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Beckman Coulter Advances Biomedical Device Development with V6 PLM



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At Dassault Systèmes, Innovation is in our DNA

Innovation is the lifeblood of Life Sciences organizations working to improve the condition of precious human lives. That's why the world's leading Pharmaceutical, Medical Device and Patient Care companies depend on Dassault Systèmes (DS) 3D and Product Lifecycle Management (PLM) solutions to master their highly regulated product development challenges and accelerate time to market, collaboratively and efficiently. Learn how DS industry-specific solutions are catalysts for innovation in Life Sciences.

Visit www.3ds.com/life-sciences

Editorial



dopted by every player in the automotive and aerospace sectors, Product Lifecycle Management (PLM) has become a catalyst for innovation and sustainable development in a growing number of industries. For the life sciences industry, faced with unprecedented challenges, the potential of the virtual world is enormous, and PLM

in particular, offers companies the ability to reinvent themselves. A certain number of players in the sector have already understood this.

While increasing life spans and changing behaviors are giving rise to new illnesses, R&D costs per drug have increased over the past 20 years from \$250 million to \$1 billion. The complexity of treatment targets, demand for absolute quality, exponential jump in information generated by scientific progress, and increase in regulatory constraints due to security concerns make scientific research more difficult.

Has discovering new treatments at the lowest cost while managing risk become an unattainable objective?

At Dassault Systèmes, we do not think so. Digitization of complex phenomena, tests on virtual models, and an entirely new form of treatment called cyber therapy, offer promising perspectives in the 3D virtual universe.

The ability to collaborate, adhere to regulatory constraints, and capitalize corporate IP - all possible with our solutions - are already invaluable assets for optimizing new drug creation, establishing new medical protocols, and rendering patient care more efficient. The first results are already in. Four of the six largest medical device manufacturers are our customers. One of the world's leading pharmaceutical companies is also on board and several others are betting on the power of the BioIntelligence research platform as a catalyst for new discoveries.

We still need to adapt our tools to meet the needs this industry to serve it better. But we are at the threshold of a new era with "Bio PLM".

Pascal Daloz Executive Vice President, Strategy & Marketing, Dassault Systèmes

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Focus on Life Sciences

Aging populations in the developed world, billions of people with inadequate access to medicines, rising R&D costs, growing financial and regulatory constraints, and increasing customer expectations – these are just a few of the difficult challenges facing the life sciences sector in the 21st century. In this special feature of Contact Mag, we look at the trends and hurdles that lie ahead, Dassault Systèmes' comprehensive Life Sciences PLM (Product Lifecycle Management) portfolio, and a number of DS customers rising to the challenge through innovation and foresight.

Life Sciences

Analyst, ARC Advisory Group

John Blanchard is a principal analyst with ARC Advisory Group, which specializes in manufacturing and supply chain issues. His focus is on advanced control and enterprise integration and regulatory compliance in the process industries, reinforced with 25 years of experience in the food, beverage and pharmaceutical industries. Contact Mag spoke with him about the trends and challenges in the life sciences industry and the role PLM can play in it.

Contact Mag: In what areas do life sciences companies stand to benefit from PLM?

John Blanchard: Basically, there are four main areas.

The new commercial manufacturing paradigm

Manufacturing has become critical to improving margin and growth, which it never was in the past. Most pharma companies are faced with manufacturing not only branded products, but generic and over-the-counter versions of products as well.

Drug development - It's clear that the speed, innovation and success rate of drug development needs to be improved dramatically. And that, in great part, relies on improving both clinical data and project management, which both closely fit the capabilities of PLM.

Increasing regulatory pressures - The FDA's (Food and Drug Administration) new risk-based approach to regulating the industry comes down, quite simply, to the fact that they want

everything done electronically. So new drug submissions, which were already closely scrutinized, require more data than ever and must be electronic - and that's a step beyond clinical data management.

Shorter lifecycles and tremendously increased

competition - Because many therapeutic areas are packed with a range of similar products, the FDA and others are starting to balk at more "me too" entries. And that's bringing new pressure on the industry in both manufacturing and drug development in terms of product innovation and increased speed-to-market.

C.M.: How do challenges in the medical devices industry compare to those in pharma?

J.B.: Although medical devices makers aren't as impacted by the shorter lifecycles pharma is seeing, they face plenty of competition and have other unique challenges. They have to keep a tremendous design document and they have to

By Lisa Roner the Next Frontier for PLM

track the product clear to the end of its lifecycle. So in some ways, I consider many medical devices pretty much the same as the discrete industries. The difference is that medical devices makers are not highly automated. Many of their products can't be manufactured with mass customization (for example, prostheses), so keeping close track of suppliers when it comes to design criteria and the quality of the product becomes very important.

overview

ARC Advisory Group

C.M.: New drug development is slowing. Fewer blockbuster drugs are being developed, and the ones that are take longer and cost more. How can PLM help pharma companies find effective drugs more quickly and efficiently?

J.B.: It comes down to managing clinical data on a per patient basis in clinical trials, analyzing the data and making decisions through project management on whether to hold a drug, send it forward or discontinue. Until quite recently - the past six or seven years, really - pharma hasn't had any structure to this. It's all about managing the whole thing: getting closer to patients, collecting better data and keeping them in the trials to get drugs through the approval process faster and with a greater success rate - and PLM can have a major role •

More About Arc Advisory Group: www.arcweb.com



The Evolution of Life Sciences

The Life Sciences industry is moving toward connected communities of patients, doctors, researchers, pharmaceutical and medical engineering companies, working together with regulatory agencies to develop products where drugs, medical devices and services merge into a single combined product. This community approach will promote information sharing and capitalization. Among the challenges ahead: giving these communities the tools and technology to shrink distances and grow collaboration.

n the discovery-driven world of life sciences, a profound transformation is afoot. Gone are the days of research, development, and commercialization teams operating in isolation. The hallmark of tomorrow's life sciences sector will be a comprehensive care approach where diverse teams work in concert to improve life for patients through innovative therapies supported by new drugs and medical devices.

A clear illustration of this transformation is a major trend called "combined product." While pharmaceutical researchers work to develop the best drug, others actively explore how to combine drugs with medical devices or other therapies into a single, integrated treatment to provide new, innovative patient services. To achieve this vision, however, requires unprecedented collaboration. It will only occur if all actors can share information and build upon a common foundation.

Therein lies the challenge. The life sciences industry has myriad specializations, job profiles

and processes. Laboratories and development sites span the globe. The diversity of patient profiles and needs is staggering. The only way to ensure that a comprehensive-care approach will succeed is to create a collaborative knowledge and know-how-sharing environment capable of pulling down isolated information silos to allow a free flow of knowledge and ideas.

WORKFLOW IS GOOD. PLM IS BETTER

Software can be the bridge that makes comprehensive care a reality, bringing together the molecule-driven care (pharmaceutical, phyto-sanitary, cosmetic), medical device, and patient care domains - the three pillars of life sciences - to the profound benefit of patients and physicians. Software, as well as access to public and private research data, already plays an important role. Initially, 3D emerged as a powerful modeling tool for molecular structures, medical equipment, and as a way to illustrate how drugs interact in the human body. Today, however, managing the entire product lifecycle is essential. Product Lifecycle Management (PLM) provides precisely the collaborative data engine needed to drive the next great wave of patient care innovation.

HIGHLY REGULATED AND IN NEED OF RE-INVENTION

The life sciences industry is one of the most highly regulated sectors. Whether a company develops pharmaceuticals or designs and manufactures medical scanners, respecting an ever-increasing number of regulations chips away at productivity and forces companies to reinvent their ways of working. The goal is to reproduce the same phenomenal leaps in productivity and innovation in the life sciences sector that PLM brought to the automotive and aerospace industries.

SOLUTIONS FOR MEDICAL DEVICES

Dassault Systèmes (DS) has solutions to address all three life sciences pillars. For medical devices, DS offers an entire portfolio for a processDassault Systèmes' V6 integrated platform, the company's next generation PLM 2.0 environment, enables users to create and collaborate online in real-time via an immersive, lifelike experience.

driven development approach. To address the industry's strict regulatory constraints, DS has developed life sciences accelerators in the ENOVIA product line that help companies adhere to quality criteria.

