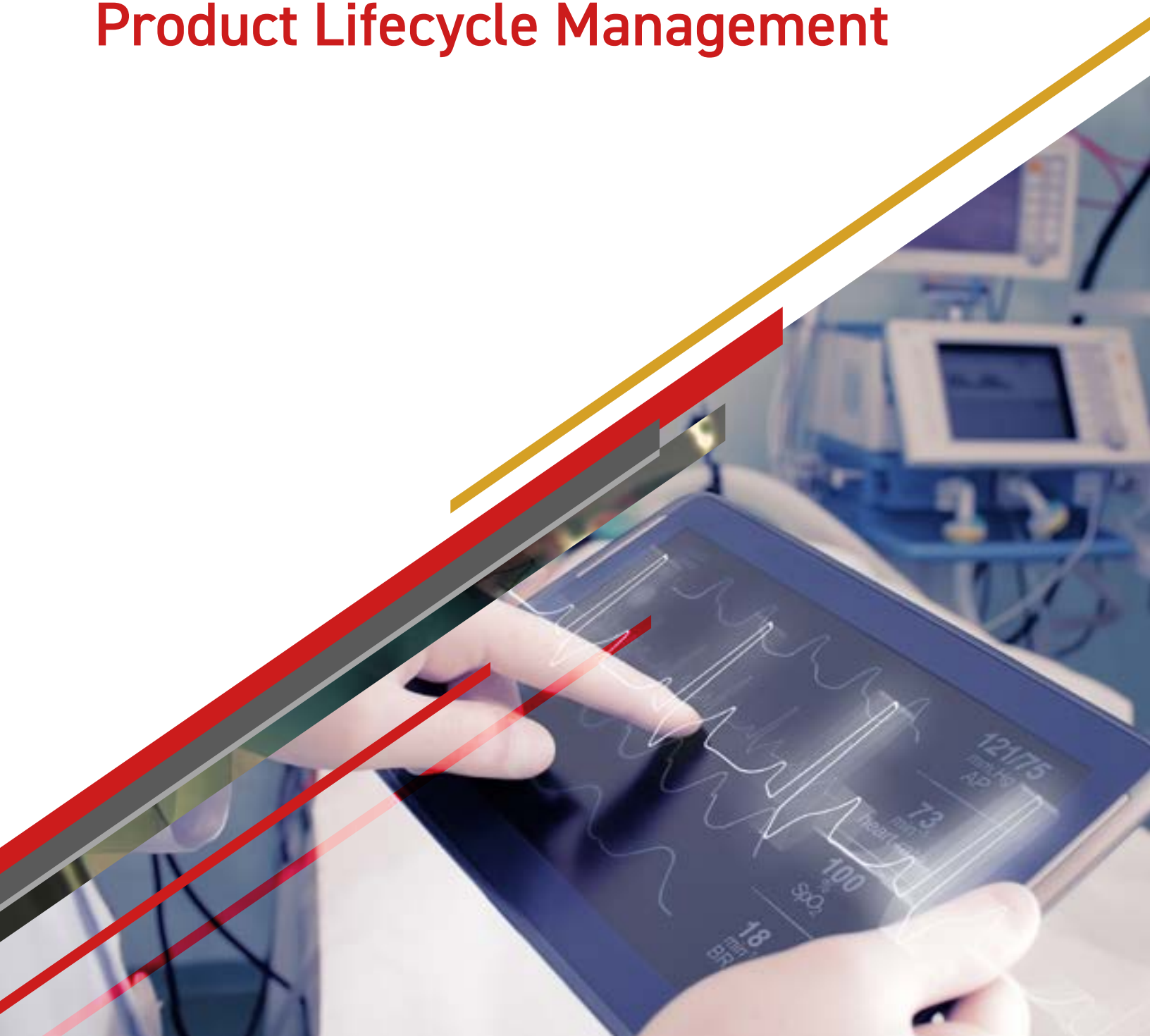
WHITE PAPER

How Medical Device Companies Can Benefit from Product Lifecycle Management



EXECUTIVE SUMMARY

More than ever before, medical device companies are being challenged to be more efficient and bring more products to market faster while reducing and controlling costs. Furthermore, Medical device companies often operate in a complex supply chain where they have to cooperate with many suppliers and partners. This can often make it difficult to achieve the expected results.

