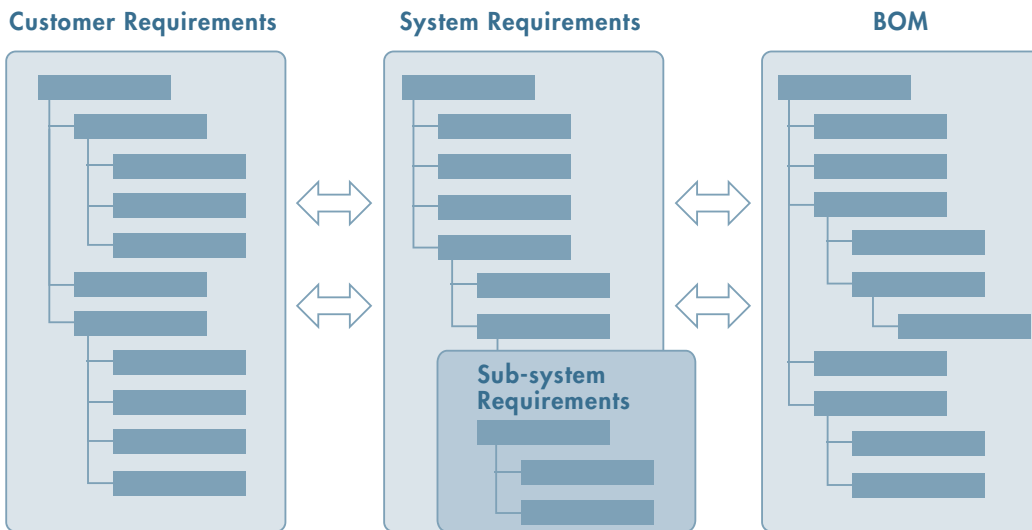


Figure 2: System requirements are traced back to the original customer requirements, as well as to the bill-of-material. Linking requirements in this way can offer a better understanding of the relationship between the design and its flow-down requirements.

Challenge: Managing Multiple Options

MedCo's wireless camera design has a variety of options described in the product specification document. These options include different optical zoom ranges and different battery options. Certain options need to be correlated with each other. For instance, the power needed for a 10X optical zoom requires a 1200 mAh battery, at a minimum, to be included in the camera. This compatibility issue is one of several identified during the design process. These issues need to be documented so that MedCo doesn't offer consumers incompatible product options. However, there is no system in place for engineers to document these issues. Procurement and Marketing have no visibility into these issues, which results in inaccurate BOMs, error-laden data sheets, and, ultimately, customer dissatisfaction.

Challenge: Integrated Change Management

After assessing the estimated product cost, it is determined that the product is too expensive. At a product review meeting, the hardware and software engineers realize they can reduce costs by enabling some of the key features with software rather than expensive hardware components. Since these adjustments will change the specification and system requirements documents, an engineering change process is required. However, the Program Manager struggles to keep track of the change process, since the hardware teams use different change management processes and tools than the software teams, who only use bug tracking software. The Program Manager is forced to continually follow up with the Software Development Manager to determine when the software fix will be completed. As well, the Program Manager must continually follow up with the Hardware Engineer and Printed Circuit Board Designer to determine the status of their work. All of these activities are highly manual, inefficient and error-prone, which results in late-stage changes due to unforeseen problems.

Challenge: Connecting the Software Development Process to the Overall Product Configuration

When Medco's camera design is released to manufacturing, the mechanical drawings are transferred to an FTP server so that the contract manufacturer can access the files. The electrical drawings are FTP'd to a different contract manufacturer. Firmware is emailed from one software team, while executables (operating system, applications, etc.) are transferred to an FTP server by another software team, so that the MedCo final assembly facility can access them. During testing at the assembly facility, it is determined that the new audible tone features are not enabled. Upon investigation, it is determined that the wrong software version was incorporated into the product. The correct version needs to be tracked down by the Project Manager working with the Development Manager, and then released to manufacturing again. This process delays manufacturing by several days, negatively impacting shipment milestones.

