sirona.
The Dental Company

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Michael Dalpiaz, Sirona Dental Systems

The Customer

Sirona (www.sirona.com) is the dental technology and innovation leader, serving dealers and dentists worldwide for more than 130 years. The company develops, manufactures, and markets a complete line of dental products, including CAD/CAM restoration systems (CEREC), digital intra-oral, panoramic and 3D imaging systems, dental treatment centers and handpieces.

Why the Change?

Sirona's developer organization initiated a request for a better lifecycle management solution, citing that the existing tool environment, which included RequisitePro, Microsoft Excel and Microsoft Word[1], along with open source solutions for Test Management and bug tracking, plus many integrations, was "proving ineffective".

The Wish List

In the early stages, project coordinator Michael Dalpiaz and his team identified several key needs any new lifecycle management tool solution must address.

Unity, Document Management, Traceability

First and foremost, it should be a fully unified end-to-end solution covering all major phases from requirements to testing, not a mere stringing together of point solutions.

Traceability Among Documents

In addition to the desired unity, Sirona wanted their new solution, at the same time, to provide both documentation management and traceability in an easier and more robust way than what they had in place.

Flexibility, Adaptability

Because Sirona already had established, proven processes in place, a restrictive solution based on rigid templates would not be acceptable. The new solution had to deliver real flexibility and adaptability in wokflows, scripting, etc.

Compliance Management

According to Dalpiaz, in the field of medical engineering in which Sirona operates, documentation requirements for the regulatory bodies are less stringent and detailed than for other verticals… aerospace, for example. The greater flexibility meant that the company was on its own when it came to devising process and methods, yet the requirement for regulatory compliance was in no way obviated. The company would still need to document their compliance with safety stadards and regulations, including:

- The European Union's Medical Device Directive standards (IEC 62304, IEC 60601, ISO 14971 etc.)
- U.S. FDA 510K, which is necessary for any commercialization in North America.

As a leading company in its industry, Sirona already had processes and systems in place to assure regulatory and safety standards compliance. Any new lifecycle management solution had to at least support their existing capabilities… and anything it could do to make compliance easier would be a major bonus. For example, if safety requirements could be tracked for compliance reporting separately from functional requirements, it would streamline things a great deal.

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"Many stakeholders, IT in particular, were very excited that Polarion is web-based. This saves a lot of work configuring client computers."

"License and maintenance costs were lower compared with the tools we had, and better than competitors."

1 RequisitePro is a registered trademark of IBM Corporation. Excel and Microsoft Word are trademarks or registered trademarks of Microsoft Corporation.

Embedded Software Support

With the importance of embedded software on a steep upward curve throughout their industry, Sirona needed a better way to trace source code changes upward to requirements, and vice-versa, while at the same time keeping the code under version control.

The Solution

Polarion is now used intensively in the company's Imaging Systems division. Currently, around 20 - 30 people regularly use Polarion, soon to be extended to around 40 - 50 people. Polarion's Professional Services were instrumental in rolling out the Polarion solution at Sirona.

"We defined a highly customized configuration with the help of a Polarion consultant, and we implemented it together at our Bensheim (Germany) facility," said Michael Dalpiaz, the project coordinator. "During the implementation, we were supported by another consultant, who prepared custom report pages, scripts and plug-ins. But right after the import of the data existing at the time, we started (using Polarion) with a limited number of users."

The rollout, from the beginning of the data import to a fully "usable" state (i.e. when reports etc. were finished) took between 5 and 6 months.

The Benefits

For Sirona, the main benefits include the unified nature of Polarion's solution, the ease of establishing traceability to prove compliance, the simplicity of administration, the extensive customizability, and the general affordability. According to Michael Dalpiaz:

- "We were looking for an end-to-end solution for both documentation and traceability - from requirements to testing."
- "Traceability is not, from our point of view, a unique selling point, but since it is very simple to handle in Polarion, it was definitely a criteria in our decision for Polarion."
- "The TÜV ISO 26262 certification of Polarion helps. Although it is not 1:1 the same as the standards in the medical engineering, it still helps because ISO 26262 is even more strict."
- "Reports and flexibility are great. Polarion's approach in this regard offers the best solution compared to other tools."
- "Many stakeholders, IT in particular, were very excited that Polarion is web-based. This saves a lot of work configuring client computers."

2 IBM, MKS, Serena

- "License and maintenance costs were lower compared with the tools we had, and better than competitors." [2]

Dalpiaz also felt that Sirona benefitted from the assistance of Polarion's Professional Services and Technical Support.

"Polarion Professional Services is, for me, very competent and we are very satisfied with their services until now."

Future Plans

The CAD/CAM Systems division will soon move to Polarion: the data are imported, the reports etc. are built, and only user instruction and training remained as of this writing. The company also has plans to introduce Polarion in the Treatment Centres division, although that roll-out is not definitively scheduled at time of publication.

Michael Dalpiaz also sees Sirona expanding its Polarion usage into the area of testing/test management, and variants management.

"To date, our focus (with Polarion) has been on requirements management," he said. "We know that Polarion covers testing, and has capabilities for managing variants. We would like to achieve optimum test coverage on different variants. We look to Polarion to continue to grow support for these areas in the solution."

About Polarion

The creators of the world's fastest enterprise scale web-based ALM solution. The success of Polarion Software is best described by the hundreds of Global 1000 companies and over 1 Million users who rely daily on Polarion's Requirements Management, Quality Assurance and Application Lifecycle Management solutions in their business processes. Polarion is a thriving international company with offices across Europe and North America, and a wide ecosystem of partners world-wide.
For more information, visit www.polarion.com.

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Conclusion

"Sirona Dental Systems uses Polarion Solutions not solely to achieve compliance with medical device regulations like FDA or IEC 62304 but moreover to make all data in the development process lifecylce more transparent for all parties involved, like developers, project managers and quality managers. That's reached by using Polarion's flexibility and adaptable reporting capabilities. The result is a more efficient and transparent document handling thanks to Polarion Solutions."

Michael Dalpiaz, Sirona Dental Systems