The ENOVIA Life Sciences Accelerator for Quality Issues focuses on four high-profile, regulated business processes within the Quality Management System: Corrective and Preventive Action (CAPA), Nonconformance Reports (NCRs), Product Complaints, and Quality Audits. To address the industry's product development requirements, SIMULIA offers a product portfolio for realistic simulation of devices, robust designs, and simulation lifecycle management tools.

SOLUTIONS FOR PATIENT CARE

In patient care, cybertherapy offers tremendous promise, from helping devise new therapies for phobias to designing more effective operating rooms. With virtual reality, highly personalized treatments become more cost-effective and pervasive, and investments in facilities and equipment can be optimized through superior design.

The EU-funded VEPSY research project for clinical psychology, for example, uses simulation to bring patients face-to-face with four virtual worlds based on scenarios defined by psychiatrists specialized in treating a variety of social phobia. 3DVIA Virtools development solutions for realistic 3D environments enable all those involved in the research project to actively collaborate at a distance during simulation.

SOLUTIONS FOR MOLECULE-DRIVEN CARE

Molecule-driven care covers all the diverse areas where the molecule is the kernel of the industry. It ranges from the pharmaceutical industry to the phyto-sanitary sector to the cosmetics world.

While demand for new drugs continues, the molecule-driven care industry's current business model, often characterized by isolated research and development teams, is increasingly unsustainable and unable to produce treatments demanded by the global community, despite being feasible due to scientific progress.

Optimizing enterprise processes to facilitate new discoveries and increase business competitiveness through PLM is the goal of the DS molecule-driven care portfolio. It ranges from the Biointelligence Research Project, designed to advance the biological dimension of PLM, to solutions to optimize regulatory processes like drug labeling, allowing drugs to become available to patients sooner. Along-term objective is to complement currentin vivo and in vitro processes with computer-driven in silico R&D. Again, the goal is to spark the same productivity revolution that occurred in other industries with the introduction of PLM. Among other things, in silico R&D will help to accelerate the discovery and commercialization of new and safer drugs to save lives.



CONNECTING COMMUNITIES WITH V6

The life sciences industry is an aggregation of multiple communities, sometimes linked by the same science (medicine, biology, chemistry, mechanical), sometimes by the same goal (availability of a new drug, a new device). These communities generate and manage fantastic amounts of data in multiple formats around the globe every day.

Connecting these communities and opening up silos of information is possible thanks to the Dassault Systèmes V6 integrated platform, the company's next-generation PLM 2.0 environment that enables users to create and collaborate online in real-time via an immersive, lifelike experience. The enablement of this new community strategy with V6 is poised to become a catalyst for innovation and discovery in an industry faced with some of the biggest challenges confronting humankind •

For more information: Jean.Colombel@3ds.com www.3ds.com/solutions/life-sciences



Profile

Jean Colombel has more than 20 years of experience in the software industry for life

sciences. He held executive management positions for sales and marketing in Europe, the USA and Japan. He is currently Director, Life Sciences Industry, for Dassault Systèmes, where he is responsible for defining, coordinating and promoting the DS offering and market positioning for the pharmaceutical, biotech, agrochemical, medical device, and patient care markets.

Stephane Bouchard Director, Canada Research Chair - Clinical Cyberpsychology, UQO



Cyberpsychology researchers from Université du Québec needed to quickly and easily create and deploy effective treatment scenarios in virtual reality (VR). They chose 3DVIA Virtools on a Microsoft development and operating platform to develop stable and reliable virtual environments, and use them to treat patients.

The six-wall immersive room requires 6 projectors RGB and 8 computers to maximize the image quality, allowing the user to feel fully immersed into the virtual world.



atients with anxiety disorders must face their fears to conquer them. But putting patients in close proximity to what they fear can be difficult. Patients who fear flying, for example, cannot change their minds about a flight once the plane is airborne – unless their experience is a virtual one.

By Lisa Roner

HELPING PATIENTS FACE THEIR FEARS VIRTUALLY

Researchers in the Cyberpsychology Lab and the Canada Research Chair in Clinical Cyberpsychpology at the Université du Québec in Gatineau, Canada, are leveraging virtual reality environments using 3DVIA Virtools on the 64-bit Microsoft Windows platform and customized with Microsoft Visual Studio.Net to help patients with anxiety disorders face and manage their fears in a safe, controlled environment.

Immersive treatment conditions are created by projecting the virtual environments on the walls, floor and ceiling of a "CAVE-like" room, or by using special 3D goggles referred to as head-mounted displays (HMD). Everywhere patients look, the environment surrounds them, changing as they react to the scenarios – much as a video game changes based on the choices players make. The applications are being utilized to treat patients with conditions ranging from phobias and Alzheimer's disease to addictions. The success rate with virtual reality is equivalent to that for traditional treatments – around 75%.

With 3DVIA Virtools, we knew we would be able to quickly and easily create any virtual environment and have it work on any multiple display system.

Treating

in Virtual

"With 3DVIA Virtools operating on a Microsoft platform, our researchers can focus on developing applications quickly and that connect easily with a VR environment," says Dr. Stephane Bouchard, director of the Canada Research Chair in Clinical Cyberpsychology at UQO.

SEAMLESS AND REALISTIC

Although phobias and anxiety disorders can be treated effectively using traditional approaches, virtual reality environments offer a more practical approach in a clinical setting. It may not be possible for every clinic to keep spiders, snakes, high places, tight spaces and other common fear-inducers on hand to treat patients – but they can all be made available in VR.

3DVIA VIRTOOLS: OUT-OF-THE-BOX EASE

With a grant for infrastructure development, Dr. Bouchard's team acquired 3DVIA Virtools, which gives life to 3D objects and allows control in real time. "3DVIA Virtools was the best choice," Dr. Bouchard says, "because it is quick and easy to learn, supports rapid development of new environments, and allows us to use our environments both on the CAVE-like and HMD platforms."

Phobias

Reality

To create virtual reality environments, the first step is to develop assets or 3D objects in a specialized DCC (digital content creation) or CAD software. Once models are optimized for 3D Real Time, they are imported into 3DVIA Virtools to create a full real-time 3D application. Finally, with the 3DVIA Virtools VR library, users can easily publish applications in different types of Virtual Reality environments. 3DVIA Virtools' use of VRPN, an open source protocol, allows its environments to be projected or displayed using virtually any hardware on the market. "All of the hardware we need is already compatible with 3DVIA Virtools, so we can just buy a piece of equipment and plug it in," says Bouchard.





The VR Library component of 3DVIA Virtools links the application running on the "master" PC and the cluster of six computers that project images to the cave-like VR environment, ensuring the image is seamless where different surfaces meet. Once the geometry of the room has been input into the system, 3DVIA Virtools makes all of the necessary adjustments. With perspective matrixes, 3DVIA Virtools changes the point of view or stretches the image to show it properly as images are distributed on the surfaces of the room, saving months during design. "If we did everything from scratch, it would take many years to get to the level that 3DVIA Virtools gives us right out of the box," says Christian Villemaire, programmer and computer section team leader for Bouchard's research group.

CUSTOMIZATION WITH MICROSOFT

Villemaire says 3DVIA Virtools was chosen for its ease of use, and it has not disappointed. "3DVIA Virtools is flexible, allowing the team to use the building blocks section for adding more functions and creating new building blocks," Villemaire says. "Or we use Microsoft's Visual Studio.Net to alter the code of existing building blocks in 3DVIA Virtools." Visual Studio.NET gives the lab the power to modify standard blocks of source code in 3DVIA Virtools to create customized objects quickly and easily.



Apartment in 3D, aerial view

entient care Université du Québec en Outaouais



If we did everything from scratch, it would have taken many years to get to the level that 3DVIA Virtools gives us right out of the box.

The lab runs 3DVIA Virtools on the popular Microsoft XP Pro operating system. The team's new development workstations feature Windows Vista 64-bit technology, which delivers the high levels of random access memory (RAM) needed to create more powerful scenarios, launch multiple applications simultaneously, and handle large VR environments.

