CASE STUDY

"Everything is centralised, and the extensive search functionality makes finding and sharing content straightforward"

Tim Powell,
Director

Biogen

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Biogen Inc. is an American multinational biotechnology company based in Cambridge, Massachusetts, specializing in the discovery, development, and delivery of therapies for the treatment of neurological diseases to patients worldwide.

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.

The issues faced

Working within Life Sciences, Biogen have to abide by strict regulations from authorities and deal with an ever-changing regulatory landscape. As a result, managing the vast amount of documentation and other content without a controlled and compliant environment in place is a significant challenge.

Prior to implementing the CARA Life Sciences Platform, Biogen were using a customised legacy system for content management to handle high volumes of submission documents. With the Research and Development division of Biogen using an older version of the system, processes were becoming increasingly difficult as the volume of regulatory submission documents grew exponentially.

Due to this limited technology, User Interface, and configurations no longer matching current business processes, end-users managing Biogen's regulatory submissions could no longer operate at optimum efficiency.

Additionally, Biogen had a different 3rd party vendor system for the distribution, acknowledgement and tracking of Aggregate Reports (e.g. PSURs), Educational Tools and SABR Signals which was not linked to the source documents. The result was a broken chain of information and considerable additional cost thanks to an IT infrastructure comprised of separate point solutions.

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The solution

By 2014, the decision was made to look for an alternative interface for our document management system, 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 after considering several options. The main drivers for selecting The CARA Life Sciences Platform were its flexibility and configurability, intuitive and user-friendly interface, as well as the high quality of customer service offered by Generis.

The extensive configuration capabilities, reduce the time and effort required to implement changes and updates to the platform. Generis' 'One-user, one-licence' pricing model meant that The CARA Life Sciences Platform also offered a lower total cost of ownership compared to other options.

Since 2015, The CARA Life Sciences Platform 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 regulatory submission. The CARA Life Sciences Platform also offered an efficiency boost in terms of content management capabilities when compared to Biogen's previous system. Tim Powell, Director, Submission Sciences, commented "Moving from a system with no versioning, no workflows or approvals and no virtual documents to one that excelled in all those areas was a real breath of fresh air."

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The result

Following migration, The CARA Life Sciences Platform was successfully implemented in August of 2015, and has since been used for preparing and submitting thousands of regulatory submissions globally. Biogen use the platform for a number of business-critical processes, including the authoring, review, and approval of regulatory submission documents, and the distribution, acknowledgement and tracking of Aggregate Reports (e.g. PSURs), Educational Tools and SABR Signals to affiliates and third parties for acknowledgement and local submission.

On top of this, end-users have utilised the platform's robust configurability to develop 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.

"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. Everything is centralised, and the extensive search functionality makes finding and sharing content straightforward. In addition, Biogen saw considerable cost savings thanks to the merging of all workflows into the platform from the organisation's legacy software.

To date, over 1600 people are using The CARA Life Sciences Platform, and Biogen is starting to think more broadly in its use by 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 and other further enhancement. As Tim observes, "the benefit of working with Generis is that everything is possible!"