

# SIEMENS

*Ingenuity for life*

Medical devices and pharmaceuticals

## Allengers Medical Systems

Medical device firm realizes significant cost savings by using Teamcenter to make design data easy to manage

### Product

Teamcenter

### Business challenges

Improve document search and traceability capabilities

Enhance compliance with FDA documentation requirements

Improve workflow integration with teams

### Keys to success

Use Teamcenter to deploy a fully integrated environment that addresses the entire product design cycle

Achieve faster time-to-market

Create new opportunities for business by meeting FDA compliance standards

Enable reallocation of resources

### Results

Realized significant cost savings by making design data easier to manage

Achieved productivity gains by enhancing knowledge sharing

Used improved document management capabilities to realize time savings

Achieved notable improvement in quality

### Siemens PLM Software solution enables Allengers to achieve productivity gains by enhancing knowledge sharing

#### Overcoming a communications gap

Allengers Medical Systems Ltd. (Allengers), headquartered in Chandigarh, India, is one of the leading manufacturers and exporters of a wide range of medical diagnostic equipment, such as x-ray systems, digital radiography (DR) systems, digital subtraction angiography (DSA) systems, cathlabs and remote controlled radiography fluoroscopy tables.

By virtue of Allengers' quality, system and safety standards, it has earned certifications from the Communaute Europeenne (CE), International Organization for Standardization (ISO) 9001:2008, ISO 13485:2012 and India's Atomic Energy Regulatory Board (AERB). It has also been certified by the Bureau of Indian Standards (BIS), which covers product quality certification, consumer affairs and development of technical standards for their largest product categories, including radiology, cardiology, orthopaedics, gastroenterology, urology and neurology.

In the past, all documentation – including the design history file (DHF), device master record (DMR), corrective action preventive action (CAPA), change management and project management reporting – was done on paper. Requirements were managed with standalone software, but they were

not connected to the new product development (NPD) process so documents were hard to search and trace, and enterprise resource planning (ERP) solutions did not help much. Most designing and approval processes were manual. This added to an already-existing communication gap between the mechanical, electronics and software teams, so all teams were working in isolation.

So the process did not serve the purpose adequately. As a matter of fact, the entire design cycle was extended due to a work environment that did not encourage knowledge sharing.



# “Siemens PLM Software’s Teamcenter helped us in setting up a fully integrated environment that addresses the end-to-end product design cycle.”

Suresh Sharma  
Chairman and Managing Director  
Allengers Medical Systems Ltd.

## Achieving greater control

Conducting requirements management using a standalone solution made it hard to share knowledge. As a result, cross-department requirement linking was a challenge, and aligning with United States Food and Drug Administration (FDA) documentation requirements (such as compiling design history files) in hard copy was difficult to manage and trace.

Allengers has to gather inputs from customers and correctly capture each of their requirements before moving to machine design. There are about 800 to 1,000 parts in each machine, including casting, forging, sheet metal, plastic, electrical and electronics. For designing machines, teams such as mechanical, electrical and software need to coordinate their activities. Allengers was facing an issue in managing these documentation transfers between the various departments, including in-house and external document transfers (first machine prototypes have to undergo external quality checks so a third-party doctor can submit a report on machine performance).

By adopting a new system, Allengers sought to achieve greater control of its requirements management, change management, project management, FDA compliance documentation and workflow

integration between teams. The company hoped this would result in significant time and cost savings, a collaborative digital environment and alignment with FDA documentation compliance guidelines, thus enhancing its competitiveness.



**“Using Teamcenter also helped us to get our necessary FDA compliance documentation in place in a digital format.”**

Sanjeev K. Marjara  
Director, Research and Development  
Allengers Medical Systems Ltd.

#### **Introducing Teamcenter**

DesignTech Systems Limited, a partner of product lifecycle management (PLM) specialist Siemens PLM Software, was introduced to Allengers. In the course of two days of demonstrations, DesignTech Systems Limited presented Teamcenter® software as a complete business process management solution for the medical devices industry. It showed Allengers the advantages of not only implementing Teamcenter as a solution for requirements management, project management and change management, but also in adopting it as a complete lifecycle management solution.

Understanding customer requirements is vital. Since medical devices are complex and relate to health, information must be captured precisely. As per FDA requirements, all design procedures need to be documented, so managing documentation is an important challenge. It is especially important for managing the collaboration between teams, such as the mechanical, electrical and software teams.

Post manufacturing support was also a challenge. Machine trial run reports were in hard copy, so managing final reports

was an issue. The design approval process was compiled manually, so it was time consuming and bureaucratic.



***“Now design data is easy to manage and share. Using Teamcenter enabled us to enhance cross-team communication and knowledge sharing, thus breaking up our information silos.”***

Sanjeev K. Marjara  
Director, Research and Development  
Allengers Medical Systems Ltd.

## Solutions/Services

Teamcenter  
[www.siemens.com/teamcenter](http://www.siemens.com/teamcenter)

## Customer's primary business

Allengers Medical Systems Ltd. (Allengers) is headquartered in Chandigarh, India, and is one of the leading manufacturers and exporters of a wide range of medical diagnostic equipment, such as x-ray systems, digital radiography (DR) systems, digital subtraction angiography (DSA) systems, cathlabs, remote controlled radiography/fluoroscopy tables.  
[www.allengers.com](http://www.allengers.com)

## Customer location

Chandigarh  
India

## Partner

DesignTech Systems Limited  
[www.designtechsys.com](http://www.designtechsys.com)

## Addressing the entire design cycle

Now everything – including requirements management, the Teamcenter medical devices solution, project management, computer-aided design (CAD) integration, corrective action preventive action (CAPA), change management, risk management, reports and digital signatures – is configured through the Teamcenter software workflow, so it is much easier to create, manage, share and trace documents.

"Siemens PLM Software's Teamcenter helped us in setting up a fully integrated environment that addresses the end-to-end product design cycle," says Suresh Sharma, chairman and managing director, Allengers.

"Now design data is easy to manage and share," says Sanjeev K. Marjara, director of research and development (R&D), Allengers. "Using Teamcenter enabled us to enhance cross-team communication and knowledge sharing, thus breaking up our information silos. Teamcenter also helped us to get our necessary FDA compliance documentation in place in a digital format."

Consequently, Allengers has developed an integrated environment for the entire design cycle, and is now able to get products to market much faster. Furthermore, the company's ability to comply with FDA requirements has opened new territories for business opportunities.

As a result, Allengers has realized significant cost savings by reducing rework; achieved improved productivity by facilitating enhanced requirements gathering and better documentation flow; saved time by implementing improved document management and proper team coordination; and increased quality by using enhanced techniques for compiling requirements.



## Siemens PLM Software

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