SPEED AND DEPENDABILITY

"Because we are funded by research grants, if we needed to spend three years just to develop the backbone and all of the codes for the virtual environment, we would be out of cash," Bouchard says. "Speed is absolutely key, and showing progress on our research is important for securing the next round of funding. You also can test everything directly in 3DVIA Virtools. If it works in 3DVIA Virtools, it will work in the VR environment."

Bouchard says 3DVIA Virtools is the dream solution for a research environment. "We're the ninth cave-like environment in the world and the only one dedicated to mental health, and it's because we're using 3DVIA Virtools," he says. "We wouldn't be able to do it otherwise" •

For more information: w3.uqo.ca/cyberpsy



Firsthand Technology Helps Doctors Reduce Burn Victims' Pain with **3DVIA Virtools**



Our clients appreciate that they

can see their concepts evolve quickly, which enhances the collaborative design process and the client's satisfaction with the final product.

Ari Hollander, CEO and Technical Director, Firsthand Technology Burn patients must endure both their initial injuries and the excruciating wound care treatments that follow. But pain experts at the University of Washington School of Medicine are using a 3D virtual reality (VR) application called SnowWorld, developed by doctors and built by Firsthand Technology in 3DVIA Virtools, to distract patients from their pain. In many cases, patients experience not just a lowered perception of pain, but as much as a 50% reduction in pain-related brain activity, as documented by brain scans.

University of Washington researchers Dr. Hunter Hoffman, a virtual reality researcher, and Dr. Dave Patterson, a pain and hypnosis expert, created the first version of the environment they call SnowWorld in 1998 using video game technology. SnowWorld whisks burn patients away to an icy canyon where snowflakes fall and patients can shoot snowballs at snowmen and other targets.

"The immersive nature of SnowWorld is what makes it so effective," Hoffman says. "Watching the nurse work on their open burn wounds doesn't make for a positive experience, especially for children. Immersing themselves in SnowWorld draws patients' minds away from the pain and blocks their view of the real world for a while." Although initial success with SnowWorld was impressive, researchers suspected that a more immersive environment would yield higher degrees of pain relief. So Hoffman and Patterson turned to University of Washington colleagues Howard Rose and Ari Hollander, then part of the university's Human Interface Technology (HIT) lab, for assistance.

......

Hollander, an expert in 3D immersion technology, and Rose, a designer of virtual environments, formed Firsthand Technology, a "serious games" company with a mission of "making technology work for people." The



Immersing themselves in SnowWorld draws patients' minds away from the pain and blocks their view of the real world for a while. 3DVIA Virtools has become an integral part of our research team's success.

Dr. Hunter Hoffman, Director of the VR Analgesia Research Center, University of Washington Schools of Medicine and Engineering

company also develops applications ranging from treatment of post-traumatic stress disorder to medical training scenarios, and optimizes software interfaces to extend the impact of factors such as sound, touch and visuals in VR environments.

FLEXIBILITY FOR CHANGE

"We originally built versions of SnowWorld in other software applications, but we needed something more flexible," Hollander says. "So we rebuilt SnowWorld with 3DVIA Virtools from Dassault Systèmes to make it simpler to modify. The flexibility of 3DVIA Virtools allows SnowWorld's creators to more easily test different experimental hypotheses and identify factors relevant to better pain control."

With 3DVIA Virtools, Hollander says, developers can easily manipulate what they already have. "Dr. Hoffman wanted us to alter the field of view, for instance. That would have

taken significant time on other platforms. But with 3DVIA Virtools, we can fine-tune quickly and easily."

"3DVIA Virtools is versatile enough to let us explore a variety of options without investing so much time and effort testing out an idea that we feel locked into keeping the change regardless of its usefulness," Dr. Hoffman confirms. "Virtools has become an integral part of our research team's success."

SIMPLY POWERFUL

The fact that 3DVIA Virtools is easy for nonprogrammers to use is one of its biggest advantages, Rose says. "I can put my ideas directly into practice. Rather than relying on a team of programmers, a small, nimble development team can achieve a lot with 3DVIA Virtools. Firsthand is a small company, and Virtools allows us to create a diverse range of applications for the widely varied needs of our

widely varied customers."

3DVIA Virtools' rendering capabilities, which allow designers to create dynamic shader effects and character animation, set it apart from similarly priced VR solutions. "The cost-toperformance ratio and ease of use of 3DVIA Virtools are key factors," Rose says. "3DVIA Virtools allows us to employ particles, shaders and sophisticated textures to deliver a highly realistic experience."

patient care



Firsthand Technology uses a range of graphics solutions from DS technology partner NVIDIA, the world leader in visual computing tools. "We prefer the professional-quality NVIDIA Quadro solution for our development environment, and the Geforce cards targeted to the consumer market enable us to deploy SnowWorld more affordably in hospitals," Rose says.

"In the 3DVIA Virtools version of SnowWorld, the snow-flakes are just incredible," Dr. Hoffman says, and increased realism helps contribute to improved immersion, which leads to greater the pain relief. "The software takes full advantage of the faster computers available today and really adds a lot of 3D depth."

Programming speed is another key advantage. "3DVIA Virtools' built-in functionality and flexibility facilitate rapid prototyping," Hollander says. "Our clients appreciate that they can see their concepts evolve quickly, which enhances the collaborative design process and the client's satisfaction with the final product" •

For more information: www.firsthand.com http://uwmedicine.washington.edu www.vrpain.com

To download the expanded flyer: www.3ds.com/contactmag-extra



Beckman Coulter Advances Biomedical Device Development with V6 PLM

As a leading developer and marketer of biomedical testing instrument systems, tests and supplies for clinical diagnostics and life sciences, Beckman Coulter is subject to strict regulations. To comply, this Orange County, California, company with I2,400 employees in I30 countries and 2009 annual sales of \$3.3 billion must precisely control and document data streams, processes, workflows, and audit trails at seven different sites across the US and in Germany and Japan.

We consider V6 a keu enabler of our ability to manage and integrate change in a rapidly evolving company.

Lora Kerr. Director of Business Process, Cellular Analysis Business Group, Beckman Coulter

SOLIDWORKS AND ENOVIA STREAMLINE DESIGN AND DATA ACCESS

With product development spread across three continents, Beckman Coulter needed a way for different groups to share and re-use designs across locations and product lines. It also needed to securely store and back up critical design and manufacturing data. "With ENOVIA, we can access the large data sets our products require across several sites without bringing our corporate LAN to its knees," says Steve Campbell, director, Application Services at Beckman Coulter. "And because our data exists at all sites. we're never at risk of losing our compliance history or documentation."

In the past, a designer could spend several days locating all the data for a design and verifying that each piece was current.





The Dassault Systèmes product suite gives us a big advantage because it has all of the best-in-class solutions and a favorable cost structure and learning CURVE. Don Dorff, Senior Projects Administrator, Beckman Coulter

"ENOVIA does that same operation in less than 30 minutes, and there's no question that you have the right data," says Don Dorff, senior projects administrator at Beckman Coulter.

SolidWorks also contributes to substantial time and cost savings. "The large pool of available engineers with SolidWorks experience, its impressive support structure and its short training times all contributed to an attractive cost structure for implementation," Dorff says.

DS PLM makes it easy to reuse existing data and knowledge for new product innovation, which speeds time to market. With ENOVIA, "we've broken the boundaries of product development between sites, and we're sharing our knowledge so that everyone can benefit from it," Dorff says.

Because Beckman Coulter's products utilize many off-the-shelf components that can become unavailable, the ability to redesign guickly is imperative. ENOVIA allows Beckman Coulter to guickly identify the current design, substitute a part from another supplier, and modify the design to get the revised product into production quickly.



3DVIA COMPOSER DRAMATICALLY REDUCES DOCUMENTATION CHANGE TIMES

Beckman Coulter wanted a manufacturing and assembly documentation solution that could take design data from SolidWorks and maintain the data relationships, but keep it separate from the data set used for regulatory documentation. "When we want to make a change that has nothing to do with form, fit or function, we don't want to require engineering involvement or changes to the engineering data set," says Jernail Hothi, staff technical operations engineer, Instrument Assembly.

With 3DVIA Composer, users can easily manipulate documents, change them, and import design changes from SolidWorks. As a result, change order times on manufacturing assembly documents in Beckman Coulter's three pilot projects have been cut from as much as a week to two days or less."3DVIA Composer paid for itself, including software, hardware and training, in less than 120 days," Dorff says.

