Minerva PLM Executive white paper

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Executive Summary

Amongst the many demands on Medical Device companies are being more efficient, bringing more products to market faster whilst reducing and controlling costs. Further, Medical Device companies often operate in a complex supply chain where they have to cooperate with many suppliers and partners. This does not make it easier to achieve the results that are expected.

So what challenges prevent Medical Device companies from achieving these goals? We see that the processes, projects and administration of information, handling everything concerning the product, from cradle to grave, are not optimized throughout the business units and out in the supply chain. This information encompasses everything from Device Master Records, Design History Files, engineering change orders to complaints from customers, 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 interchanged between these systems resulting in lack of agility, and a costly and ever increasing administrative overhead.

Aras Innovator targets solving exactly those challenges in the Medical Device industry. It gathers and combines all these processes and information from the product concept, on to product launch and through to the 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. Thus companies can reduce their time to market, reduce their administrative costs and reduce their quality related costs just to mention some of the advantages that other companies have realized.

The solution is revolutionary as unlike any comparable solutions Aras Innovator is offered as a NO upfront license cost product. Essentially you save the entire upfront license cost which for most companies will be hundreds of thousands of dollars.

The solution has been adopted by many market leaders and has proven itself at large corporation such as CareStream Health Inc. However it is also widely used at medium sized and small companies

More information is to be found in the main body below.

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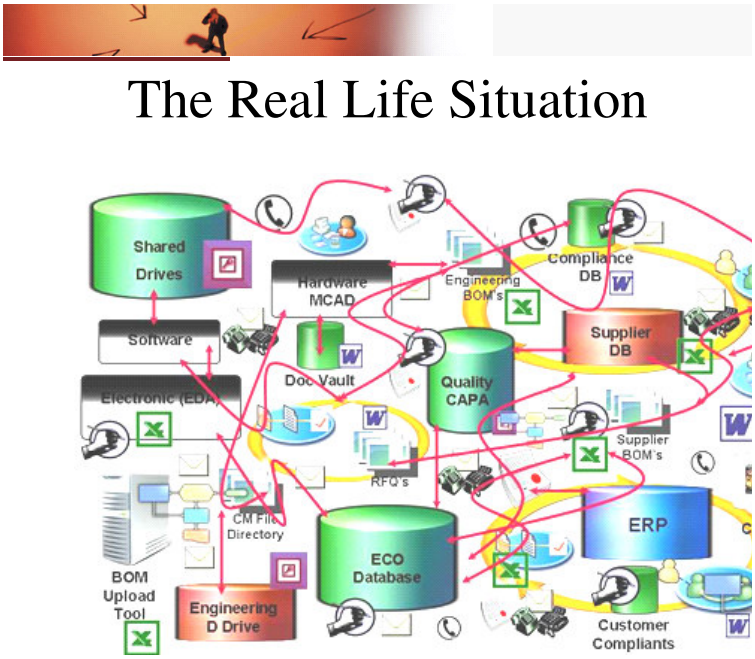
Introduction

The demands on Medical Device companies, amongst others, are to be more efficient, to bring more products to market faster and to reduce costs. Medical Device companies operate in a still more complex supply chain where they have to cooperate with many suppliers and partners. This does not make it easy to achieve the results that are expected.

The challenges in handling products from concept, through launch to retirement are large and involve many processes across business units, even extending out to supply chain partners. Not only are the processes complex but they typically involve many isolated independent databases, spreadsheets and files as is illustrated below:



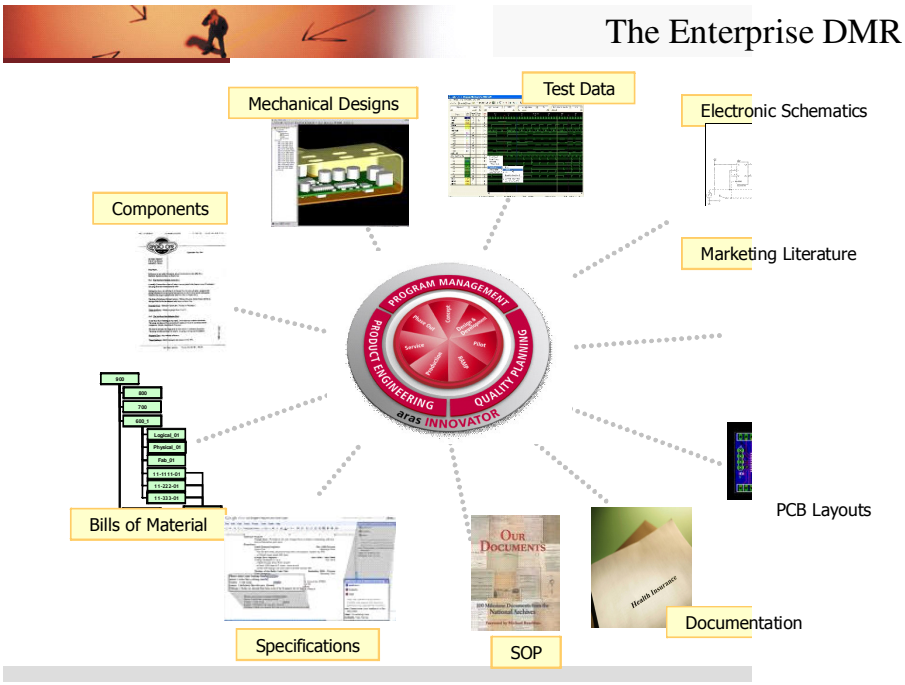
Minerva has applied best practice processes to Aras Innovator resulting in a targeted solution creating order and efficiency when compared to the scene above. Thus products can be launched faster with full traceability and visibility throughout the whole process.

To give a better understanding the description of what the solution is able to do it is divided into different sections.

Device Master Records & Design History File

The first thing Aras Innovator does is to centralize and create a transparent structure in all product related information, Device Master Records and Design History Files. Aras Innovator can co-exist with already existing document handling systems. However, Aras Innovator gives the extra dimension that is not found in document handling systems, which is structure and relation in all documentation, bills of material and traceability. By documentation we mean everything from specifications, SOPs, drawings and test instructions through to marketing information and more. In other words everything is gathered in Device Master Record and Design History Files in one and the same system. Further processes such as the handling of changes will be more efficient through use of best practice processes from the Medical Device industry which are implemented in global electronic workflows which support electronic signatures.

The information and processes are shared with all relevant partners/suppliers through Aras Innovator supply chain architecture. By executing the global best practice method for the 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.



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 there is a need for additional improvements in the area of earlier collaboration and better global project and portfolio management.