Challenge: Engineering and Manufacturing Collaboration

As mentioned above, in an effort to save costs, MedCo engineers need to make a significant design change between hardware and software partitioning and still meet key requirements. This major change impacts the PCB fabrication and assembly step of the manufacturing plan. Since the manufacturing plan and manufacturing BOM are already being developed, the plan needs to be overhauled and the manufacturing BOM needs to be revised. Because MedCo doesn't have a system in place to link these documents, a lengthy manual effort between the designers and manufacturing engineers is required to synchronize the plans. Not surprising in such circumstances, a key assembly step is overlooked and goes unnoticed until manufacturing starts. The impact will be a late-stage change that delays the scheduled product launch date even further.

A Better Way: A Product Development System

PTC, in alliance with IBM® Rational®, provides a single system to improve life science manufacturers' management of global BOM and product definition activities. This single system, the first of its kind, is called the Product Development System, or PDS. The PDS improves the life science manufacturer's ability to view, understand and manage the overall product definition globally.

Key aspects of the Product Development System (PDS) include:

- Complete, multi-discipline product definition synchronized by a single enterprise system
- Management of options and variants, product families, and configuration processes, such as assemble-to-order (ATO), engineer-to-order (ETO), configure-to-order (CTO) and build-to-stock (BTS), from the earliest stages of design
- Integration with IBM® Rational® ClearCase® to: facilitate tight linkages between software and hardware development; to synchronize change and configuration management; and to enhance the ability to find and reuse existing and proven software assets
- Integration with Telelogic® DOORS® for overall requirements management and traceability with product configurations and product options
- Secure global access, facilitating global collaboration while protecting intellectual property (IP)
- Manufacturing Process Management (MPM) with associative linkages between engineering and manufacturing BOMs to facilitate concurrent development

How the Product Development System Overcomes Key Challenges

The first step to improving global BOM development is to make multi-discipline design data accessible in a controlled fashion using the Product Development System (PDS). The PDS breaks down the barriers between different silos of product data, such as those systems used to manage mechanical, electrical and software data. With Windchill®- PTC’s content management and process management software – as its cornerstone, the PDS provides a complete product definition in a single system. In addition, product options, and the various compatibility rules associated with them, are accessible in this single PDS. See Figure 3.

Once all of this data is managed in the PDS, the next step is to optimize and automate the processes that govern product development in a global environment, such as change and configuration management. One of the key benefits of having a single definition of a product is how much easier it is for everyone to understand the impact that a change will have on different disciplines across product development. This knowledge is enabled through the linkage between the change workflow in IBM Rational ClearCase. In addition, the system can identify any potential unforeseen consequences to customer requirements through the linkage to Telelogic DOORS.