First-pass yield - errors found by Quality Assurance (QA) after the first assembly attempt - has improved by more than 20%, Hothi savs, which raises Beckman Coulter's end-customer satisfaction rates even higher. Improved production and process control and improved employee training with 3DVIA Composer also are contributing to impressive ease in complying with regulations. Animated instructions with reduce isometric views manufacturing errors, and traceability with associated ID numbers and time stamps are

collaboration and knowledge-sharing difficult. Therefore, Beckman Coulter sought a platform that would quickly integrate the operations of new acquisitions while enabling the company to better leverage its intellectual property across a global and highly matrixed organization. In 2007, Beckman Coulter began standardizing on Dassault Systèmes (DS) Product Lifecycle Management (PLM), including SolidWorks for 3D product design,

ENOVIA for global collaborative product lifecycle management, and 3DVIA Composer for virtual product documentation. In 2009, the company continued its standardization strategy by selecting DS PLM Version 6 (V6) to manage its product development and related compliance processes.

The company has grown, including several

mergers and acquisitions that brought with them

a wide range of disparate systems that made



incorporated in final assembly reports, providing detailed product traceability from the smallest part to a total assembly.

FASTER TIME TO MARKET AND IMPROVED QUALITY AND VALUE FOR CUSTOMERS

With 3DVIA Composer, Beckman Coulter routinely completes its assembly documentation in parallel with development of a new product design, streamlining instrument design and assembly document creation and release. Beckman Coulter's designers previously spent as much as 20% of their time working on documentation," Hothi says. "3DVIA Composer has freed up 15% of their time for higher-value tasks."

V6: THE EFFICIENCY ENGINE

Beckman Coulter perceives DS V6 as an enterprise-level solution for all of its product development and related compliance processes, and V6 as the engine to help enable additional efficiencies and continued excellence in its business. "Our goal is to achieve operating excellence by enabling operational autonomy for our various businesses while providing the appropriate level of corporate governance," says Lora Kerr, Director of Business Process, Cellular Analysis Business Group. "We consider V6 a key enabler of our ability to manage and integrate change in a rapidly evolving company. Dassault Systèmes is helping us drive our products to where we think they need to be".

For more information: www.beckmancoulter.com

Sunshine Heart's novel

C-Pulse heart pump design consists of a cuff that encircles the aorta, inflating and deflating

to enhance blood flow

workload

and decrease the heart's

Sunshine Heart Helps Optimize Heart Pump with Abaqus FEA From SIMULIA

CAD geometry of

C-Pulse unit on

which Matrix's

Abaqus FEA models were based

Treatment for heart failure can range from drugs and defibrillators to internal heart pumps or a transplant as the final option. No single therapy works for everyone, and side effects and mechanical issues can arise for the implanted pump devices. Dr. William Peters, a cardiothoracic surgeon and research fellow at Auckland City Hospital in New Zealand, thinks there has to be a better way.

Peters, who invented a minimally invasive bypass system, says common implanted blood-contacting devices such as leftventricular assist devices (LVADs) can be lifesavers for people awaiting transplants, but require that the patient remain on blood thinners which, although they prevent clots, can increase the risk of stroke. Reliability has also been an issue with some heart-assist device designs.

NOVEL PUMP WORKS FROM OUTSIDE THE HEART

As an alternative, Peters conceived of a novel pump system called the C-Pulse, which works inside the body but outside the bloodstream. It consists of a cuff that wraps around the aorta, with a membrane (balloon) that inflates and deflates against the vessel's external walls. The positive and negative pressure of the balloon make the aorta pulsate in time with the heart, augmenting blood flow through the circulatory system and reducing total strain on the heart. A battery-powered pump worn outside the body powers the device.

Peters patented his pump concept and formed Sunshine Heart to develop and test the device. But once the balloon was ready to be scaled up to a human model, the company decided it needed a more sophisticated design and development approach to reduce lead time and provide a level of confidence that long-term performance would satisfy physicians' requirements.

FEA HELPS OPTIMIZE FATIGUE PERFORMANCE

"Because C-Pulse is essentially a permanent

Abaqus FEA submodel solution showing variation of strain through thickness of balloon wall.

We arrived at a design solution the first time through.

Scott Miller, Manager of Mechanical Engineering, Sunshine Heart

implant, we needed to ensure that our physical design solution was optimized to give us the long-term fatigue performance required," says Scott Miller, manager of mechanical engineering at Sunshine Heart. "We decided to look at it from a computational perspective using finite element analysis (FEA)."

Miller and his product development team worked with technical engineering software services firm Matrix Applied Computing Ltd., which recommended Abaqus FEA software from SIMULIA, the Dassault Systèmes brand for realistic simulation. The software was used to model the interaction of the C-Pulse cuff and balloon with the aorta. "The FEA analysis was an iterative process



that required some very unique approaches because of the way our device works, the materials we are using, and how the device is actually assembled," Miller says. The balloon had to be easy to manipulate during implant surgery; conform to the shape of the aorta; have the strength and flexibility to repeatedly "snap through" from concave to convex and back again: compress the artery; and perform reliably from initial inflation through years of use all within a very limited space. The goal of the FEA modeling was to accurately represent the real-world behavior of the device to guide design decisions and optimize the C-Pulse's performance through every stage of this process.

ELEMENT AND MATERIALS CHOICES ARE CRITICAL

To determine the elements to use for modeling the artery, cuff and balloon, Matrix created a series of test models. The material modeling portion of the analysis was constrained by previously conducted physiology and anatomy studies. "We were given pre-existing data for the biocompatible material (a polymer approved for medical device applications) from which the device would be manufactured," says Don Campbell, principal engineering analyst with Matrix. "The Ogden hyperelastic material model in Abaqus provided an excellent fit with the experimental data."

With the FEA models of the C-Pulse set up, Matrix ran simulations to determine what shape the device's balloon should be during

It was a project

physics, and the final

model we came up

with has performed

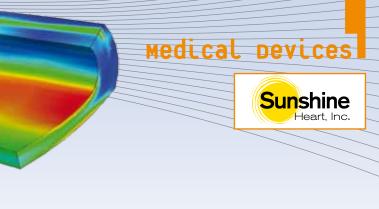
veru well in the test

Don Campbell, Principal Engineering

Analyst, Matrix Applied Computing Ltd.

with interesting

environment.



surgical implantation. Next they simulated the complete balloon "snap through" motion of convex to concave and back again.

The ultimate goal of the design analysis was to arrive at a device shape that had the least variation of strain amplitude and the maximum mean compressive strain during an operational cycle. "It was a project with interesting physics, and the final model we came up with has performed very well in the test environment," Campbell says.

FEA PROVIDES FINAL DESIGN SOLUTION

The FEA models more than met Sunshine Heart's requirements. "We arrived at a design solution the first time through," Miller says. His group has subsequently proven that the solution holds true for different sizes, important for tailoring the device to individual patients.

The durability of the C-Pulse design – simulated with Abaqus – is being borne out by ongoing testing, Miller notes. "We have been running devices day and night literally for years now. The test machine requires regular maintenance because the C-Pulse keeps wearing the test unit out"•

For more information: www.sunshineheart.com

To download the expanded case study: www.3ds.com/contactmag-extra Minimal residual volume luer activated stopcock

By **Shelli Zargary**



Ori Ziv, PLM Project Manager, IT Dept.

Mid-sized manufacturer of injection-molded disposable medical devices, Elcam Medical needed a collaborative product data management and process validation solution to comply with regulatory standards. By selecting ENOVIA SmarTeam, the company has improved production efficiency while ensuring product quality. company that combines ingenuity with product and process knowledge can succeed in the challenging medical device market. The company capitalizes on its product design and production procedure know-how by executing a smart business methodology supported by ENOVIA SmarTeam PLM. As a result, the company can offer a broad scope of validated medical products and services far beyond the capacity of most companies its size. With ENOVIA SmarTeam, Elcam Medical ensures regulatory compliance and product quality while increasing design and manufacturing process efficiency, saving time and money.

