

# Elekta

Ensuring compliance to regulations with ENOVIA



## Overview

### ■ Challenge

*Elekta needed to manage vast amounts of product data and to easily locate documents and process information for audits*

### ■ Solution

*ENOVIA provides Elekta's 2,500 employees and partners a single digital source of information, consolidating all engineering data and processes across the product lifecycle*

### ■ Benefits

*ENOVIA has unified Elekta's global product development teams, ensuring visibility and collaboration, and made documentation immediately accessible for audits at any time*



"Regulatory authorities have no reason to question anything since mistakes and misunderstandings can easily be avoided. As a matter of fact, the FDA praised us by saying that we have excellent control over our information."

Bo Nilsson  
Manager R&D  
Elekta



### World leader in radiation therapy and radiosurgery solutions

Elekta is a pioneer for 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.

Founded 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. A global company like Elekta requires a robust PLM system," said Bo Nilsson, R&D manager, Elekta.

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. Thanks to ENOVIA, we can ensure that everyone looks at the single version of the truth," said Christian Rossby, Design Engineer, Elekta.

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," said 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," said 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."

### Transition to V6

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 said.

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Christian Rossby  
Design Engineer  
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