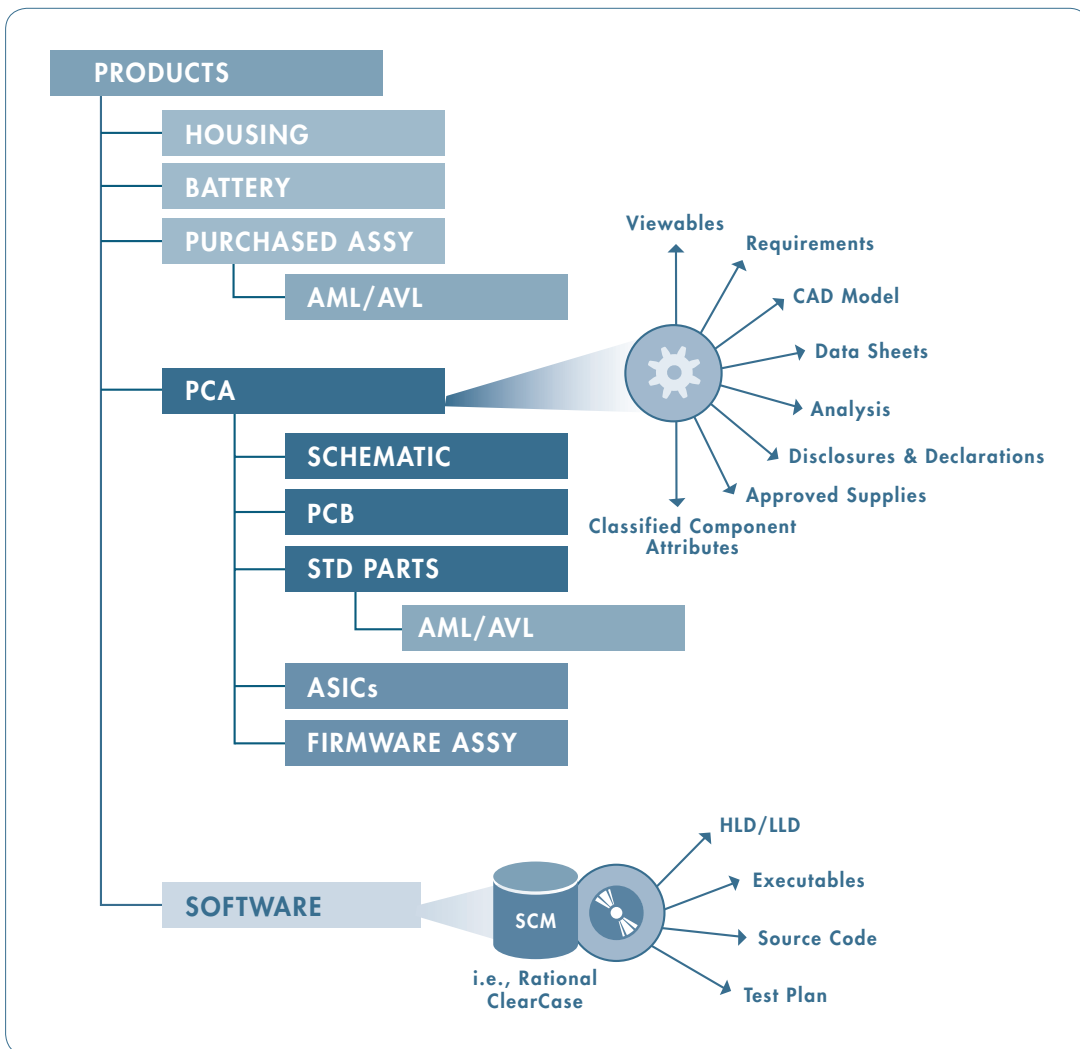


Figure 3: A single definition of the product is being managed in a single system – the Product Development System (PDS) – which ties together all facets of product and component data that drive the product development process. Requirements from Telelogic DOORS, and software objects from Rational ClearCase, are linked with the overall product definition managed within the PDS, as shown.

Let's take a look at how the PDS can address the product development challenges at MedCo:

Solution: Understanding the Latest Project Status

By synchronizing all product and process-related information in a single enterprise solution, the PDS offers MedCo unprecedented visibility into the latest project status. MedCo program and project managers can now link their project execution tools with the product development environments using Windchill's project execution capabilities. This solution provides MedCo with a clear view of dependencies and real-time status across teams, eliminating the need to manually search through cryptic emails from the various development managers to determine status. Project managers can now anticipate problems and prevent them from occurring, reducing the unforeseen risk that plagued them previously.

Solution: Understanding If the Design Meets the Requirements

The PDS provides traceability between requirements and design objects. Now, when a MedCo designer changes a key aspect of the design, that change can be traced back to the original customer requirement. In MedCo's case, Telelogic's DOORS manages requirements and seamlessly integrates with the PDS to provide traceability with the product BOM. This traceability will allow the designer to understand the potentially unforeseen impact a change might have on other aspects of the product or designs. MedCo now has the unprecedented capability to determine how well the product design meets requirements at any stage of the design process.