Icam Medical is proof that a small

FROM IDEAS TO SOLUTIONS

The world's third largest supplier of disposable stopcocks, valve-like devices used for a variety of clinical applications such as measuring and administering drugs, Elcam Medical today delivers a broad range of fluid management, drug delivery and vital signs monitoring systems and devices to customers and OEM suppliers worldwide. In addition to its many products, Elcam Medical also offers full medical product development services "from Idea to Solution for the End-user", with particular expertise in high-volume precision molding, high-speed assembly and laser applications.

Validating Innovation

at Elcam Medical

Elcam Medical selected ENOVIA SmarTeam to both organize its validation documentation, working with a comprehensive and easily accessible repository of all its validated product and process data, as well as to enforce these documented, standardized production procedures. This structured access to its knowledge has empowered Elcam Medical engineers to agilely and efficiently reuse validated designs to more rapidly develop more products, as well as to capitalize on its technological and production capacities by selling turnkey services to third parties with ideas for new medical products.

Saving time and preventing errors when building new product structures.

"To strictly comply with FDA (Food and Drug Administration) and ISO (International Organization for Standardization) standards, the medical device industry requires comprehensive tracking of development and manufacturing processes, forcing engineers to employ standardized procedures," explains Ori Ziv, PLM Project Manager in the IT Dept. "ENOVIA SmarTeam facilitates easy, complete implementation of such procedures. In this way, each engineer working on a drawing uses the latest, most accurate version, eliminating data duplication and human error."

nnovative drug delivery

device primarily for

anesthesia procedure

LEVERAGING DESIGN REUSE

As a small manufacturer, Elcam Medical also needs the PLM system to enable design reuse to efficiently and concurrently manage its broad product configuration portfolio. According to Ziv Naftalovitz, R&D Leader, "The job of the design engineers is to translate specifications of customer requirements from the marketing department to SolidWorks 3D models. Receiving a new customer request, the engineer looks for relevant existing designs in off-the-shelf products that meet the specifications and copies them into the new product."

Project Leader Danny Moshe explains, "We try to avoid having to carry out a long, expensive validation process for a new product that involves only a small design change; we produce a huge volume of parts and sub-assemblies, therefore our documentation has to be very accurate and we must be very precise in design storage and reuse. ENOVIA SmarTeam has rapidly accelerated searching of design data. Efficient access, finding and reusing validated parts in new designs saves time and assures quality. Design engineers attach drawings to every work order that goes to production, and thanks to the system, production staff can print the correct drawings without involving the engineers."

In addition to tracking of product histories and

With one click, the team sees the right design data they need, and only this data.

Disposable pressure transducer

enabling design reuse, the system facilitates collaboration via secure access to authorized users, with full transparency and measurability of all processes. "The main users are the product design and manufacturing engineers, QA and production planning," says Ori Ziv. "ENOVIA SmarTeam allows transparency in the interface between departments, so that, for example, the production team with one click, sees the right design data they need, and only this data. In the future, the Marketing and Business Development departments will also have access."

THE KEY: A METHODICAL APPROACH

"To comply with FDA regulations, medical device manufacturers must perform process validation for all products, which requires adherence to strict methodologies, involving a very high volume of documentation." says Danny Moshe. "There are four stages in the validation process - Risk Analysis, Installation Qualification, Operational Qualification, and Performance Qualification. All of them must be fully documented. We automatically create process validation templates on top of the ENOVIA SmarTeam platform, saving a lot of time and preventing errors when building new product structures. Then the SmarTeam integration to MS Office enables efficient transfer to MS Word forms." He adds that they use SmarTeam Integration when designing equipment

medical pevices



Slit-septum and cannula line Needleless components for intravenous applications

> in SolidWorks, entering metadata into the ENOVIA SmarTeam profile cards. This correct data is then automatically featured on the drawing templates, saving a great deal of time and errors.

> Moshe explains that the experiments they run during their production processes, involve several lots of tests with statistical information and voluminous documentation. In the future, they plan to use SmarTeam Workflow to automate the procedures.

> By organizing the validation documentation, ENOVIA SmarTeam helps Elcam Medical improve knowledge management, moving them towards their future vision of running a paperless office. "ENOVIA SmarTeam protects and enables collaboration around all our valuable corporate knowledge," concludes Lior Izenberg, Elcam Medical Engineering Manager

For more information: www.elcam-medical.com

More about Elcam

With over 25 years experience in the medical device field, Elcam Medical develops precision injection-molded disposable medical devices for a variety of clinical applications: IV Therapy; Anesthesia; Patient Monitoring; Cardiology & Radiology and Endoscopy/ Laparoscopy, as well as drug delivery devices such as auto-injectors. Elcam is the premier provider of stopcocks and manifolds to the US and European OEM markets, supplying over 30% of their stopcock needs.







The interactive, immersive environments that we're able to create using 3DVIA Virtools really set us apart from our competitors. Michael Schuldt, Principal and Director of Technology, EwingCole DMG

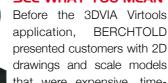
EwingCole DMG and BERCHTOLD Bring Operating Room Design to Life with **3DVIA Virtools**

As a division of EwingCole, a 350-person architectural and engineering firm headquartered in Philadelphia, EwingCole DMG (Digital Media Group) focuses on 3D modeling, animation and interactive applications development for a broad range of clients, from manufacturers and equipment designers to entertainment facilities and law firms. Using real-time 3D has helped EwingCole grow its business well beyond traditional architectural disciplines. And whether it is giving prospective buyers of luxury suites at a new baseball stadium a lifelike, panoramic view of the field before the facility is even built or providing 3D re-creations of crime scenes for legal trials, EwingCole DMG always relies on the same solution: 3DVIA Virtools from Dassault Systèmes.

In its work with medical equipment maker BERCHTOLD of Charleston, S.C., EwingCole DMG used 3DVIA Virtools to create a visualization application for operating rooms that allows Berchtold's sales

representative to work with hospital staff members to interactively design highly complex and functionally precise operating rooms.

SEE WHAT YOU MEAN



application. BERCHTOLD presented customers with 2D drawings and scale models that were expensive, time-

consuming, and difficult for non-architects to interpret. "We wanted to create an interactive planning tool that would run on a salesperson's laptop, allowing BERCHTOLD's designers and their customers to work collaboratively during meetings to evaluate infinite combinations of operating room equipment," says Michael Schuldt, principal and director of technology at EwingCole. "After doing the legwork on a variety of software solutions - gaming solutions, primarily - we decided on 3DVIA Virtools because of its ease of use and easyto-learn scripting interface."

Dave Buchhofer, technical director at EwingCole DMG, says that while his background is primarily as an architectural artist, he found 3DVIA Virtools' visual development environment easy to learn on the fly. "3DVIA Virtools has a pretty extensive set of built-in building blocks to start with, but also offers the ability to expand with text-based scripting and flow chart-based scripting to create more custom and complex behaviors on your own," he says.

Jon Mueller, architectural design supervisor at BERCHTOLD, confirms that the operating room visualization application EwinaCole DMG built with 3DVIA Virtools is everything his team hoped it would be. "We love it," Mueller says. "We think of it as our secret weapon. It's an amazing tool for our sales reps."

EASY DESIGN. NO SURPRISES

Today, a large percentage of operating room equipment is mounted on a boom suspended from the ceiling, to free floor space and simplify cleaning and traffic flow, Schuldt says. But such concepts are difficult to envision, especially for healthcare workers who might get one chance in a lifetime to help design a new operating room.

"These pieces of equipment articulate on the ceiling booms and move in every

conceivable direction," Schuldt says. "For each linkage on the hierarchy tree of possible equipment, you can grab it and move it to see the effect on that piece itself and everything else associated with it. Everything stays connected."

Mueller says many of BERCHTOLD's customers have never been involved in designing an operating room before. "The 3DVIA Virtools operating room visualization application really helps them see what they're trying to achieve," he says. "And it easily facilitates input from broad and diverse teams of hospital workers."

Buchhofer savs user-friendliness is particularly important to ensure a wide range of input. "This kind of application allows hospital workers to get involved in a design meeting who might not have otherwise," he says. "It lets BERCHTOLD's team get more input from people with greater ease and come closer to designing the 'ideal' facility the first time."

