

## End-to-End (E2E) Labeling for one of the world's largest biopharmaceutical company



### The Client

The client is one of the world's largest biopharmaceutical companies that develops, manufactures and markets pharmaceutical drugs in more than 100 countries worldwide.



### The Project Objective

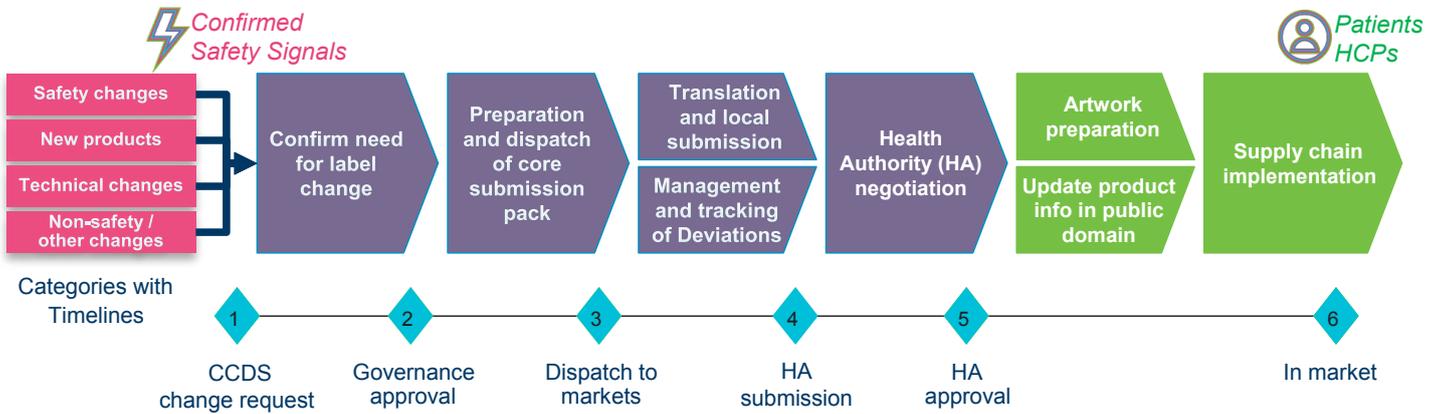
The overall objective of this project was to assess the current End-to-End Labeling processes, roles and responsibilities and technologies, compare these to industry best practices, and then design and implement a robust and systemically compliant 'To-Be' solution.

### Approach and Deliverables

This End-to-End (E2E) Labeling project set out to provide the client with complete, global end-to-end visibility and traceability of the implementation and management of label changes and to ensure that these were aligned to regulatory and specified organisational timelines.

#### Key activities included:

- A detailed current state assessment to prioritize improvement opportunities utilizing data from all relevant stakeholders across the E2E process including Affiliates
- Alignment of Signal and Label categories to simplify as well as ensure the priorities continue through the E2E process
- Tracking points, timelines and KPIs were established for the different types of label changes based on their safety implications for submission and implementation
- A fit for purpose cross-functional governance structure was defined with active input from stakeholders to obtain buy-in and ensure implementation success
- Evaluated existing technology and provided options for establishing E2E tracking for further consideration
- Designed fit-for-purpose process refinements including a new timeline waiver process with clearly defined roles and responsibilities. All recommendations were supported by emerging best practices from our industry network labelnet
- Supported the implementation of process and governance improvements including reviewing controlled documents, incorporating revised responsibilities into role descriptions, and developing training plans and materials for roll-out across functional stakeholders



## Some key Metrics from the engagement

TAKE Solutions ensured that we completed all key milestones on-time with a high quality outcome. This is a result of our focus on delivering outcomes while ensuring compliance.

- Developed a future state solution grounded in a thorough fact base
  - Involved more than 250 participants from 14 departments
- Identified more than 500 pain points throughout the assessment phase, to be addressed through the redesign
- Reduced the number of E2E process steps by more than 50%
- Reduced the number of governance bodies from 10 to 2, and reduced the membership by more than 50%
- Clarified all roles and responsibilities
- Implemented a tool allowing clarity and visibility for supply chain

## General Principles - From Signal to Patient, not just HA submissions:

- Joined up processes i.e. End-to-End, Signal-to-Patient, HQ-to-Affiliates
- Effective cross-functional working and communications: PV, RA, Medical Affairs, Supply Chain, etc.
- Defined timelines for all process steps and milestones, together with metrics to monitor adherence

By leveraging our process and change management expertise, together with TAKE Solutions' and our client's subject matter experts, who have deep institutional knowledge, improvements were implemented smoothly to ensure that realized project benefits, were embedded and maintained far beyond the end of our contractual engagement.

## TAKE Solutions helped the client achieve the following changes

- A redefined labeling department with clear roles and responsibilities
- Rationalized and simplified labeling governance bodies accompanied by the enhancement of a Quality Management System for labelling
- An integrated single process, applicable to medicinal products, combination products and biosimilars
- Clear Label content - new, user-friendly templates with consistent look and feel and patient-friendly label components
- New technology, enabling end-to-end capability through automated integration with other key label-related systems

## About TAKE Solutions

TAKE Solutions delivers domain-intensive services in Life Sciences. In the fast-growing Life Sciences space, TAKE offers clients a unique combination of full-service Clinical, Regulatory and Safety services backed by unique technology expertise. Our range of services span from clinical trials to regulatory submissions to post-marketing safety, all backed by insights derived through proprietary industry networks forums. With a team of leading Life Sciences experts, best-in-class systems and processes, and bespoke, industry-specific technology and analytics, TAKE delivers successful outcomes for clients. Our global roster of clients includes large and small innovator biopharmaceutical companies as well as generics manufacturers. With operations spread across North America, Europe, Asia, and South America, TAKE is a Public Company, listed in India on the Bombay Stock Exchange and the National Stock Exchange. Led by a team of industry stalwarts and domain experts, TAKE has been growing steadily with FY18 revenues touching INR 15,872 Mn, (USD 246 Mn).



## For more information

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