So, what challenges prevent medical device companies from achieving these goals? We see that processes, projects, and administration of information—handling everything concerning the product from cradle to grave—are not optimized throughout the business units and in the supply chain. This information encompasses everything from Device Master Records (DMR), Design History Files (DHF), engineering change orders to customer complaints, corrective and preventive actions (CAPA), and project data.

Typically, this information is scattered across different data islands—from locally created databases and spreadsheets to paper files. There is no connection between these systems and no transparency. Consequently, we often see the information is manually exchanged between these systems resulting in lack of agility, and a costly and ever-increasing administrative overhead.

Solving these challenges requires a new approach—a resilient, product development platform that gathers and combines these processes and information from the product concept, to product launch, and through to product retirement. The result is optimal process efficiency through the adoption of the best practice framework for the medical device industry, delivering an integrated administration of information. With these solutions in place, companies can reduce their time to market, reduce administrative costs, and reduce quality related costs.

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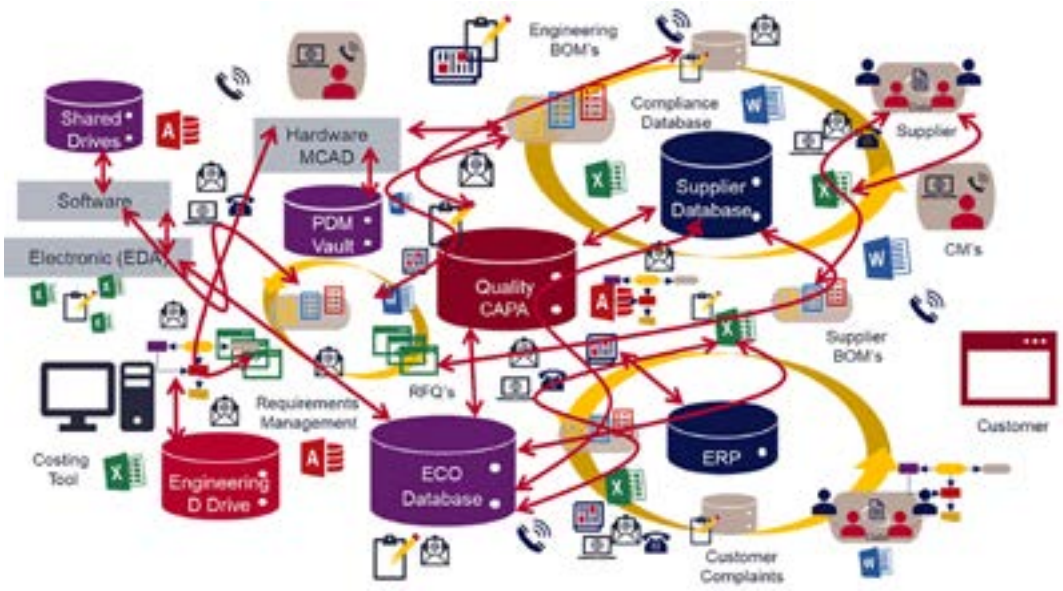
INTRODUCTION

In today's highly competitive landscape, medical device companies are striving to be more efficient, bring more products to market faster, while at the same time, reducing costs. Medical device companies operate in a complex supply chain that requires cooperating with many suppliers and partners. This does not make it easy to achieve the expected results. The challenges in handling products from concept, through launch to retirement are large and involve many processes across business units, extending to supply chain partners. Not only are the processes complex, but they typically involve multiple, isolated, independent databases, spreadsheets, and files as is illustrated below:

Bring Data, Processes and People (and systems) together



Aras has applied best practice processes to Aras Innovator resulting in a targeted solution creating order and efficiency when compared to the scene above. Products can be launched faster with full traceability and visibility throughout the whole process.

