

# Customer Success Story: Advanced Oncotherapy

## Learn how Advanced Oncotherapy is using PLM to achieve and sustain ISO compliance and FDA validation.

### Summary

As a company transitioning from research and development to manufacturing, Advanced Oncotherapy recognized the significance of efficient, defined business processes supported by integrated systems. Their primary goal was to develop processes to support their highly-educated and talented workforce with a minimum of paperwork and manual intervention.

As a premier designer and manufacturer of medical devices, Advanced Oncotherapy will be subject to regulatory compliance. Advanced Oncotherapy recognized that manual systems and its existing PLM software would not allow the company to develop business processes that would achieve and sustain ISO compliance and FDA validation. Already a user of several Autodesk® software products, Advanced Oncotherapy added Fusion Lifecycle as the tool to develop workflows and control business processes in every area of the organization.

### Challenges

Although Advanced Oncotherapy is still manufacturing prototypes, the company recognized the importance of a fully-integrated business system to support its operations and meet the upcoming requirements of regulatory bodies. However, the company soon realized that its legacy PLM system would be an impediment in achieving a fully-integrated business system.

“As a stand-alone PLM system managing our engineering change control process, our old PLM software worked fine,” said Neil Barker, Quality and Process Improvement Manager. “However, we realized that we needed to integrate data from our PDM, CAD, and eventually our ERP systems. With our old PLM software, this was not possible. As we were already using many other products from Autodesk including Inventor (3D CAD software), Vault (data management software), and A360 (project collaboration software), it made sense to evaluate Autodesk’s PLM software, Fusion Lifecycle.”

Another consideration for Barker was cost. “We were developing many of our business processes from scratch. We wanted a platform that would enable us to control the business without mounds of paperwork. Our goal was to expand beyond the traditional PLM functionality of managing the product, and include other areas such as quality and non-conformity. Initially, we looked at expanding the use of our previous PLM system. Even though it contained some of the functionality we required, it came at an extra cost. The advantage with Fusion Lifecycle is that you get access to all its capabilities for a single license fee.”



*Advanced Oncotherapy is taking proton beam therapy into the new age with its novel proton beam therapy (PBT) system, LIGHT.*



**Industry:**  
Medical

**Products:**  
Proton beam therapy systems

**Employees:**  
100

**Number of Locations:**  
London, England; Geneva, Switzerland; Syracuse, NY USA

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NEIL BARKER  
QUALITY & PROCESS MANAGER AT ADVANCED  
ONCOTHERAPY

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## Implementation

Advanced Oncotherapy commenced their implementation in late Spring, with the assistance of D2M3, a consulting firm and Autodesk partner. “3 months later, we had transferred all of the data and went live with the basic components,” said Barker. “D2M3 provided the training and support as well as helped us to improve our understanding of Fusion Lifecycle and ultimately refine our processes. D2M3’s commitment to the project was excellent.”

Previously, Advanced Oncotherapy only had six users on its legacy PLM system. By taking advantage of the additional capabilities available in Fusion Lifecycle, the company expects that everyone in the organization will eventually have access to the system.

“During the first few months we only had a few users, but quickly added more,” said Barker. “I expect everyone in the company will eventually have some level of access. Currently, we are using 64 out of 66 licenses. In the near future, we will increase the number to 100. With this effort, everyone in the company will have access to Fusion Lifecycle.”

## Expanded scope

Whereas most companies that implement PLM software look to control product data, Advanced Oncotherapy is looking far beyond the initial scope by using Fusion Lifecycle to manage all of their business processes.

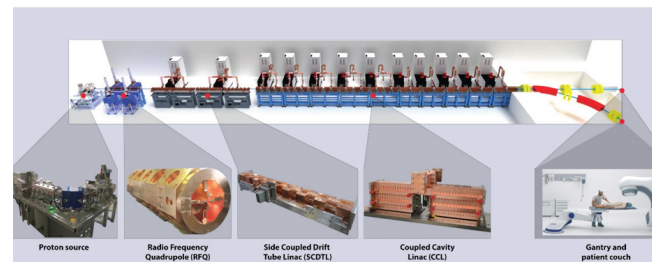
“Originally, we were looking to replace our existing PLM system to facilitate integration with our other software systems,” said Barker. “As our knowledge of Fusion Lifecycle expanded, we realized we could manage much more than just the traditional bills of material and change control normally associated with PLM. With the various capabilities of Fusion Lifecycle, we are planning to manage documentation, suppliers, quality, non-conformity, corrective actions, audits, deviations, post-market surveillance, and customer complaints. Recently, we have been discussing including intellectual property as well. As yet, I haven’t found a process that we couldn’t manage with Fusion Lifecycle.”

In addition to Fusion Lifecycle, Advanced Oncotherapy is implementing Epicor® ERP. “This is another area where we need to integrate both systems,” said Barker. “Early on we decided on a clear demarcation to avoid maintaining data in two separate systems. We decided that PLM will manage all of the master data, and ERP will manage all of the transactional data. We are planning to integrate Fusion Lifecycle with Epicor® ERP so that parts, bills of material, supplier records, and documentation will be passed from Fusion Lifecycle to Epicor.”

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Advanced Oncotherapy plc  
LIGHT (Linac for Image Guided Hadron Therapy) system



*Advanced Oncotherapy’s linear accelerator for PBT, LIGHT takes up less space, does not require expensive cryogenic cooling, and demands less shielding compared to circular accelerators.*

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## Benefits of Cloud-Based Software

The ability to access data anywhere at any time has proved invaluable for Advanced Oncotherapy. The fact that Fusion Lifecycle is Cloud-based allows authorized users to access company data with just an Internet connection anywhere in the world.

