

Gedeon Richter Plc. is a major pharmaceutical company headquartered in Budapest, Hungary.

Our client has an expanding direct presence in Western Europe, Mainland China, Latin America and Australia. Its product portfolio covers many important therapeutic areas, including women's healthcare as well as central nervous system and cardiovascular areas. With its widely acknowledged steroid chemistry expertise, Gedeon Richter is a significant player in the women's healthcare field worldwide and is active in biosimilar product development.

The situation

A need to streamline businessspecific regulatory monitoring and impact assessments.



Each day, thousands of regulatory and industry-related documents are released from different regions and companies all over the world. Before partnering with Clarivate™, Gedeon Richter teams would spend hours manually triaging these regulatory documents to identify and communicate impacts across their organizations. This required a significant amount of time to sift through multiple regulatory intelligence sources to identify and locate essential data.

Gedeon Richter staff would travel to the sites of EMA (European Medicines Agency), FDA (Federal Drug Administration) and other regulatory authorities to manually review updates in regulations or guidelines. These documents would be downloaded and sent manually via email to subject matter experts. This proved inefficient because:

- During regulatory triage, there
 is a massive time investment as
 regulatory intelligence experts
 scour each individual site and
 repository. Each region has its own
 storage solution, and it is difficult
 to collect information globally.
- Only the recipients of the email would be aware of specific changes. The changes in regulations and guidelines are not searchable by others who may need them unless a storage solution is created to house them, which requires regular updates.
- The risk of documents being out of date increases as people tend to save local copies rather than reference the most current versions available.



How Clarivate helped

Gedeon Richter is one of the earliest subscribers to the Clarivate Regulatory Intelligence Tracking Application. This end-to-end solution helps organizations manage regulatory intelligence by providing a single source of truth, unifying data and making that data more actionable.

The Clarivate solution has helped empower professionals at Gedeon Richter to think and act more strategically by providing the following.



Customizable dashboard that delivers the regulatory update data specific to regions and topics of interest — all in one place.



Solution powered by Al that automates the daily processing of new regulations and legislation, saving valuable time in triaging.



Notification and alerting system that keeps their experts up to date on the latest regulatory requirements around the world — allowing them more time for action and impact assessments.



Searchable storage solution that consolidates regulatory updates on a global level — one single source of truth that increases visibility and collaboration across their organization.



Source for all departments and experts to complete and view impact assessments.



Automated method of delivering alerts and newsletters, increasing visibility on regulatory updates and changes.

The impact

After using the tracking application from Clarivate for many years, Gedeon Richter recognized the value that this solution provides and is expanding its use within its organization.

Now with unified data sources from Clarivate, Gedeon Richter has more visibility into regulatory changes. The company saves valuable time previously lost to manually triaging data, and instead can reinvest its time on higher value activities such as actions and impact assessments.

Gedeon Richter's key roles and expert teams are integrated through the tracking application from Clarivate, providing visibility into subject matter expert assignments and impact assessments that are already completed. With the ability to automate their newsletters with ease, Gedeon Richter is able to include the relevant and neccesary data to notify its experts in a timely matter.

Technology and regulatory consultants from Clarivate provided full support during Gedeon Richter's transition into the tracking application. Clarivate was able to leverage Gedeon Richter's global regulatory knowledge and technological expertise to help the customer improve its efficiency and expand its usage of the application.

Putting new improvements to work

The latest features that Clarivate consultants have delivered for Gedeon Richter include:

- Self-service user subscription to notifications created by the admin using the user profile icon. This change allows experts to opt in to alerts that impact them directly. It also removes the administrative burden of manually assigning these notifications.
- Auto-status mapping rules for one-step publication to daily updates from pre-publication triage. This feature saves more than four clicks per document, which multiplied by the hundreds of daily documents to triage, is a quality-of-life and time save.
- Auto-prioritization rules based on reviewer question responses mapped to custom priorities

(i.e., "business impacted"). This provides more visibility across experts and teams working together within the Clarivate solution.

Clarivate solution teams are constantly enhancing the tracking application to provide more quality-of-life features.

This solution is configurable on demand, but there is a pathway for incremental releases as all features are opt-in and can be activated based upon business needs.

With the Clarivate Regulatory Intelligence Tracking Application, Clarivate consultants provide Gedeon Richter with a customized consulting experience that adds in automations, shortcuts, rules and new features, all without the need for timely build cycles and re-releasing the entire application.

"Clarivate has been very
approachable and responsive
to taking our business needs
into consideration when working
with the tracking application.
We are now able to efficiently
triage and manage our regulatory
alerts, send out newsletters with
ease and so much more!"

Kinga Pallay,

Regulatory Intelligence Expert, Gedeon Richter

Make better informed decisions with Clarivate

Unlock efficiency and regulatory visibility with Clarivate Regulatory Intelligence Tracking Application, an industry leading solution and companion to Cortellis Regulatory Intelligence™. Let the technology consultants from Clarivate help you to navigate the regulatory landscape with ease. Click here to learn more.

Contact our experts today:

clarivate.com

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