The true value of 3D visualization in an architectural context is to eliminate design surprises, Buchhofer says. Employing 3D to visualize and validate designs before construction allows mistakes to be caught

It lets BERCHTOLD's team get more input from people with greater ease and come closer to designing the 'ideal' facility the first time.

Dave Buchhofer, Technical Director, EwingCole DMG





early in the process, when they are easier and less expensive to correct. "You see things that you'd never catch in 2D renderings," Buchhofer says, "Using 3D models to do interference and clash detection makes the process more timeand cost-efficient."

3D ELIMINATES MISTAKES

BERCHTOLD executives guickly realized the advantages of helping customers experience their spaces in real-time 3D. "The 3DVIA Virtools application EwingCole DMG designed for us helps customers figure out what they are trying to achieve much faster and with fewer design 'mistakes,' " Mueller says. "It really helps people who aren't architects visualize these rooms."

The special beauty of 3DVIA Virtools is its broad applicability, Schuldt says. "3DVIA Virtools is capable of creating a wide range of real-time 3D applications for many different audiences and industries," he says. "We use a variety of applications in our work, but for interactive 3D visualization applications in real time, we rely on 3DVIA Virtools" •

For more information: www.ewingcole.com/DMG www.berchtoldusa.com





The non-invasive treatment is shaped by beams of ionizing radiation that have sufficient penetration to reach even the most deeply seated tumors.



sparing the surrounding tissue

Elekta Neuroscience continues to advance significant innovations for treating cancer and brain disorders

Elekta relies on ENOVIA to consolidate all engineering data and processes across the product lifecucle and to provide its 2,500 employees and partners with a single digital source of information. With ENOVIA, Elekta can manage vast amounts of product data and easily locate documents and process information for audits.



Elekta Synergy[®], the first advanced multi-functional linear accelerator with intensity modulated radiation therapy and image guided radiation therapy

lekta is a pioneer in innovative clinical solutions for the treatment of cancer and brain disorders. Based in Sweden and with approximately 2,500 employees worldwide, Elekta is the global leader in image guided and stereotactic clinical solutions for radiosurgery and radiation therapy, giving radiation oncologists and neurosurgeons an unprecedented capability to aggressively treat tumors with ultra-high precision without damage to nearby healthy tissue.

Introduced in 1972. Elekta's solutions in oncology and neurosurgery are currently used in over 5,000 hospitals worldwide that each day provide more than 100.000 patients with diagnosis. treatment or follow-up thanks to Elekta's advanced technology.

COMPLIANCE TO REGULATIONS -A PREMIUM CONCERN

Companies in the life sciences industry face a unique challenge that sets them apart from other manufacturers - the high degree of regulation imposed by governments used to ensure product quality. A crucial part of Elekta's activities is monitoring and adhering to regulations established by the U.S. Food and Drug Administration (FDA) as well as other international regulators. These regulatory bodies expect Elekta to master vast amounts of data. During an audit, for example, the company must be able to quickly provide any document related to its products and development processes. Elekta realized that its former paper-based data management system was unworkable and turned to ENOVIA five years ago for product development and compliancy.

EXTENDING COLLABORATION WITH ENOVIA

With ENOVIA, Elekta has a flexible, enterprisewide PLM solution that covers all areas of product development including administration, security, workflow and integration. It provides a single digital source of information, consolidating all engineering data and processes across the product lifecycle. "Even at an early stage, our management had big plans for ENOVIA," says Bo Nilsson, R&D manager, Eletka. "A global company like Elekta requires a robust PLM system."

We have a very intuitive user interface and a smarter view of our work. Thanks to ENOVIA, we can ensure that everyone looks at the single version of the truth.

Elekta has design centers in Sweden, the UK and China. Each office is responsible for designing different parts of a treatment system. Elekta uses ENOVIA Engineering Central to facilitate communication and collaboration among these teams, as well as its sales, service, production

facilities and external resources. It also uses Engineering Central to manage parts and bills of material (BOM), and drive its global product development and change processes. "We have a very intuitive user interface and a smarter view of our work," says Christian Rossby, Designer Engineer, Elekta. "Thanks to ENOVIA, we can ensure that everyone looks at the single version of the truth."

The system delivers prescribed doses/shots of radiation in compliance

with a pre-prepared treatment plan, to the exact site of the target,

The company uses ENOVIA Designer Central to integrate its CAD data. In addition, Elekta is planning to expand global collaboration between offices through PLM and integrate more partners in the system. "It's a big advantage for our purchasers to work with subcontractors who are already integrated in the system," says Nilsson. Elekta also plans to link its ERP system and ENOVIA so that data can be transferred between the different systems seamlessly.

SUCCESSFUL AUDITS

ENOVIA has helped Elekta to better adhere to FDA regulations and provide auditors with the information they require immediately. A recent FDA audit was a total success. "The inspectors were very satisfied with our system, which gave them a clear and honest view of our operations," says Nilsson. "Authorities don't have any reason to question anything since transparency in the system helps avoid mistakes and misunderstandings. As a matter of fact, the FDA praised us by saying that we have excellent control over our information."

We're looking forward to V6 so that we can benefit from even more efficiency thanks to a faster system, better maintenance, and a solution that is more adjustable to our needs.

In January 2006 Technia became the official PLM partner to Elekta. "Technia is a proactive and valuable partner to us that provides support and other application management services in the best possible way by constantly challenging our thoughts of how to use PLM. They also provide a network of customers within the life sciences industry, which makes it possible for us to benchmark and gain knowledge about system validation and other important aspects of PLM," says Bo Nilsson.

Collimator close-up







ELEKTA

By Erik JOHANSSON

Elekta will transition to ENOVIA V6 in the near future. "ENOVIA has saved us a lot of time," said Nilsson. "It's now much easier to find a particular document or plan than it was before. We're looking forward to V6 so that we can benefit from even more efficiency thanks to a faster system, better maintenance, and a solution that is more adjustable to our needs," he says •

For more information: www.elekta.com Jonas.Gejer@technia.com The Surgical Division offers peace of mind in the operating theatre by providing a range of outstanding products such as drapes, packs and staff clothing, customized procedure trays, surgical powder free gloves and skin antiseptics, along with various service solutions.

By Emmeli Häggström

A Consolidated Global PDM Solution

Mölnlycke Health Care has created a consolidated global PDM solution from Technia and ENOVIA.

11 The PDM-strategy originates from a central solution. When we decided to leave the paper-based system behind in 2001 it was extremely important for us to consolidate and create one single communications platform. Our R&D departments are situated in Gothenburg but our production units, internal and outsourced, are all spread out geographically which meant that a web-based solution was a matter of course", says Claes Göran Andersson, Project Manager DCS, System Owner PDM at Mölnlycke Health Care.

Mölnlycke Health Care (MHC) is one of the world's largest manufacturers of single-use surgical and wound care solutions for the health care sector. In the biotech industry there are high demands on product control, both when it comes to R&D and production. In 1995 Mölnlycke began scouting the market for a centralized product data management (PDM) solution. The aim was to ensure that all changes and upgrades were performed in accordance with current rules. There was also the obvious benefit of streamlining the organization, making it more effective. When Nordic Capital did the acquisition of Mölnlycke from SCA 1998, MHC decided to change all the old IT systems. The decision resulted in an IT project where all existing SCA systems were switched to SAP R/3. Following the large changes in the IT structure the implementation of a PDM system project was delayed and was not implemented until 2001-2002.

FOCUS ON R&D

In 2002 Mölnlycke's research and development department deployed a new PDM solution, based on ENOVIA. Mölnlycke's IT system is based on the outsourced hosting of data operations, servers and a global network. The PDM system works inside this global network which is open to everyone in the company.

"We chose to start the implementation of ENOVIA in the R&D department because they had the biggest need for structure when it came to documents and R&D projects. At that time they had a single database for all paper documents, making control and knowledge sharing difficult. Many times one single person had all the product-specific information and knowledge which made product development vulnerable," says Claes-Göran Andersson. The Wound Care Division offers gentle and effective wound healing with a range of unique products."

