

# GLOBAL LABELING A CASE STUDY



**CHALLENGE:** STREAMLINING THE MANAGEMENT OF GLOBAL LABELING AND CORE DATA SHEET INFORMATION.

**Solution:** A comprehensive solution for creating and managing product labeling information and related core data sheet/safety updates.

## **The Client:**

The client is one of the world's foremost biopharmaceutical companies with annual revenues exceeding \$3 billion. With many established drug products and services helping patients in nearly 90 countries, it is a leader in the effort to develop and apply the most advanced technologies in the life sciences.

## **Business Need:**

The client supports its operations with a sophisticated IT and communications infrastructure that connects sites and teams globally. As part of this environment, the company uses a mix of voice, e-mail, fax, in-person conference and web conferencing systems to share safety and labeling updates and collaborate with colleagues worldwide. The lack of centralization and integration between them makes it difficult for distributed employees to work together in real time and get real time notification of critical updates. While the existing systems and processes do help in communicating critical safety and labeling updates the lack of integration and manual steps introduce significant business liabilities and risks. As the scale of operations grows, so grows the potential for reporting delays, errors, or loss of critical safety information. This, in turn, increases business liability and risk.

As a result of these risks and inefficiencies, the company decided to explore other alternatives to automate the dissemination of safety and labeling updates within a compliant environment that is traceable and retrievable. The solution in turn will also help drive efficiency by requiring lesser meetings, travel and eliminating inconsistencies. The most important ability is to centralize the management, dissemination and disposition of the updates that is currently handled by multiple groups locally. Although it's difficult to quantify the potential savings with this approach the company expects that they will be significant in the long term.

Centralizing the management of labeling and safety updates promises significant productivity gains within the company. By establishing a centralized system compliant with 21 CFR Part 11 guidelines, employees will be able to communicate changes, view regional acknowledgment and disposition in real time. In addition, they will be able to create relationships between the core labeling information to the derivative regional labeling information. These relationships will ensure changes in the core label are communicated and/or reflected in the regional labels.

## **Solution:**

The company chose to upgrade its collaborative working environment with Virtx CDS. Virtx CDS helps people communicate changes and collaborate more effectively in real time with colleagues in different locations and time zones and help decrease the potential for errors due to delays. It plays a key role in centralizing, streamlining, and organizing core safety and labeling information, and thereby, greatly reduce the chance for delays or errors. Additionally, it can remove the reliance on individuals to be the sole maintainers of safety information.

The capability within Virtx CDS to integrate with the existing document management system greatly helps adoption of the solution with minimal process changes and training necessary to implement the solution. The solution integrates with the existing e-mail system allowing communication through familiar interfaces in real time with regional status and result thus delivering clear time savings and productivity benefits. It also allows management to see if someone is not available or is not responding to a critical update and take appropriate action.

Virtx CDS delivers the necessary capabilities to track and disseminate labeling changes, track acknowledgment and response, determine impact of core changes to regional derivative documents in real-time utilizing the communications and storage infrastructure available at the company. This provides a seamless communications experience and giving them a fully integrated communications infrastructure.



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## Benefits:

With the Virtify Virtx CDS global labeling solution, the employees are able to manage and communicate labeling changes more effectively with colleagues around the world. Employees can escalate important discussions to involve key stakeholders and project members, resolving queries faster and working together better. Virtx CDS fully integrates with Microsoft Exchange Server and Document Management Systems which in turn maximizes the value of previous investments. Key benefits of the solution include:

- Disseminate changes in labeling/safety information in a precise, consistent and timely manner - An important benefit of the Virtx CDS solution over the existing system is the dissemination of pertinent change information based on the user security profile in a precise, consistent and timely manner. This eliminates the business liability risks due to delays or inconsistent content.
- Facilitate Regulatory compliance and conformance - The solution ensures regulatory compliance by ensuring that changes to the core information are reflected in the appropriate regional documents. Furthermore, it tracks to the type of regional action that was taken, document versions affected and the person responsible for making these changes.
- Generate reports on receipt and regional conformance - The system offers capability to generate reports on change acknowledgment, regional conformance, documents affected and others. These reports can be helpful to determine statistics on the cycle time for a change to be absorbed in globally, within a region, for a product, etc.
- Increase Employee Productivity - A key benefit of Virtx CDS solution is its seamless integration with familiar Microsoft desktop productivity applications, including Microsoft Outlook. With Virtx CDS employees will no longer have to wait for availability of their colleagues to be informed of changes. The availability of change information via a centralized system also drives efficiency by not requiring them to go to different systems or resources to procure the change information.
- Share knowledge easily and quickly between geographically dispersed groups - The centralized web based interface within the system offers the capability where geographically dispersed groups can share information easily in an integrated, roles based secure environment.

## About Virtify

Virtify is a global company, with headquarters in Cambridge, MA and other international locations in India, Philippines and Bulgaria. We use cutting edge web-based technologies and global delivery capabilities to develop and implement innovative software products and solutions for the Life Sciences industry.

One of our strengths is our deep domain knowledge and demonstrated leadership in emerging global standards. Virtify is one of the first companies to introduce a pure web-based Structured Product Labeling (SPL) solution for managing the entire life cycle of labels. Virtify was the first to submit a SPL demo to the Food and Drug Administration (FDA) and the first company to submit a Regulated Product Submission (RPS) drug device and combination drug submission to the FDA. The first RPS Viewer was also introduced by Virtify we were the first to submit an Electronic Common Technical Documents (eCTD) drug and device submission to the FDA. In addition, we have recently been the first to submit messages in emerging standards such as eStability and ICSR. Such leadership on standards has enabled us to work closely with clients in effectively planning for emerging standards while addressing current mandates and standards for clinical and regulatory submissions.

Virtify's clients include several pharmaceutical, biotechnology, medical device and animal health companies, and its projects have spanned the R&D lifecycle, from discovery through commercialization. For information about our offerings, please contact us at:

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