Deloitte.

A global biopharma company streamlines regulatory filings and accelerates time to market for new products

Deloitte Industry Solutions and Process Enablement
A biopharmaceutical giant's journey

The challenge

This biopharmaceutical giant is a leader in healthcare research, with products to diagnose and treat a wide range of chronic and infectious diseases for patients around the world. The company's embrace of science and technology has contributed to their reputation for innovation in the pursuit of human health.

Life sciences companies must secure the necessary approvals from regulatory agencies before they can bring new drugs to the US market. That process includes submitting a dossier of all the data that the company collected and analyzed from the drug's clinical trials. Modern dossiers are electronic rather than paper files, and they follow a standard format called a common technical document (CTD).

Even so, dossiers can be lengthy—sometimes running millions of pages—not to mention time-consuming to assemble. This company depended on a network of medical content experts to manually create each dossier—an often expensive, time-consuming process that can erode patent duration.

Deconstructing the dossier

We adopted a component-based authoring approach utilizing a structured content authoring technology to drive collaboration among authors. Content components are authored per set guidelines respective to a regulatory document. Component-based approach lends itself to reusability within a relevant context.

To enable these capabilities, we assembled a team of business advisory, operations, and technology specialists, along with medical writers who understood the nuances of working with clinical data and content in a highly regulated environment.

Together with the client, we standardized documents across four areas of a dossier:

• Clinical

• Labeling

• Safety

• Chemistry, manufacturing, and controls (CMC)

After identifying the reusable components, we helped the client convert their active labelling documents into a structured content format, then added them to the client's content management platform.

The new content authoring solution reflects the fact that different modules of a CTD often include the same pieces of information. Examples include the name of the drug, a description of the manufacturing process, and a summary of clinical safety.

By deconstructing this kind of content into reusable components, users canautomatically plug information into the appropriate places of a dossier and reuse information in other dossiers (think sister drugs that use the same molecule). Updating documents this way is faster and simpler because users need to enter revised information only once. The solution then propagates the changes wherever that information appears.

Results

The newly deployed Structured Content Authoring (SCA) platform, along with labeling deconstruction and SCA configuration as a service (including packaging labels and patient instructions), a top priority for optimization, grew to support:

• More than 1,300 users

• Over 100 active filing regulatory documents

• 60-plus therapies across the United States and European Union

More content authoring capabilities are on the horizon. To support these initiatives, the Deloitte team has developed a streamlined operating process for content development and maintenance, development backlog management, change management, and continuous improvement through a program management office. A strategic roadmap, built in collaboration with the company, aims to continue delivering insights and efficiencies via information reuse and automation.

About Deloitte Industry Solutions and Process Enablement Operate Services

Deloitte Industry Solutions and Process Enablement Operate Services provide ongoing management of critical business processes (both horizontal and vertical). The work we deliver includes, among other examples:

• Management/operations of business processes such as supply chain, human resources, finance, and marketing

• Industry-specific process solutions (e.g., revenue cycle management)

• Capacity/foundry-based support for business operations

• Creative services

All are enabled by market-differentiated assets and AI solutions.

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