STRICT DEMANDS FOR CONTROL

The product process, as opposed to many other traditional PDM/PLM users, is a little different for Mölnlycke as a biotech company. For example the product is destroyed after use. In addition there are no spare parts and no need for repairs. However, the need for control is of utmost importance. Every production batch needs documentation. Every release of newly developed or changed products must be verified, validated and documented in accordance with the Medical Device Directives that Mölnlycke chose to follow in order to be CE-branded. "Two of the medical directives we adhere to are the Medical Device Directive (MDD) in Europe and the Food and Drug Administration (FDA) for



the USA, to name a few. Products are classified in different levels depending on the directive. The traditional Mölnlycke range is class 1-2 but lately we have started developing higher classified products, class 3, which require higher control and comprehensive documentation. Class 3 products are usually used close to the body and close to body fluids, which can affect, for example, the blood system. In short we needed to develop our system and our documentation processes to be able to manage these types of products in a satisfactory way. With a PDM/PLM system we can handle the process much more effectively and ensure we don't miss anything," continues Claes-Göran Andersson.

GLOBAL SOLUTION WITH SPECIAL ADJUSTMENTS

Since 2002, PDM has been implemented in several areas in Mölnlycke, and is integrated with the SAP system. As a result many of the processes are shorter and more flexible. Since the PDM solution is centrally implemented in a global system, it is easy for employees to reach the product data from anywhere in the world.

Mölnlycke's PDM system currently has around 700 users, of which 150 are heavy users in R&D and manufacturing. The ENOVIA system development is made in close collaboration with Technia and today Mölnlycke has

The Mölnlycke Health Care headquarters is located in Gothenburg Sweden. MHC employs 5500 people and has manufacturing facilities in Belgium, the Czech Republic, Finland, Malaysia, Thailand and the UK. In 2007 the company was bought by Investor.

More about Mölnlycke Health Care

www.molnlycke.com

Medical Devices





a relatively advanced solution with a couple of adjustments and improvements custom-made to fit their organisation, one example being a central solution for project-related work. "Mölnlycke and Technia have enjoyed a good partnership for PDM during the past six years and together they have developed an extensive PDM system which is globally used at Mölnlycke. The foundation of this complex project has been the mutual collaboration between Technia and Mölnlycke as well as both companies' ambitions to achieve good results," states Claes-Göran Andersson •

For more information: jg@technia.com

More about Technia

Technia is a world-class supplier of Product Lifecycle Management (PLM) solutions for the creation and management of product information throughout the entire product lifecycle. www.technia.com

Contact mag = 23





A-dec: Automating Dental Cabinetry Design and Production with DS PLM and Microsoft .NET



hen A-dec, one of the world's largest producers of dental equipment, introduced a greatly expanded catalog of standard-order cabinetry in 2000, orders skyrocketed. The strategy helped make A-dec's furniture division the North America market leader, manufacturing more than 17,000 parts per week. But the additional volume pushed Adec's production system beyond its limits, and orders quickly outstripped capacity.

Designs created on 2D and 3D CAD systems were entered into the production system by programmers, not designers. Multiple rounds of physical prototypes were needed just to locate and eliminate the coding errors before production could begin. And as order volumes grew, the system began introducing errors of its own.

Squeezed between the limits of its production system and high demand for its standard-order offerings, A-dec reluctantly turned away high-margin requests for custom designs and scaled back its new product offerings. A-dec clearly needed a new approach – a system that could automate growing volumes of routine orders from design to production, giving designers more time to spend on custom orders and new product development.

A-dec initially focused on solutions specific to the cabinetry industry, but expanded its search to include knowledge-based 3D modeling solutions. A-dec narrowed the field to three competitors and ran full pilots to evaluate performance against A-dec's 34 requirements and 21 wants. PLM from Dassault Systèmes, including CATIA for 3D modeling and ENOVIA SmarTeam for data management, was the clear winner. The close links between DS PLM and Microsoft technologies, including SmarTeam's use of SQL server and the potential to employ Microsoft.NET framework for system integration, offered additional value.

CATIA LINKS DESIGN AND MANUFACTURING IN ONE ENVIRONMENT

CATIA's ability to integrate the design and manufacturing environment within a single platform was a key differentiator. "If the other systems offered parametric rules they were part of a different system, but they were built into CATIA," says Wes Snyder, Engineering Manager for A-dec's furniture group.

CATIA features parametric design capabilities driven by Knowledgeware, which allows A-dec to store its standard assemblies as design templates. When a customer's order is processed, CATIA and an in-house control application automatically configure the templates to the right size, shape and color.



CATIA generates the numerical control (NC) instructions to manufacture the components, outputting them to A-dec's milling and routing machinery directly from the 3D model. This eliminates data re-keying and its inherent potential for error. "Designing the whole product in 3D and being able to see the results of what we were doing was another major differentiator," says Staff Manufacturing Engineer Chris Etzel. "CATIA lets us see the product virtually in 3D, eliminating the multiple rounds of prototypes we needed to find the errors. Now we're virtually paperless."

ENOVIA Smarteam AND SQL SERVER MANAGE THE INTELUGENCE BEHIND THE PROCESS

ENOVIA SmarTeam, based on the Microsoft SQL Server[™] database, serves as the data engine. It manages the intelligence behind the parametric modeling capabilities as well as the history of CATIA designs. A Microsoft SQL Server database designed by A-dec stores the results of every project for future reference. "The ability to store design history, work in process and production data is the real power of the system," Etzel says.

A custom control application receives information from A-dec's order configurator, which resides in A-dec's ERP system and integrates with ENOVIA SmarTeam to relay information to CATIA. The control application then opens the appropriate product models in CATIA, adjusts the parameters, and outputs the NC routing and milling instructions to Manufacturing. The result is a fully automated system that takes an order from sales entry to the shop floor without human intervention, removing the limits on Adec's production capacity and freeing its designers to focus on custom orders.

3D XML PROVIDES EASY-TO-USE VIEW OF DATA WITH BOOST FROM MICROSOFT SHAREPOINT

3D XML allows Manufacturing engineers and assembly workers to resolve questions by viewing CATIA designs in 3D. As an intuitive viewing tool similar to an Internet browser, 3D XML requires virtually no training. "It's

CATIA lets us see the product virtually in 3D, eliminating the multiple rounds of prototypes we needed to find the errors. Now we're virtually paperless.

Chris Etzel, Staff Manufacturing Engineer A-dec pretty quick for them to walk over, pull up the 3D XML, and get visual verification of what they're building," Etzel says. "It took us all of about 90 minutes to set up."

A-dec uses Microsoft SharePoint to make 3D XML viewing available to any authorized A-dec employee, regardless of whether they have access to a CATIA-enabled desktop. "It makes delivering information easy and lets us display it for each user exactly the way they need to see it," Etzel says.

FOCUS ON RAND

One of the best PLM decisions A-dec made was to hire RAND to manage the implementation, IS Manager Becky Urwiller says. "Having the team from RAND partner with us was a good decision. Their understanding of APIs and how the software functions was invaluable to us. We could never replicate that level of knowledge."

RAND served as A-dec's guide into the world of PLM, Snyder says. "During our evaluation process, RAND worked to find another CATIA user that had developed a fully automated production system like the one we were building. Even though no one had taken an implementation as far as we were going to take it, RAND pulled together customers that had done portions of the process, so we knew it could work. They also understood our focus on avoiding scope creep and were very supportive."



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A team of at least six RAND employees worked on the project, creating the framework and best practices to move data from A-dec's ERP system to CATIA, entering product data into the system and migrating the standard parts library. "One of the real successes from my standpoint is that we didn't concede a single system requirement," Snyder says. "A lot of the responsibility for that goes to RAND."

MICROSOFT .NET SIMPLIFIES MAINTENANCE OF INTEGRATED APPLICATIONS

The control application that moves data between the ERP system and CATIA is built on the Microsoft .NET framework. The framework supported modular design based on standard interfaces, making it easier to update software packages. "Microsoft .NET makes it painless," Urwiller says. "We've upgraded from V5 R14 to R17 without the need to revise our control application. That lets us quickly take advantage of new functionality as upgrades are released, because of the Microsoft .NET framework."



A-dec also appreciates that CATIA and ENOVIA SmarTeam are Microsoft Windowsbased, allowing A-dec to leverage its existing investment in Microsoft Office and Microsoft SQL Server to wring even more value from the project.