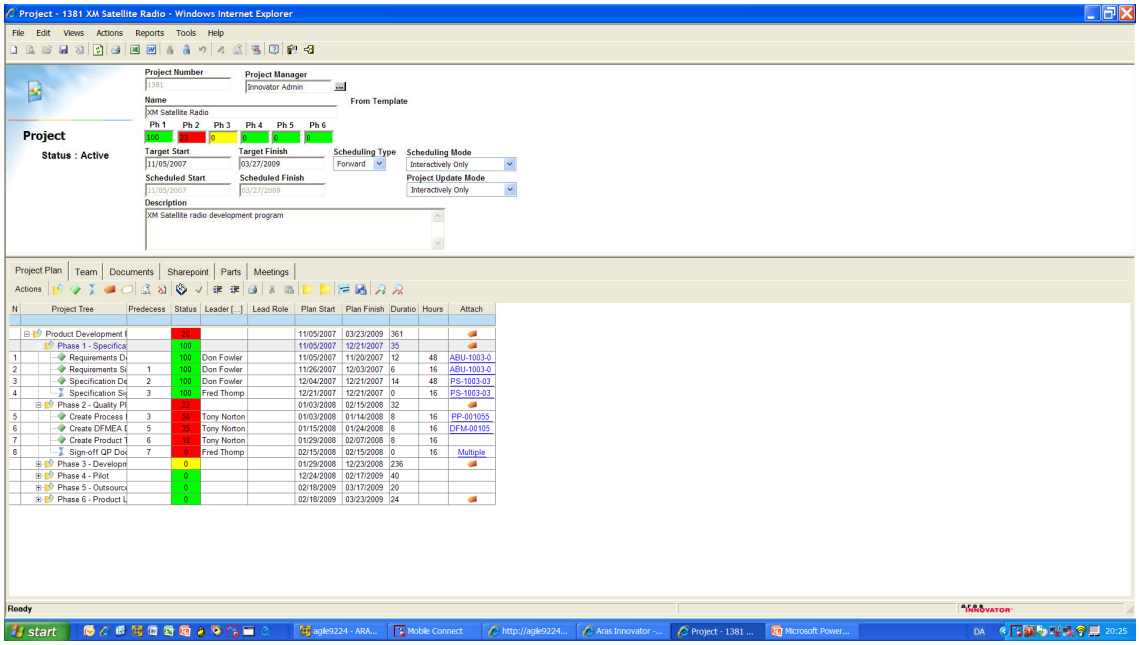
Most companies today have established the phase gate model for their development project, but managing and executing them in an efficient way can be improved in most companies. For many companies there is a lot of energy spent on ensuring that the deliverables in each phase are completed and approved. Getting a clear picture of the status of the project and connecting that to the buildup of the project (DHF, SOP etc) is not easy with many dislocated data islands for both project information and product information. It gets even more challenging executing and managing a project that involves external partners like e.g. design partners, contract manufacturers or tool manufacturers. Last but not least 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 that complexity is challenging as companies are relying on too many manual process to execute and manage these projects.

Minerva's solution targets these challenges and more. The essential thing is the project plan is connected to deliverables, which again are connected to the product data management (e.g. DHF, DMR, etc). This allows the company to develop templates of their phase gate model where the project plan is connected to deliverables with templates of what documents, CAD models etc have to be finished where and when. The status of the project is automatically driven from the users actions. Activities are completed when users check in their deliverables which are then routed through an approval workflow with (electronic) sign-off. If the approval is a part of the device it is placed in the right area as everything is within the same solution. These capabilities are not restricted to internal collaboration but can include any number of supply chain partners that are a part of bringing this product to market. This becomes the collaboration platform that improves cross departmental collaboration as there is complete visibility in all that has to be done and the information needed for other functions to execute is automatically built up through the process.

As the status is updated from the individual activity 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 usage. Management with this level of visibility can limit the meetings, focusing only on exceptions instead of spending time on the entire project portfolio. With all this information, management will be empowered with the insight needed to not only optimize their work effort but also make the right decisions.

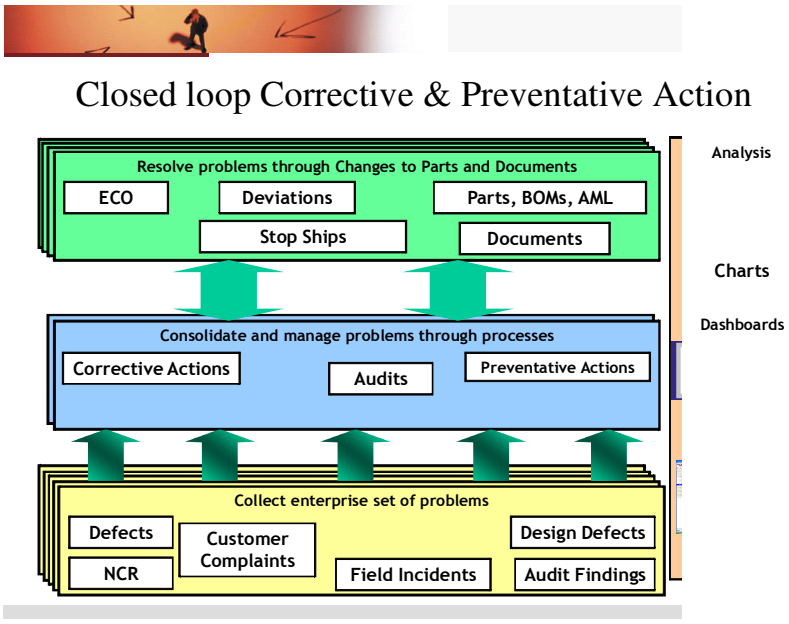
Besides this global resource management is an integrated part of the solution together with an improved way of handling project issues. All of the components used to improve time to market and product launches are illustrated below:



Quality, CAPA, Audits and more

Being a Medical Device company puts a lot of emphases on Quality. Most companies have therefore invested in getting best practice processes in place together with one or more quality related systems. The challenge is that there is not a closed loop from the Quality system to the DMR which results in manual procedures to ensure that the link is there and a lot of manual work to ensure that the entire process is executed. Often companies are spending a lot of time on ensuring that a corrective action is completed and that the CAPA process is closed and updated with the right information. Furthermore companies are struggling with the traceability when e.g. a customer complaint will be with the top level product but through analysis it is found that the issue is a with an error in a subassembly. In addition transferring quality knowledge across the organization to prevent R&D from reusing designs or component that have had quality issues is a challenge when all the information is spread amongst departmental data islands.

Minerva's solution optimizes the process from start to end in one solution with best practice processes. Having all information in one solution improves visibility and the entire organization including its supply chain partners has a clear view of what is and has happened with the device. Furthermore processes right from e.g. a customer complaint through CAPA to an Engineering change are handled in one connected closed loop ensuring not only compliance but also a vast reduction in cycle times (See below).

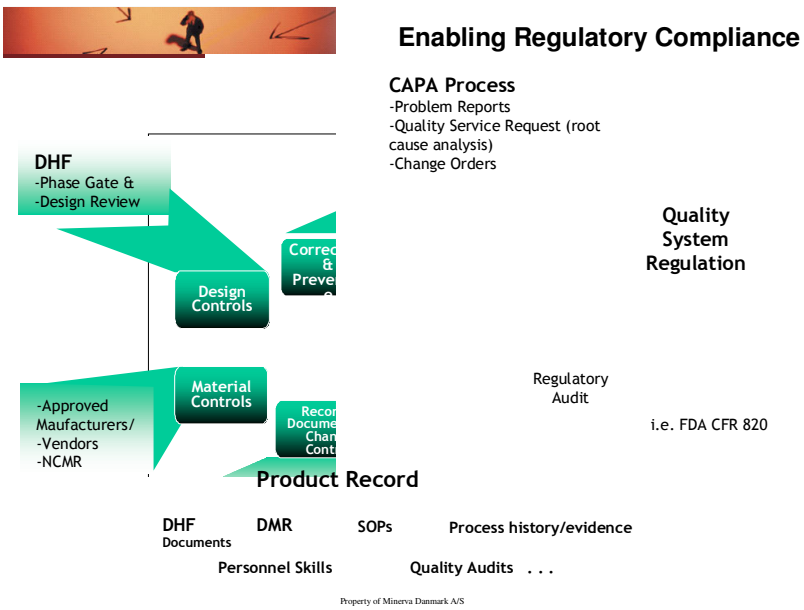


Another area of focus for Medical Device companies is traceability as the regulatory bodies come to audit the company and request information or it might be in an internal request where a

detailed product history has to be built. In order to reduce the time it takes to prepare for an audit or to build a product history it is important to have a solution that encompasses a comprehensive picture of the functionality and information needed for generate that history. Aras Innovator has an out of the box solution addressing that.

