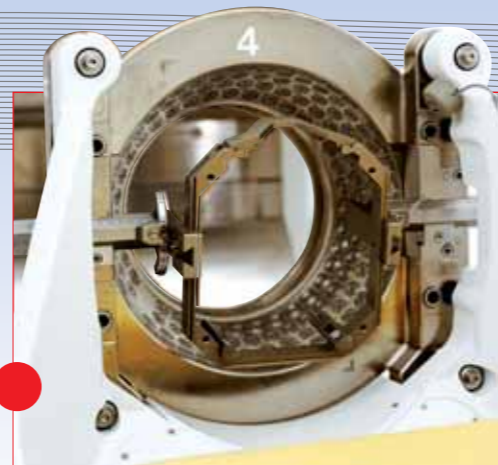




Elekta Neuroscience continues to advance significant innovations for treating cancer and brain disorders.



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



The system delivers prescribed doses/shots of radiation in compliance with a pre-prepared treatment plan, to the exact site of the target, sparing the surrounding tissue.



Collimator close-up

feature



# Ensuring Regulatory Compliance with ENOVIA

By Erik JOHANSSON

Elekta relies on ENOVIA to consolidate all engineering data and processes across the product lifecycle 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 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, enterprise-wide 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, Elekta. "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 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.

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.

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



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