

“Moving from our old system to CARA was a real breath of fresh air”



Thanks to CARA's speed, agility, flexibility and intuitive user interface, CARA is now mandated across the company for all submission documents.

Company overview

Biogen is one of the world's leading biotechnology companies, with a focus on developing therapies for serious neurological, autoimmune and rare diseases.

Founded in 1978, Biogen is a pioneer in biotechnology, and today has the leading portfolio of medicines to treat multiple sclerosis and is at the forefront of research into new medicines for neurological conditions and rare genetic disorders. The company creates, commercialises and manufactures transformative therapies for patients with few or no treatment options.

With corporate headquarters in Cambridge, Massachusetts, it employs over 7,000 employees across its global network in the Americas, Europe and Asia.

The challenge

Like all organisations working in the global Life Sciences sector, Biogen is heavily regulated within an ever-evolving regulatory environment. As a result, managing the vast amount of documentation and other content within a controlled and compliant environment has proved a significant challenge.

Documentum is the mandated content management system for Biogen, but for the Research and Development division who were using an old version of the system, the situation was becoming more and more difficult: the technology of the existing software was dated, functionality was poor and its configuration no longer matched current business processes. On top of this, people found it hard to learn and complicated to use, resulting in inconsistent and inaccurate usage.

Biogen

- Leading global biotechnology company
- Over 1,400 employees use CARA across R&D departments and for all submission documents

Benefits include:

- Easily find and share content
- Cost savings
- Employees now take ownership of their content
- Workflows simplify processes

Easy configuration ensures the company meets business objectives.

“ The benefit of working with Generis is that everything is possible!

“ We selected CARA for its flexibility and intuitive user interface and I am glad to say that in practice, CARA is easy to use and a reliable tool

The solution

By 2014, the decision was made to look for an alternative interface for Documentum and Biogen's Global Delivery team set out to identify a robust, functionality rich and easy to use system to manage their regulatory documents. Through their RFP process, Biogen selected CARA for its flexibility and intuitive user interface as well as the customer service offered by Generis.

Since 2015, CARA, in conjunction with Documentum, is used by the majority of Biogen's R&D departments and is also mandated throughout the company for any documents that are included in a submission. Tim Powell, Associate Director, Global Regulatory Operations, leads the Global Delivery team responsible for delivering regulatory submissions to health authorities around the world and was instrumental in introducing CARA to Biogen. As he puts it “Moving from a system with no versioning, no workflows or approvals and no virtual documents to one that excelled in all three was a real breath of fresh air”.

Following the migration to CARA, Biogen went live in August 2015. “In the early days we did struggle, as it was a huge cultural shift and adjustment took longer than anticipated”. However once adopted, positive change soon occurred, and CARA is now widely used for authoring, review and approval of all submission-related documents. CARA is both highly configurable and customisable and the team have since developed several customised workflows to meet different business objectives. Examples include a data verification workflow for Manufacturing documents, an endorsement workflow for Clinical documents and two complex distribution workflows for Safety-related documents.

“ With CARA, everything is in one place - and its great search functionality makes finding and sharing content straightforward

The results

“CARA is easy to use and reliable and we appreciate the helpful support when looking to resolve any questions or explore enhancement opportunities” commented Tim. Users of the system appreciate that everything is in one place and the extensive search functionality makes finding and sharing content straightforward. In addition, considerable costs have been saved thanks to the merging of all workflows into CARA from Biogen's old and expensive software.

Now, with over 1400 people using CARA, the company is starting to think more broadly in its use and are looking at new features to employ including adding new document types, creation of new workflows and developing a detailed business process for virtual document management - as Tim observes, “the benefit of working with Generis is that everything is possible!”.