In addition, Telelogic DOORS automatically flags traceability links as 'suspicious' if either the source or target of the link has changed. Thus, if a product requirement has changed and it is linked to multiple design elements, each of those links will be marked as 'suspicious,' indicating that the change to the requirement has a potential impact on those design elements. This feature works in the other direction as well. Such impact analysis facilitates accurate scoping of the effort to implement a change before it is made, and ensures that approved changes are fully and correctly implemented. Thus, if a requirement will impact both a software and a hardware component, a change to that requirement is flagged as such, and the product team can ensure that both components are changed to meet the revised requirement.

Solution: Maximizing Design and Software Reuse

As mentioned above, one of the first steps to improving global BOM development is getting designs and product structures under the control of a single enterprise system: the PDS. On top of managing this data, the PDS provides advanced parametric search capabilities coupled with the industry's most robust classification system. This solution spans hardware, electrical and software disciplines through a deep integration with the IBM Rational product suite, including IBM Rational ClearCase and Telelogic DOORS. This combination of solutions will enable MedCo designers to quickly and accurately search in one place for previous designs.

Now, when the MedCo designer starts the task of designing the LCD driver, they can easily search the PDS to find an LCD driver that already exists. By accessing the complete product definition for the driver, the PDS provides the information necessary for the engineer to determine whether the existing driver can be reused to address the new requirement.

Solution: Managing Multiple Options

MedCo engineers need strong tools to support the design of multiple options and to communicate any compatibility issues between them. Now, with the PDS, MedCo engineers have a solution to maintain all potential options during product development. The PDS allows engineers to easily visualize option combinations, document compatibility issues, and define product configuration rules within Windchill. MedCo engineers are now able to define compatibility rules between the battery and zoom mechanisms in a single system that is visible to Engineering, Manufacturing, Marketing and Procurement. Since the product and product options are tied back to the original requirements in DOORS, any impact on requirements can be identified and managed.

Solution: Integrated Change Management

The PDS, in combination with IBM's solutions for change management and embedded software development – Rational ClearCase and ClearQuest, enables MedCo to manage changes that span multiple disciplines. A single change process can tie together changes in both hardware and software development teams. MedCo now has a single workflow to make sure changes are implemented, tested, approved and released with proper visibility and notification. Heroic, manual efforts are no longer needed by Project Managers to keep track of change implementations. The change workflow in the PDS pulls all of the different organizations together, aligns them with a common process, and reduces confusion regarding latest project status.

Solution: Connecting the Software Development Process to the Overall Product Configuration

PTC, in partnership with IBM, delivers the PDS to drive synchronization across disciplines, preventing MedCo's problem of releasing the wrong ring-tone software with the camera. With this seamless integration between the PDS and IBM Rational ClearCase, program managers can tie together software artifacts with the overall product configuration, ensuring accuracy.

MedCo also struggled to collaborate with its external software development teams. The PDS offers them a way to control access and visibility to ClearCase data in support of collaboration between internal and external teams, while also protecting critical intellectual property (IP). Connecting all the product development teams to a single, central repository of the requirements, and having total traceability to all the product design elements and parts, ensures that all of the development disciplines are working from the same page.

Solution: Engineering and Manufacturing Collaboration

The PDS improves MedCo’s ability to perform Manufacturing Process Management (MPM) in synch with product development. Enabling design and manufacturing engineers to operate from the same design data, the PDS provides the tools they need to digitally design and manage all of their process plan deliverables concurrently with design. Now, changes on one side can be immediately correlated to the other, so that an impact of a design change on the manufacturing process plan can be identified and managed (see Figure 4). And, it is all tied back to the original market requirements. MedCo is now able to ship the new product on-time, with higher quality than any of their previous releases.

Conclusion: Clear Benefits of the Product Development System (PDS)

IBM and PTC have partnered to deliver a Product Development System (PDS) that can address the key challenges of global BOM management.