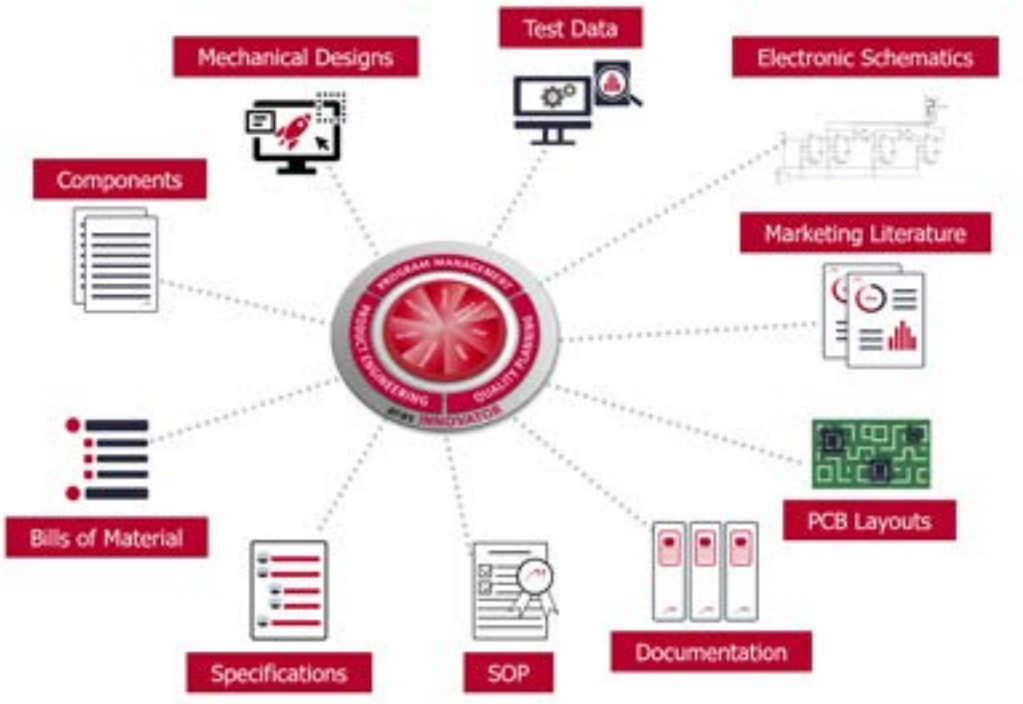
The solution's description is broken down into four main parts.

DEVICE MASTER RECORDS & DESIGN HISTORY FILE

Aras Innovator centralizes and creates a transparent structure for all product related information, Device Master Records, and Design History Files. Aras Innovator can coexist with existing document management systems. However, Aras Innovator provides an extra dimension that is not found in document management systems such as structure and relationship to documentation, bills of material (BOMs), and traceability. Documentation here includes specifications, standard operating procedures (SOPs), drawings, neutral viewable files, and test instructions, marketing information, and more. In other words, everything is gathered in Device Master Record (DMR) and Design History Files (DHF) in one system. Further processes such as change management are made more efficient through the use of best practice processes from the medical device industry and implemented in global electronic workflows supporting electronic signatures.

The information and processes are shared with relevant partners/suppliers through Aras Innovator supply chain architecture. By executing the global best practice method for engineering change processes, including extending out to the sub-suppliers, **reference customers have gained 70% efficiency** in reducing the time it takes to carry out changes.

Product Data Management



TIME TO MARKET AND NEW PRODUCT INTRODUCTION

Managing information like the DMR and DHF is important in improving efficiency, visibility into what is happening with the device, and much more. However, to have a bigger impact on reducing time to market and speeding up new product introductions, additional improvements are needed in early collaboration processes and global project and portfolio management.

Many companies today have established the phase gate model for development projects but managing and executing them in an efficient way can still be challenging for many companies. There is often a lot of energy spent on ensuring that deliverables in each phase are completed and approved. Getting and maintaining a clear picture of the status of the project and connecting that to the development of the project (DHF, SOP etc.) is not easy due to many dislocated data islands for both project and product information. It gets even more challenging when executing and managing a project that involves external partners such as design partners, contract manufacturers, or tool manufacturers.