In addition there are often additional company specific challenges for which support is needed and for that specific purpose there are many selective add-ons that the company can pick and chose from ranging from training and skilld tracking, requirements management and much more:

The Minerva solution based on Aras Innovator it is designed to support the regulatory bodies' requirement as e.g. the FDA as illustrated below:



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. Minerva best practices for validation will speeds up the validation process and reduce the administrative burden.

Unique business model

Aras offers its customer a unique business model where a compressive enterprise software solution is offered without any upfront license cost. This means that the customer can get a solution that fully can support the most advance requirements, but without having to spend the traditional hundreds of thousands of dollars/euros/kroner up front just to get the software.

The business model is refered to as Enterprise Open Source and this not to be confused with the old view of amateur development or of a student doing night code the product. This is a professional profit driven company developing and supporting the product. The core of the product is being maintained and developed by Aras.

Aras revenue is driven from annual subscription packages and consulting. The unique thing about the subscription packages is that not only does it provide the usual support features known from all other software vendors, but they also include upgrading the customers system for free which in the enterprise PLM software space is not seen before.

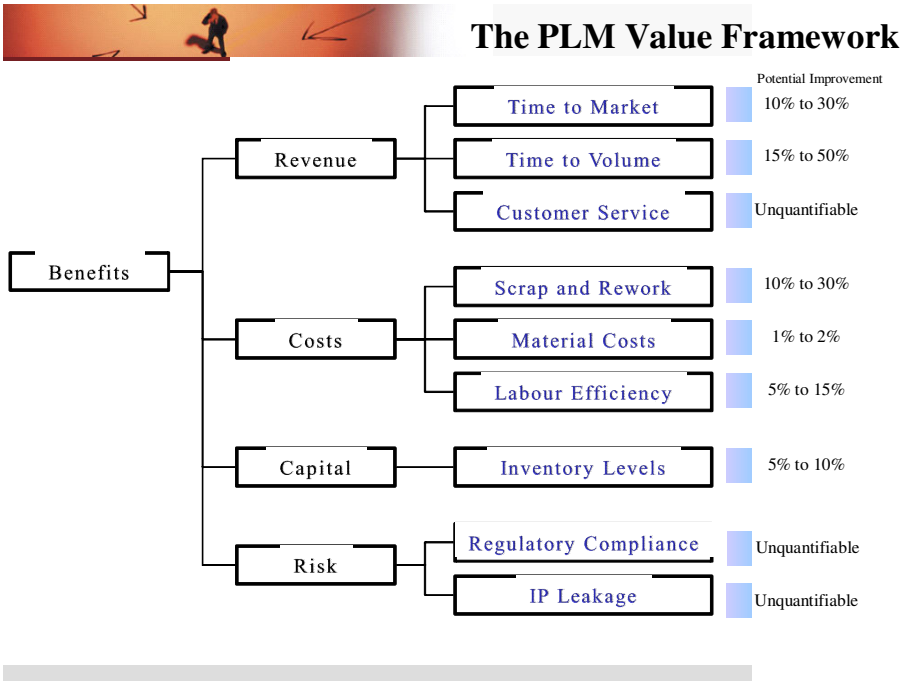
Summary

Minerva's solution including best practice together with Aras Innovator is a complete solution designed specifically to optimize Medical Device companies:

Focusing on bringing more products to market faster, needing to increase efficiency and having to maintain an even larger product portfolio, all through a more complex supply chain are just some of the reasons that are pressuring 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. Evidence of this is the extensive number of visionary medical device companies that either have implemented a solution or who are currently evaluating.

The companies who have made their investigations and subsequent investments in Aras and Minerva have done so on the basis of sound financial judgment and with recourse to the proven results that other Medical Device companies have gained – these results are monitored continuously and are shown below:



With the recorded benefits other companies have achieved, with a industry domain expert like Minerva and low risk investment model of the software, why not investigate it in detail as there is significante savings in the investment compared to all other PLM solutions.