How **Carestream Health** manages Projects and DHF using Minerva Medical Device PLM
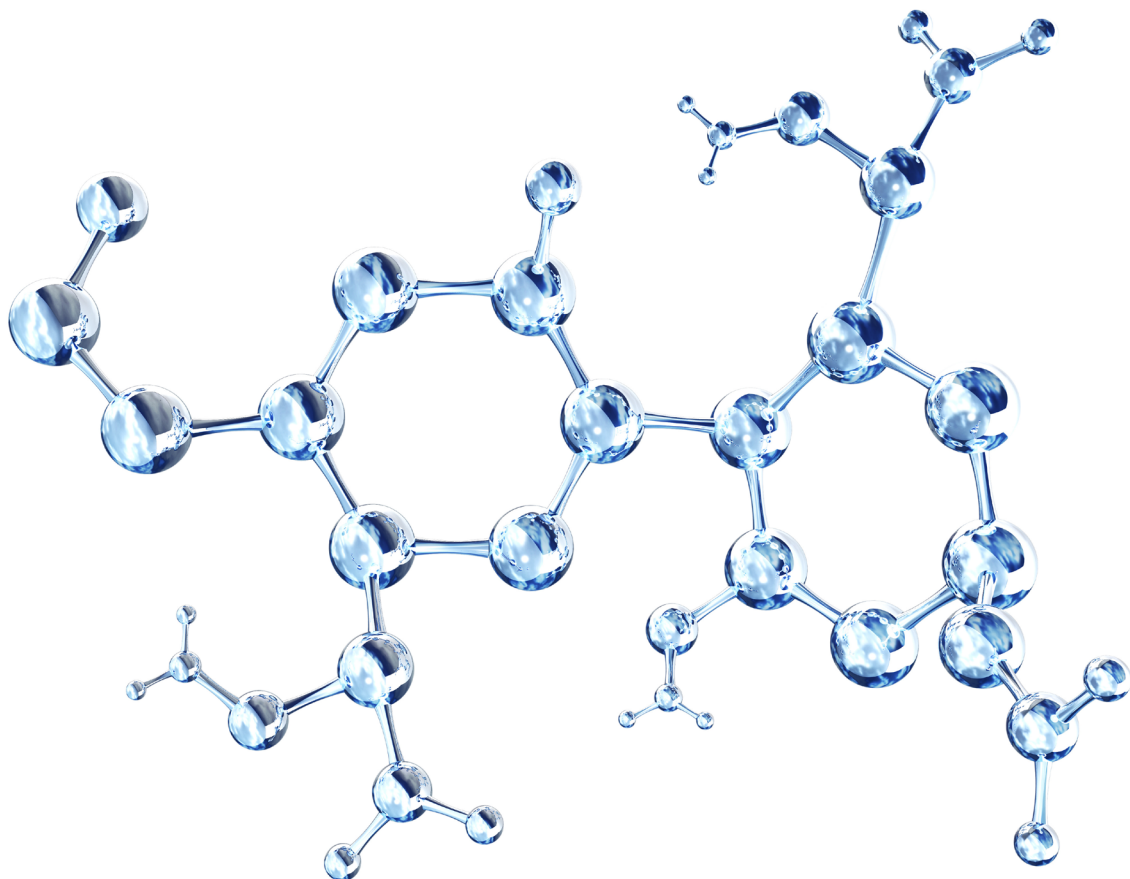
Minerva

Optimizing business

Carestream

About Carestream Healthcare

Carestream Health is an internationally successful leader in medical imaging systems and healthcare information technology solutions. Carestream products can be found in 90 percent of hospitals worldwide.

The company delivers scalable solutions for every step of the diagnostic imaging process, from exam ordering, image capture and diagnosis to results distribution, billing and beyond to customers across the globe. Among its products, is digital medical solutions, medical film and printing solutions as well as high-quality products for a wide range of industrial applications for non-destructing testing.

Carestream employs more than 7.300 employees across North America, Europe, Middle East and Asia.

Aras Innovator® – also known as the "PLI" – Product Level Information - internally at Carestream

Having been a heavy user of the Lotus Notes client-server software platform for many years, Carestream began their Aras Innovator journey in 2010. Since then, the company has expanded the use of Aras Innovator to improve collaboration and project management across global sites as well as make New Product Development more efficient.

In 2016, the Minerva Medical Device PLM solution was implemented to improve Project Management, especially improving the management of deliverables for both medical and non-medical device projects. After migrating a vast amount of data from the former Lotus Notes platform into Medical Device PLM, now Carestream Health has all their DHF information inside the Aras platform.

DHF and DMR:

Per FDA requirements, medical device companies must keep extensive project and design documentation in a regulated repository. These documents are part of the Design History File and must record the revisions and approvals per the phases and gates process of a project.

The Journey

Carestream Health had a very clear understanding of what they wanted in a system – the system should support the specific requirements that medical device companies must adhere to. In addition, the ability to link data elements together – to create a Product Level Information repository – was top of the priority list for Eli Tuber, IT process manager at Carestream Health.