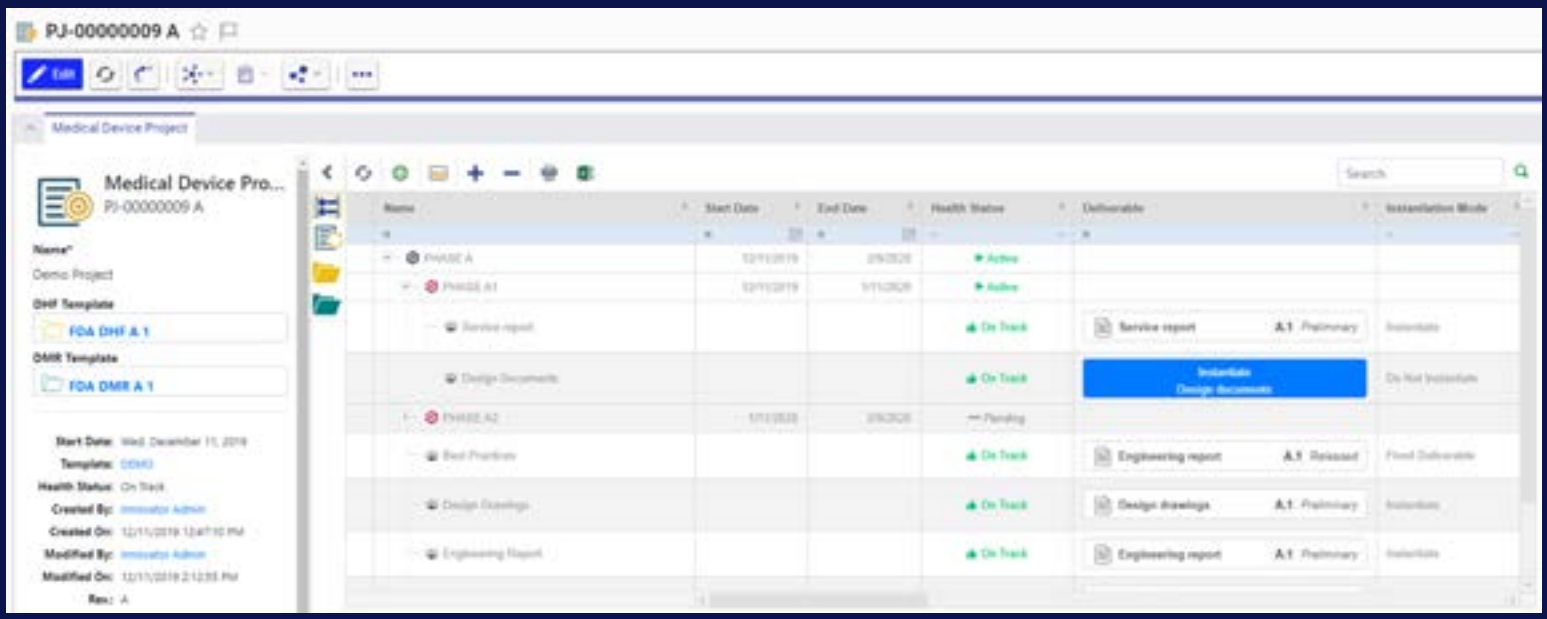
Finally, collaborating across departmental boundaries early in the development cycle is proven to be an important factor to reduce time to market. But executing a project of high complexity is challenging as companies are relying on too many manual processes to execute and manage these projects efficiently.

The power of Aras targets these challenges and more. Connecting the project plan to deliverables, connected to product data management (DHF, DMR, etc.), is essential to achieving results. This creates a holistic view, allowing the company to develop rapidly deployable phase gate templates where the project plan is connected to deliverable templates of documents, CAD models, and more, each with milestones and lists of responsible parties. The project status is automatically driven from the users' work. Activities are completed when users check-in their deliverables which have been routed through an approval workflow with compliant electronic signoff. If the approval is a part of the DMR, it is placed in the correct location as everything is maintained inside the solution. These capabilities are not restricted to internal collaboration and can include any number of

supply chain partners required to bring this product to market. Aras becomes the innovation platform, improving cross departmental collaboration, providing complete visibility to requirements and tasks as well as the supporting information for other departments to execute automatically throughout the process.

As the status is updated from individual activities of project members, the status on the entire project is rolled up into the portfolio level as well. This optimizes visibility and improves management time spent. With this level of visibility, management can limit meetings, focusing only on exceptions instead of spending time on the entire project portfolio. With this information, management is empowered with the insight needed to optimize their work and make better decisions.