“Advanced Oncotherapy is diversified across three locations,” said Barker. “Our headquarters is in London, engineering in Switzerland, and an office in the U.S.A. We have to share information, and we have multiple people in different locations approving engineering changes. Many of these people are travelling, so the ability to access Fusion Lifecycle via a mobile device has proved invaluable.”

“It’s essential to our business model that we can easily and securely share information. We are operating an outsourced manufacturing model, so it’s important to be able to securely share data with our partners, and reduce errors resulting from miscommunication. The capabilities in Fusion Lifecycle will facilitate collaboration with our suppliers and manufacturing partners worldwide.”

As a relatively new company, Advanced Oncotherapy had the advantage of designing a business system from scratch instead of being encumbered by legacy systems. According to Barker, the company had started to document a management system, but without any indication of the business systems needed.

“The proposed system was very manual and I realized that we would soon be drowning in paperwork. My goal was to introduce management systems with as little paperwork as possible, and to eliminate the possibility of manual errors. We wanted to avoid anything that will add costs to the process. Our people are highly-skilled scientists and engineers; a PhD is the norm rather than the exception. We wanted our employees to spend their valuable time working on their primary tasks and not become encumbered with mounds of paperwork. The goal is to make these processes as simple and efficient as possible. Fusion Lifecycle is the enabling software to make that happen.”

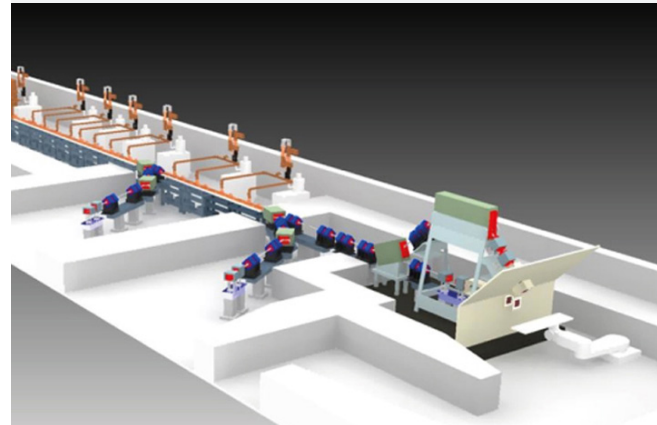
In the near future, Advanced Oncotherapy will be subject to regulatory authorities such as the FDA and compliance with ISO 13485, the standard for the design and manufacture of medical devices.

“Fusion Lifecycle will make it a lot easier to gain and maintain FDA approval and meet the stringent requirements of ISO 13485, as it provides a single source for much of the data required to meet auditing and compliance requirements,” said Barker. “We will be able to use Fusion Lifecycle to explain our processes, rather than running around trying to find paperwork. As we are using pre-determined workflows, if there is a problem, we can correct it once and be sure that everyone is following the correct procedure.”

Prior to Fusion Lifecycle, supplier selection and approval was a manual process. Today, supplier audits are now managed in Fusion Lifecycle. The system can automatically schedule the auditor and collect all the audit data. The integration between Fusion Lifecycle and Epicor will also improve supplier management. Barker explained:

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NEIL BARKER  
QUALITY MANAGER



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“As an example, if we place a purchase order in Epicor ERP, and incoming inspection flags a non-conformity, Epicor will automatically notify Fusion Lifecycle. We will manage the non-conformity in Fusion Lifecycle relating to the supplier, the part, and any corrective action needed. The interconnectivity between the two systems is maintained and ensures data integrity.”

During the next 12 months, the company plans to introduce all the processes throughout the organization. “We want to generate some graphical reports and dashboards to help provide the information we will need to manage the business,” said Barker.

## About Advanced Oncotherapy

Advanced Oncotherapy is headquartered in London, UK, with a research and development facility located on the campus of CERN (the European Centre for Nuclear Research), Geneva, Switzerland, and a manufacturing plant, clinical research, and clinician training facility in Syracuse, USA.

Advanced Oncotherapy’s focus is to develop technologies to maximize the destructive effect of radiation on tumors whilst minimizing damage to healthy tissues. The company’s goal is to help healthcare providers and hospitals expand their repertoire of treatments to ensure clinicians and patients have choices. Advanced Oncotherapy’s aim is to cost-effectively deliver the next generation of proton therapy which is clinically superior to the alternative radiation therapies currently available.

Learn more at: [www.advancedoncotherapy.com](http://www.advancedoncotherapy.com)

## About Autodesk

Autodesk’s product innovation platform brings together a set of connected design and manufacturing tools in a single data-centered solution. This cloud-based platform, Fusion, supports the new ways that products are designed, made, and used while giving you access to tools for the top manufacturing trends.

Learn more at [www.autodeskfusionlifecycle.com](http://www.autodeskfusionlifecycle.com)

## Key Takeaways:

- Advanced Oncotherapy needed a system to help achieve ISO compliance and FDA validation.
- Previous PLM system did not allow integration of data from PDM, CAD, and other critical business systems.
- Within 3 months, transferred all product data and went live with the base implementation.
- Only 6 users utilized legacy PLM system, compared to 60+ users actively accessing Fusion Lifecycle.
- Currently using Fusion Lifecycle for Audit Management, Goods Receiving, Customer Complaints, Change Control, and Intellectual Property Management.
- With multiple global sites, cloud-based PLM allows real-time collaboration among key contributors, regardless of location.