

Smith & Nephew Streamlines Engineering Change Control Process to Shorten Review Cycle



Smith & Nephew
Memphis, TN, USA
www.global.smith-nephew.com

Industry:

Life Sciences

Annual Revenue:

US\$2.8 billion

Employees:

9,600

Oracle Products & Services:

AutoVue Electro-Mechanical
Professional

Key Benefits:

- Ensures timely and reliable access to product data and information
- Shortens design review cycle by days and facilitates decision making
- Improves visibility and control over the engineering change process
- Improves quality levels due to automated and standardized workflow
- Helps with compliance of strict government regulations
- Cuts time needed to print documents by almost 90%.
- Eliminates need for converting documents saving precious hours and resources

“Using AutoVue to access and review digital files minimizes errors and misinterpretations and allows us to expedite the design approval process, while meeting regulatory requirements” – Randall Reavis, Manager of Computer Aided Engineering, Smith & Nephew, Memphis, Tennessee

In the medical devices world, Smith & Nephew is synonymous with high standards of performance, innovation and trust. With over 9,600 employees operating in 32 countries, and revenues that amount to nearly US\$2.8 billion, Smith & Nephew is a global leader in arthroscopy and advanced wound management, and one of the fastest growing orthopaedics companies. The company’s business strategy is based on designing and manufacturing technically innovative and advanced medical devices, which help patients, get back to their normal lives faster.

To support its global strategy and stay ahead in its markets, Smith & Nephew heavily invests in products and research and development, and remains on the lookout for cutting-edge software solutions that will help its engineering teams bring innovative products to market faster while ensuring compliance with increasingly stringent federal regulations.

Providing Real-Time Access to Product Lifecycle Management Documents

Smith & Nephew relies on a product lifecycle management (PLM) solution to manage the entire lifecycle of its products and provide globally distributed design and manufacturing teams with control of its product-related data. The company’s orthopedic reconstruction unit began searching for an enterprise visualization solution to replace a previously discontinued viewer. One major requirement for the new visualization solution was its ability to integrate with the company’s PLM system which would enable users to access and view any document type directly from within the PLM environment.

“Our engineering change control process is very thorough. It captures every piece of history of each design change, and we use AutoVue to quickly and easily communicate these changes graphically in the context of the master model.”

Randall Reavis
Manager of CAE
Smith & Nephew

The global manufacturing activities of the orthopedic units required a visualization solution that would allow engineering and manufacturing teams across the globe to easily access, view and review documents and drawings.

Most importantly, because the medical devices industry is highly regulated, Smith & Nephew needed a robust solution that would complement and streamline its engineering change control process, assist with compliance of regulatory bodies, like the Food and Drug Administration (FDA), and improve the company’s product time-to-market and competitiveness.

Enabling Enterprise-Wide Visibility into the Product Development Process

Smith & Nephew deployed Oracle’s AutoVue 3D Electro-Mechanical Professional for the visualization needs of its orthopedic divisions. AutoVue was immediately tied to the company’s PLM system, allowing documents to be viewed and reviewed directly from within the PLM environment. “It is so easy. Users, no matter where they are located, simply need to double click on any document; it could be a Unigraphics drawing, a Cadence OrCAD Printed Circuit Board (PCB) layout, or a PDF file, to instantly view and interact with it. Users do not need to have copies of the native software application anywhere on the system to view the documents,” said Randall Reavis, manager of computer aided engineering at Smith & Nephew, Memphis, Tennessee.

AutoVue has quickly become a mission-critical application for Smith & Nephew, enabling enterprise-wide visibility into the product development process, and allowing design problems to be identified and resolved earlier. With support for 450 document types, AutoVue has tremendously extended the ability of Smith & Nephew’s global teams to interact with original electronic files; users can now instantly access product data and information in its original form, without undergoing costly document conversions, saving precious hours and valuable resources in the process.

AutoVue has also become an integral part of Smith & Nephew’s engineering change control process. Engineers, draftsmen and non-technical personnel use AutoVue’s native document viewing

and markup capabilities on a daily basis to review engineering designs, quickly detect part defects, communicate changes, and gather the multiple sign offs and approvals required even for the smallest of changes. “Our engineering change control process is very thorough. It captures every piece of history of each design change, and we use AutoVue to quickly and easily communicate these changes graphically in the context of the master model,” Reavis said.

Collaboration is enhanced, and engineering changes are communicated in a faster and more thorough fashion, improving operational efficiency and cutting days from the review cycle. “Medical devices today are very complex,” explained Reavis. “Design processes incorporate a broader array of contributors and stakeholders. The combined use of AutoVue and our PLM solution helps us collaborate on native documents faster and more effectively, minimize engineering changes, and do the right thing the first time.”

Time Savings and Improved Regulatory Compliance

AutoVue helps Smith & Nephew better comply with strict regulatory requirements, and reduce the time spent by employees in meeting these requirements. Reavis explained that the advantages of using AutoVue for regulatory compliance are threefold. First, AutoVue respects the PLM system’s permission settings, ensuring that only authorized users have access to documents. Second, authorized users can create markups and annotations, which enable teams to document and track engineering changes, ensuring traceability across the board and reducing audit time. “We get better visibility and control over our data and information through the integration of AutoVue with the PLM system,” Reavis said. “We can trace exactly who may have accessed a file, when and what comments he or she added to the document on that date.” Third, AutoVue automates the extraction and inclusion of metadata onto printed documents. Information such as when a document was produced, its expiration date, status, etc. are captured by AutoVue in the headers, footers and watermarks of printed documents, allowing Smith and Nephew to comply with strict government regulations.

AutoVue has also enabled Smith and Nephew to reduce its dependency on paper and increase its ability to interact with digital documents. Reavis explained that people can easily compare 3D documents using AutoVue's compare feature and track changes without having to print and look at a physical paper copy. "Using AutoVue to view and review digital files minimizes errors and misinterpretations and allows us to expedite the design approval process, while meeting regulatory requirements," Reavis concluded.

Yet, there are still plenty of occasions where paper is needed. Thus, AutoVue provides users with an extensive array of printing options for scaling, page ranges, printed area, alignment, headers/footers, watermarks, and margins, making sure users can effectively print the information they need. Reavis indicated that AutoVue has also made printing much more efficient, reducing the time needed to print a document by almost 90%.

Bringing Collaboration One Step Further

Today, AutoVue is used globally by Smith & Nephew's orthopedic teams, but the company wishes to extend the use of AutoVue to its external supply chain. Currently, teams have to undergo a time-consuming translation process to share documents with third parties. "We anticipate great time and cost savings through the improvement of collaboration and communication with our partners and customers," Reavis said. The company also plans to use AutoVue's Web-based real-time collaboration capabilities to enable instant and seamless collaboration throughout the product development process.

Why Oracle?

Smith & Nephew considered several solutions for its visualization and collaboration needs, but only Oracle's AutoVue offered the necessary integration with the PLM environment. "On top of delivering native document viewing and supporting a comprehensive range of document types, AutoVue was the only visualization solution that offered a reliable integration with our PLM solution," explained Reavis. "It was essential for our global design manufacturing strategy that the PLM and the visualization solution work together. AutoVue was the perfect fit."