In addition, global resource management is an integrated part of the solution with improved project issue handling. Components used to improve time to market and product launches are illustrated below:

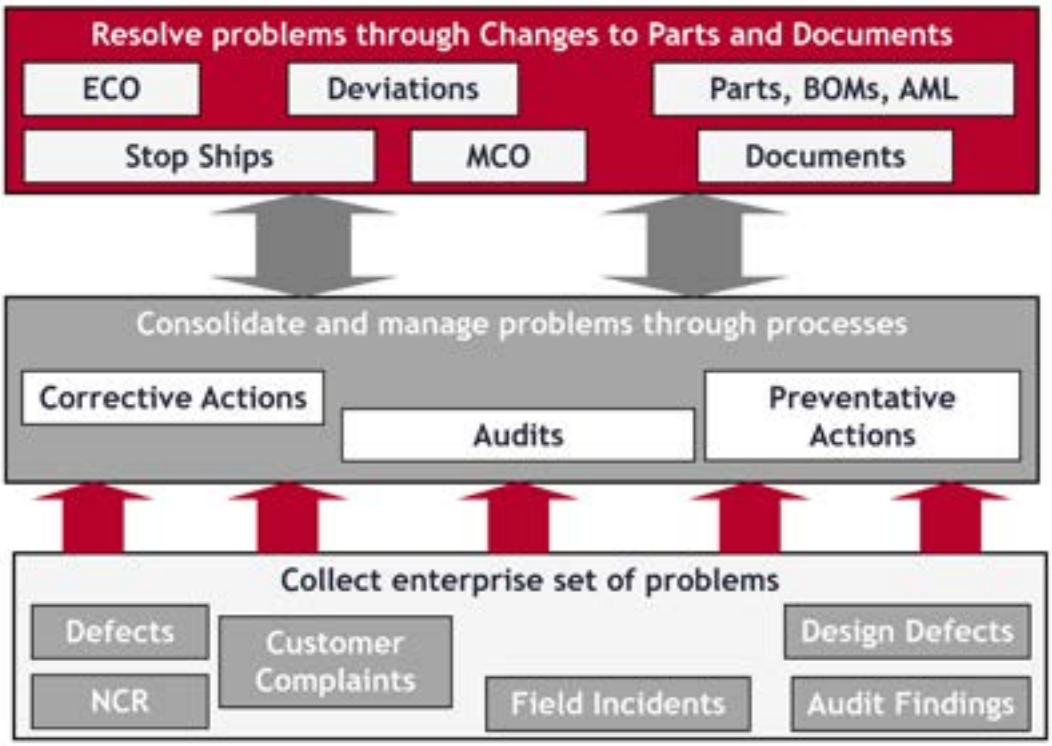


QUALITY, CAPA, AUDITS AND MORE

Medical device companies place a lot of emphasis on quality. Most companies have invested in getting best practice processes in place together with one or more quality related systems. The challenge is that there is no closed loop from the Quality system to the DMR which results in the need for manual procedures to ensure links are there, combined with manual work to ensure the entire process is executed. Often companies are spending a lot of time ensuring corrective actions are completed and the CAPA is closed and updated with the right information. Furthermore, companies are struggling with traceability when, for example, a customer complaint is at the top-level product, but analysis finds the issue is actually an error in a subassembly. In addition, transferring quality knowledge across the organization to prevent R&D from reusing designs or components that had quality issues is challenging when the information is spread across departmental data islands.

Aras' solution optimizes the process from beginning to end in one solution with best practice processes. Having the latest information in one solution improves visibility. The entire organization, including supply chain partners, have a clear view of current and historical device data and decisions. Processes from customer complaints through CAPA and engineering change are handled in one connected, closed loop solution ensuring compliance and providing a vast reduction in cycle times (See below):

Closed Loop Corrective & Preventive Action



Another area of focus for medical device companies is traceability. This is key for regulatory bodies audits and Requests for Information (RFIs) as well as for internal requests for a detailed product history. In order to reduce the time it takes to prepare for an audit or build a product history, it is important to have a solution that encompasses a comprehensive picture of functionality and information needed to generate that history. Aras Innovator has an out-of-the-box solution addressing traceability.

In addition, there are often additional company specific challenges for which support is needed. For that specific purpose there are a multitude of available solutions—ranging from training and skills tracking, requirements management, and much more—that companies can pick and choose from to meet their specific needs:

- Electronic & High-Tech industry solution
- Requirements Management
- Component Engineering
- Office Integration
- Variants & Options
- Part and Lot Traceability
- Lean Product Development
- Environmental Compliance
- CAPA / SCAR
- Manufacturing Process Planning
- Work Instructions & Routings
- Training & Skills Tracking
- Mobile Android, iPhone, Blackberry
- SharePoint Integration
- Full CAD Integration Suite
- ERP Integrations

Aras Innovator is designed to support regulatory body requirements like FDA, EUDAMED, and more as illustrated below:

Enabling Regulatory Compliance with PLM

Last but not least, medical device companies need a validated system to release the benefits of an electronic solution which can be a cumbersome job. Industry best practices for validation speeds up the validation process and reduces the administrative burden.