Companies that standardize on the PDS can differentiate themselves from their competitors by being able to:

- Improve the ability to meet diverse customer requirements in less time by managing multiple design variants in a single unified BOM

- Reduce time-to-production ramp-up by deploying one, integral change management process across distributed engineering disciplines, leveraging tight linkages between PTC’s and IBM Rational’s leading solutions
- Continuously improve the ability of mechanical, software and electrical engineers to work more closely via collaboration between PTC and IBM Rational
- Make release-to-manufacturing and manufacturing ramp-up as quick and efficient as possible, by linking the engineering BOMs and manufacturing BOMs to rapidly identify and resolve conflicts and changes
- Increase customer satisfaction and reduce warranty returns by ensuring that all products, components, and software content conform to the item and revision level documented by Engineering
- Make better decisions at the beginning of the design process by leveraging content in other systems like ERP, PLM, etc.

Learn More about the PDS
 For more information about how top companies are optimizing all facets of their operations using the Product Development System, please visit:
<http://single-sourcing.com/products/contentmanager/>

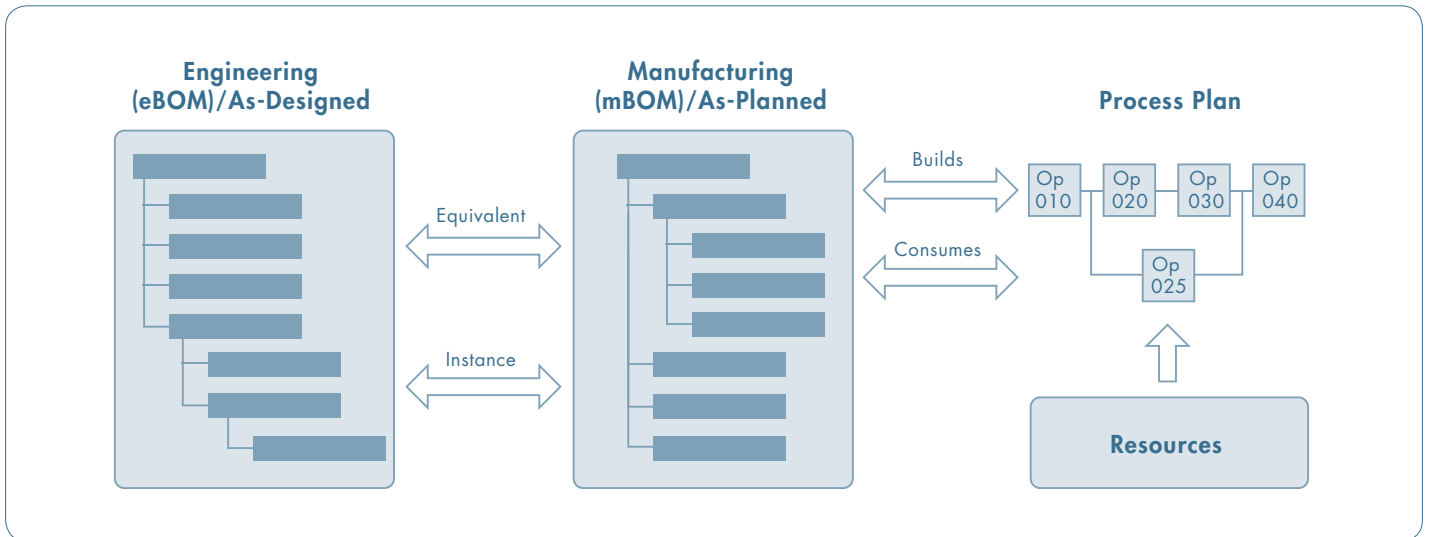


Figure 4: The Product Development System (PDS), with integral MPM (Manufacturing Process Management) capabilities, can associate the engineering BOM with the manufacturing BOM, as well as the manufacturing process plan. Thus, any user will be able to instantly see how a change to one area will impact another.

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