A-dec has achieved impressive results from its DS PLM implementation, including a 75% reduction in the need for physical prototypes, doubled production system capacity, and a 90 percent reduction in paper-based documentation. Results include:

- Production capacity limits eliminated with no delivery impacts. "In the past, our capacity was limited to what our software could handle and to how many production planners we had working," Etzel says. "DS PLM allows us to do more with less. On a purely theoretical basis, our capacity is now infinite." What's more, the system went into production over a span of six months with no impact on product delivery or quality. "It was invisible to our customers," Etzel says.
- Physical prototypes for design "checking" reduced. Since data is never translated or re-entered, errors that once made multiple physical prototypes necessary have been dramatically reduced. "Now, instead of building prototypes, designers sit in front of a CATIA screen making sure the design template configures and fits together properly," Etzel says. "That is much faster and less expensive than repetitive prototyping."
- Fully automated manufacturing code generation. "In the past, every job on the floor required some intervention by our NC programmers," Snyder says. "This has been eliminated by building the NC output into the models parametrically."
- Greater capacity to accommodate special orders. Special orders are back on the menu

since A-dec adopted DS PLM. "We're in a relatively small industry and we sell through dealerships that also sell products from other manufacturers, so we like to offer what our customers ask for," Snyder says.

- Increased design innovation to expand product line. Now that its product capacity limits have been eliminated, A-dec has the ability to develop new product offerings.
 A-dec also has significantly more designers who know how to use the system; hiring is simpler because CATIA is so widely used.
- Corporate knowledge capture. The limits of A-dec's previous system forced employees to remember which products required exceptions to standard practice. By using Knowledgeware to build that "tribal knowledge" into CATIA, the system automatically propagates changes to all affected parts for higher levels of quality control. Microsoft .NET, meanwhile, simplifies the process of sharing data with A-dec's ERP system and makes it easy to update integrated applications without damaging the links between them.

EXTENDING THE VALUE OF DS PLM WIDER AND DEEPER

For the future, A-dec's focus is on gaining even more value from what it has already accomplished with DS PLM, and possibly extending its 3D XML offering to suppliers and dealers. "The majority of the project to date has been geared toward stabilizing the design and manufacturing," Snyder says. "Overall, we think that continuing to go deeper into what we've already built will greatly reduce our throughput times, and we've set ourselves up for some big gains that are not yet realized" •

For more information: www.a-dec.com www.rand-na.com By Dora Lainé aid performance

GN ReSound Uses **SIMULIA** to **Optimize Product Performance**

he rate of hearing loss in the global population is estimated at between 1.5 and 5 percent, depending on the definition of "deafness." Total lack of hearing is actually rare, but when hearing loss occurs within the normal frequencies of human speech, it can create significant challenges at any age. Most cases of hearing loss can be improved with externally worn, behind-the-ear (BTE) hearing aids. But designing high-tech hearing aids that are light, comfortable and stylish can be a challenge for BTE hearing aid design engineers.

HEARING AID SPECIALISTS

The GN ReSound Group is one of the world's largest providers of hearing instruments and diagnostic audiological instrumentation. GN ReSound engineers perform design analysis and testing in a high-tech acoustics laboratory at the company's corporate headquarters in Copenhagen, Denmark. Just a few years ago, hearing aid prototypes were physically tested in the lab, and modifications in their design and composition were made according to the results. But now GN ReSound uses Abaqus FEA software from SIMULIA to test its designs thus reducing the number of prototypes needed and significantly shortening development time.

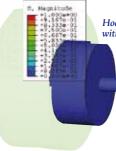
FINITE ELEMENT ANALYSIS FOR ACCURATE RESULTS

"Before simulation, we were limited to a trialand-error approach for all our hearing aid design and testing," says Morten Birkmose Sondergaard, Senior Acoustic Engineer at GN ReSound. "With Abaqus we can accurately evaluate and alter the behavior of a hearing aid in the early design stages making the device more stable and improving its performance."

MODELING THE HEARING AID

Abaqus software enables GN ReSound engineers to make computer models of all the critical elements of a hearing aid. They run their models through virtual vibration and sound pressure stresses that approximate real-world conditions, assess performance, and then validate the results with laboratory tests of actual units.

Within Abaqus, models of critical connections, such as that between the steel receiver housing and the rubber tube that goes over the receiver sound port, are a particular focus for simulation. Abaqus' "shrink-fit" function is used to model the important pre-tension in the part of the rubber tube that stretches over the underlying receiver sound port. Acoustic resonance





frequencies are also studied using an FEA modal analysis, which incorporates both natural vibration frequencies and the specific vibration patterns of the structure being studied. And with Abaqus' multiphysics capabilities, engineers can analyze the air that conducts the sound as well as the interaction between the air and the unit itself.

Medical Devices

GN ReSound

VIRTUAL TESTS VALIDATE REAL-WORLD RESULTS

Virtual test data and real-world results are in close agreement. Consequently, materials and components can easily be adjusted to produce a device that provides maximum sound with no "squeal". "We now have a greater understanding of what causes instability so we can eliminate these causes in the early design stages," says Sondergaard. "Thanks to SIMULIA we can optimize designs for all our hearing instrument products"

For more information: www.gnresound.com

Hook-housing torsion and pvc bend with SIMULIA Abaqus FEA

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eharmaceutical

Toward an Era of BioIntelligence"

Life sciences is the next frontier for PLM and Dassault Systèmes (DS) is driving several to provide answers to the growing complexity in biological and medical research and development.

&D spending in healthcare is more than that of the automotive and aerospace industries combined. The sheer complexity of drug development, scientific research and patient care, combined with the siloed nature of pharmaceutical activities, prompted DS to consider the benefits that a PLM approach could bring to this sector. Although PLM is not yet the norm in life sciences, this market offers promising opportunity.

After several contacts with a number of pharma companies. DS realized that potential significant synergies could be achieved through collaboration with key partners aimed at addressing the many and varied requirements and challenges facing the pharma industry. Among a number of initiatives in progress is BioIntelligence, an innovative and ambitious long-term R&D project whose objective is to bring together a DS-led consortium of industrial firms, software companies, and academic and government research labs. The goal is to create a "BioPLM" platform dedicated to the discovery and development of new and improved biological products in the life sciences sector, and in particular, in the pharmaceutical, biotech, and phyto-care industries.

The project is viewed positively by the European Community. EU Competition Commissioner Neelie Kroes said: "The systemic modeling and simulation tools in this particularly innovative program will substantially improve the efficiency of biological research. BioIntelligence and the

BioPLM platform that will be developed by it are entirely consistent with key objectives in European research."

There is a revolution sweeping life sciences. The industry is at a turning point and ripe for dedicated solutions that will transform its processes and help meet the increasing demand for new drugs and treatments. The potential impact on

drug research and development of a PLM platform that fosters new collaborative practices between research labs is huge. Applying PLM "next" practices should enable life sciences organizations to optimize their research phases, improve the efficiency within their supply chains and help companies comply with increasing regulatory constraints. And this is just the beginning! •

Two questions to Patrick Johnson, head of research at Dassault Systèmes:

Contact Mag: Dassault Systèmes has made a name for itself transforming manufacturing industry processes thanks to PLM. What will PLM bring to the sector of life sciences?

Patrick Johnson: We believe that there is a real potential for PLM to transform the life sciences industry with collaboration, modeling, and simulation. Due to its innovative cross-disciplinary collaborative approach, Dassault Systèmes' V6 platform is expected to be the foundation for BioPLM and aims at going past what people thought they could do. Given the silos of information in sectors like agrochemicals and pharmaceuticals, V6 can offer a unique framework for managing intellectual property and scientific knowledge as well as promoting collaboration between different research entities. It therefore can help companies manage the complexity of data and adapt their logistics along the product development pipeline.

C.M.: How will PLM have to evolve in order to adapt to the needs of this sector? P.J.: In industries such as pharma or cosmetics, we are facing new challenges. With life sciences, we are challenged to embrace the complexity of nature. We therefore need to extend PLM as a means to understand this new scientific data in its full variety, scope and size, and to leverage the discovery process of our customers by enabling simulation, analysis, and collaboration on top of it. We are therefore considering a new horizon for PLM 2.0 extending from product to nature and life and fueling our passion for innovation in this new sector.





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