UNIQUE BUSINESS MODEL

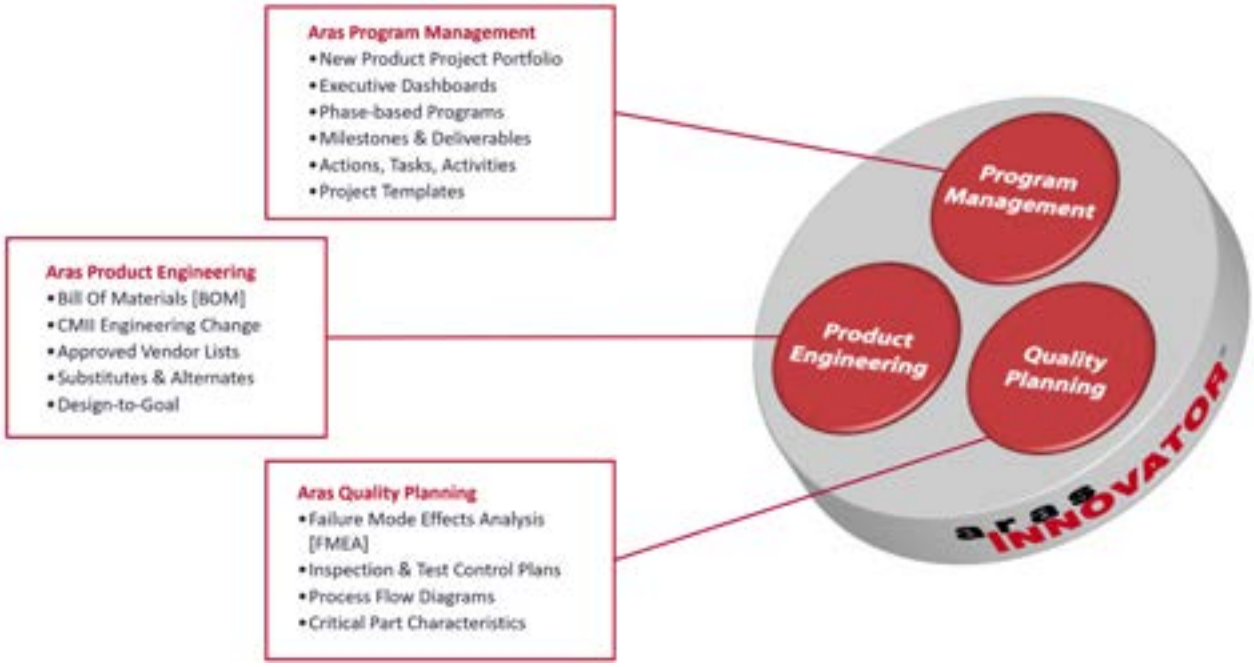
Aras offers customers a unique business model where a compressive enterprise software solution is offered without upfront license cost. This means the customer can get a solution that fully supports the most advanced requirements, but without having to spend the hundreds of thousands of dollars/euros/kroner traditionally required up-front just to get the software.

The business model is referred to as Enterprise Open Source, not to be confused with the old view of amateur development or old school open source. Enterprise Open Source is professionally developed by the company developing and supporting the product. The core of the product is maintained and developed by Aras.

Aras revenue is driven by annual subscription packages and consulting services. One unique thing about the subscription packages is that not only does it provide the usual support features known from traditional software vendors, but also includes upgrades of unique customers systems for free, which in the enterprise PLM space has never been seen before.

