# MasterControl<sup>®</sup>

# Carestream

#### **Company Overview**

Focus: Medical Device

Headquarters: Rochester, NY

Employees: 4,400+ global employees



Carestream Health provides digital X-ray products and X-ray film for the medical and non-destructive testing market worldwide. Based in Rochester, New York, the company has sites all over the world – from Oregon and Colorado to Mexico and China.

After becoming an independent company in 2007, Carestream evolved its product portfolio from traditional film to provide cutting-edge digital radiography (DR) systems and has become a global leader in digital imaging and medical technology.

"When I started working prior to Carestream, there was no digital. We were starting to work towards computed radiography (CR) at the time. Basically, you took a plate, you took the image, and you still had to convert that plate through electronic format into an image and then actually print it," according to Eli Tuber, process manager at Carestream. "Now, we're all digital. We've gone to a whole digital platform."

Despite the digital innovation in its product, modern digital applications and tools hadn't been heavily leveraged by Carestream in its own technology stack. With more than 4,400 employees in globally distributed locations operating on legacy systems over 15 years old, the medical device company needed to modernise its tools and standardise its processes to evolve its business, reduce risk and improve productivity.

Today, Tuber is leading a digital transformation of Carestream's operational technology in much the same way as the company's product transformation – from outdated legacy systems to modern digital platforms.



#### Modern Tools. Consolidated Tech Platform.

When Carestream became an independent company, the biggest challenge was transferring all of the inherited legacy tools, according to Tuber, who had 22 years of experience in this field and has been with Carestream for 13 years. To avoid disruption, the company brought over the enterprise resource planning (ERP) systems, design tools, databases and everything else as part of the divestiture.

Carestream prioritised the modernisation of its applications landscape, taking steps to modernise the stack that connects quality and manufacturing processes on a single platform globally.

Recognising that a digital platform strategy would accelerate connections and information exchanges between systems, processes and locations, Carestream's approach is to leverage fewer, more connected platforms that better unify data and processes. Among the company's priorities is to replace its device history record (DHR) system, which relies on a platform that is over 15 years old and is unsupported.

"There was a risk on the system because of that, so we needed to move on to something more modernised with capabilities of advanced reporting, a user interface and things of that nature," according to Tuber. "When we started looking at tools, that was our first goal."

In addition, the company needed a solution that could support a global footprint with diverse manufacturing needs – in particular, low-mix, high-volume manufacturing of X-ray film in China and high-mix, low-volume digital imaging equipment at other global locations.

This required finding a solution that was flexible enough to support different manufacturing processes, while still enabling data, policies and controls to be harmonised between different sites and processes.

#### Flexible, Data-Driven eDHRs. Standardised Work Instructions. Relevant Data Shared Across Sites.

Carestream had a long list of DHR requirements for its X-ray film and digital imaging lines. Particularly for its high-end digital imaging production, in which each machine the company builds is often customised to a customer's unique requirements, the company's DHR has to support rapid user configurability needed to support highly mass-customisation.

Carestream's legacy system was essentially a homegrown system that required a lot of manual effort to build the DHR content. The MasterControl Manufacturing Excellence<sup>™</sup> solution lets the company easily build and deploy fully digital DHR templates that provide a rich source of real-time production data while maintaining the familiarity and usability of paper-based records, enabling Carestream to build, execute and review electronic DHRs (eDHRs) much faster than before.

# We want to remove all paper from the process. That's the ideal solution we are working toward."

–Eli Tuber Process Manager, Carestream



Data input errors have been virtually eliminated, improving data integrity on the shop floor and giving Carestream the ability to segregate production data between sites. This is highly valuable because Carestream's sites essentially function as different business units that often function as vendors to each other, which requires the ability to share some data across sites while restricting data that doesn't need to be shared.

"We do need to share QMS [quality management system] information, so corporate standard operating procedures (SOPs) and things of that nature should be global," according to Tuber. "But plant-specific SOPs and processes are unique to the plant and the team. MasterControl's vaulting capability and ability to segregate the data between sites is very useful and critical in some cases. Sites are independent, and we need to see the DHR for the products and the data independently."

Work instructions are another part of the equation in Carestream's legacy tools. The company wanted a solution that would make it easier for work instructions to be created, version controlled and accessed by front-line workers. The Manufacturing Excellence solution enables Carestream to bring in and standardise its work instructions, ensure operators and shop floor personnel are always accessing the latest versions, and tie them directly to employee training under the same platform, helping to enforce training compliance.

Tuber said using MasterControl to standardise new templates and workflows is going to help the company immensely.

"Under legacy systems, we have a lot of processes, different tools, different ways of accessing data," Tuber said. "We're trying to standardise, and that's critical to what we're trying to do in the future – reduce the footprint, reduce the risk and increase the productivity."

### Platform Dynamics. Connected Solutions.

One of the things that Carestream is looking at in standardisation is moving crucial manufacturing and quality functionality to the same platform, so everyone is doing procedures the same way.

"That's critical to what we're doing," Tuber said. "We can have our SOPs, we can have our corrective and preventive actions (CAPAs), we can have our complaints all under one platform."

MasterControl offered Carestream a platform that brings together documentation, electronic DHRs, digital work instructions, SOPs, CAPAs and complaints.

"We looked at this as an opportunity to bring in additional pieces of the puzzle

Our previous, legacy system was pretty much a homegrown solution, and it required a lot of manual effort to build it up. It worked, it did what we wanted – but it was hard to build the content."

–Eli Tuber

The decision to go with MasterControl was easy to sell to management because we could do multiple things under one tool, instead of having it distributed all over, and then trying to connect all these pieces together."

–Eli Tuber

under one roof. That made it extremely easy to sell – that we were all using one tool instead of having distributed tools that we were trying to connect, in versioning, sign offs, training and things of that nature. That was one of the big points in choosing MasterControl."

Carestream now has a digital solution that will support its global footprint with diverse needs, allowing the company to easily integrate between all its sites and systems with one platform, now and in the future.

"At the end of the day, our goal is to have a PLM [product life cycle management] solution, a QMS solution with DHR and an ERP solution. That would be our end goal to have all this under one of three platforms that we have. Users are going to be familiar with one tool, one system, one platform across multiple use cases. They're going to use it for CAPA, they're going to use it for DHR, they're going to use it for work instructions, they're going to use it for SOPs," according to Tuber. "And everything else will be in one home instead of having distributed, archaic or hard-to-use tools in the system."

The Challenge	Modernising outdated legacy tools; advancing digital manufacturing; streamlining eDHR creation, execution and review; and consolidating production and quality management processes to reduce risk and improve productivity.
The Solutions	Quality Manufacturing VxT Cloud
The Results	Carestream now deploys fewer, more modern technology tools across their global manufacturing environment with a single platform for production and quality management, which has resulted in improved visibility, efficiency, productivity and risk mitigation.

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