Other specific requiremenets were:

- Support of the Design and Development Plan (DDP) that contains documents for design inputs and outputs, design review, design verification and validation, design transfer, regulatory and several others.

- Project management functionalities like Project Record that allows project definition and the Deliverable Matrix that defines all the deliverables associated with the project phases.

- Document change management and PLM driven change control

- FDA Title 21 CFR Part 11 compliant document structure.

After using the Minerva Medical Device PLM for several years, Carestream approached Minerva with some productivity enhancement requests.

After agreeing on the requirements, the project team at Carestream Health and at Minerva held two discovery sessions to clearly understand every aspect of the requirements and to map out implementation strategies. Using an Agile sprint implementation methodology, the project team at both ends started building the solution.

The users are on board

As Eli Tuber, IT process manager at Carestream Health, explains it, it was not always smooth sailing for the users to adjust to a new platform, because "change is difficult". But after a few training sessions, Eli has managed to get more users onboard the new platform.

"Fortunately, I just have to show them once how to do stuff. And then they go like: Oh! I can do that. It's not that hard," says Eli Tuber and continues:

"Once they open their mind to the fact that the tools delivered by Minerva and Aras make their job so much easier, they adapt themselves quickly to the new system. With Minerva Medical Device PLM, on top of Aras Innovator, we have a nice and clean solution that is extremely easy to use, and the feedback is that everything is easier to do now. The functionalities are much more useful now, so our users are very satisfied with working with the system,"
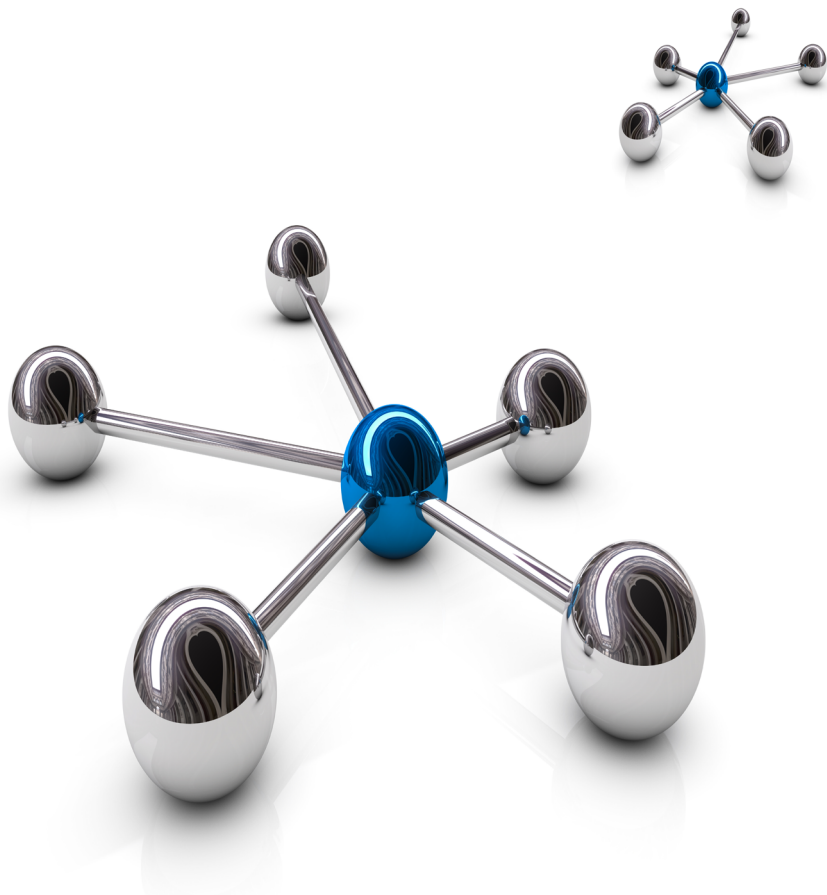
The results achieved with Medical Device PLM®

Beforehand, project managers at Carestream Health spent a lot of time tracking the owners for specific deliverables.

Today, the commercialization and IT projects at Carestream Health have been standardized using phases and gates inside Aras Innovator. And with Minerva Medical Device PLM, project managers can create the project structure and deliverables, and manage status in a very easy way with good visibility, allowing project managers to identify deliverables that are overdue, on track, not done yet etc.

Other advantages of using the Minerva Medical Device PLM project management module include:

- **Performance** – a full list of DDP deliverables can be created in less than two hours

- **Repeatability** – all projects will contain the same deliverables specified by template

- **Fewer steps** – users can now create new deliverables without having to exit the Deliverable Matrix

- **Access** – Users have quick access to all project/product deliverables in one location

- **History** – DHF maintains history of what revision was released at each phase

In general, the processes at Carestream Health has improved its workflow beyond the Aras standard DCO. Through the Minerva Medical Device PLM, users have approximately 50 different templates all together between production, IT and other requirements. The users know exactly which template to use and they can create those within a couple of minutes.