SUMMARY

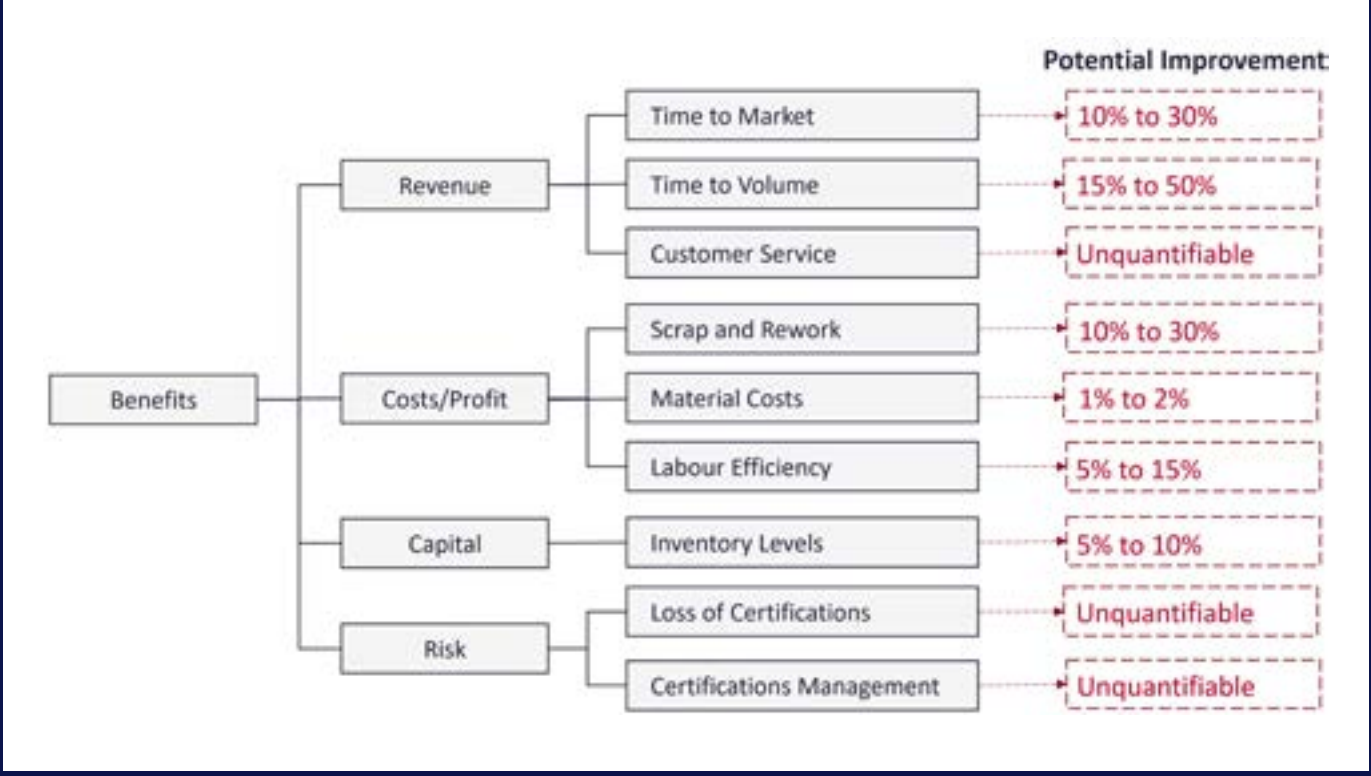
The out-of-the-box, best practice capabilities together with Aras Innovator is a complete solution designed specifically to optimize the development, design, manufacturing, and testing of medical devices.



Focusing on bringing more products to market faster, increasing efficiency, and maintaining an even larger product portfolio, all through a more complex supply chain, are just some of the factors motivating medical device companies to change and optimize.

Product lifecycle management in the medical device industry is growing very fast as there are now suppliers that have focused solutions for the very specific demands in this industry. The extensive number of visionary medical device companies that either have implemented a solution, or are currently evaluating them, provides evidence of the focus on the impact of these solutions.

The chart below illustrates some of the quantifiable results medical device companies have gained with the Aras solution.


Potential Improvement
Benefits
Revenue
Costs/Profit
Capital
Risk
Time to Market
Time to Volume
Customer Service
Scrap and Rework
Material Costs
Labour Efficiency
Inventory Levels
Loss of Certifications
Certifications Management
10% to 30%
15% to 50%
Unquantifiable
10% to 30%
1% to 2%
5% to 15%
5% to 10%
Unquantifiable
Unquantifiable

Aras provides the most powerful low-code platform with applications to design, build, and operate complex products. It's technology enables the rapid delivery of flexible, upgradeable solutions that build business resilience. Aras' platform and product lifecycle management applications connect users in all disciplines and functions to critical product data and processes across the lifecycle and throughout the extended supply chain. Airbus, Audi, DENSO, Honda, Kawasaki, Microsoft, Mitsubishi, and Nissan are using the platform to manage complex change and traceability. Visit www.aras.com to learn more and follow us on Twitter and LinkedIn.