"So, in a matter of minutes, a project manager can tailor a project record easily. In the old days, everything was instantiated. That meant we were burning a lot of document numbers because several hundred documents were created each month with no real purpose. Today, we are creating documents that we need, and nothing else. Those days with excessive documents that pollutes the system are gone," says Eli Tuber.
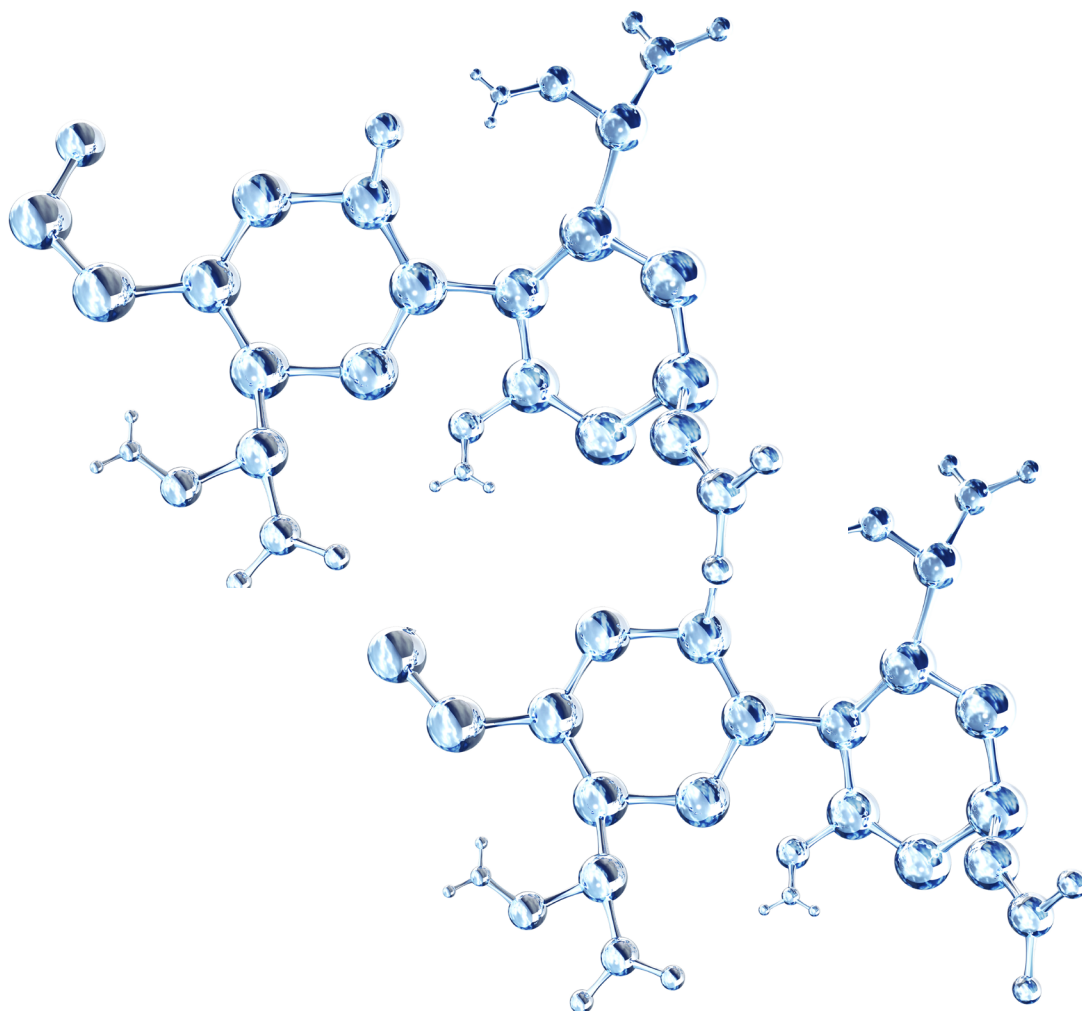
About Minerva

With many customers worldwide, Minerva Group is one of the most flexible and fastest growing vendors of Product Lifecycle Management (PLM) software solutions, globally. Our core competence is providing manufacturing organizations with the tools they need for managing products' development throughout their complete value chain, while supporting them in their pursuit of process efficiency and streamlined collaboration.

Our industrial solutions and add-ons for Aras Innovator® help our clients speed up the implementation process, and take advantage of Minerva's experience from multiple implementations, and support their constant growth.

Read more about the Minerva Group at **www.minerva-plm.com**

About Aras

Aras provides Aras Innovator® as a free enterprise open source software suite of solutions on the Microsoft platform. Enterprise software for new product introduction, advanced product quality planning, and enterprise product lifecycle management provide businesses with a process-oriented approach to manage innovation and collaboration from concept through development and launch. Aras solutions are designed to support Lean in the product development process while addressing product quality, risk management, and compliance in an integrated manner.

For more information on the Aras Innovator® software solution suite and to download the software visit **www.aras.com**

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