



## Customer Profile

A mid-sized global pharmaceutical company, headquartered in Europe, required a program of work that would see three major projects completed to overhaul their Pharmacovigilance processes, governance, and technology.

## The Program Overview

Our client had experienced significant turnover within their team which, in turn, had seen their global PV system neglected for some years. As a result, their affiliates were left fending for themselves in a somewhat decentralized and uncoordinated manner.

After a string of 18 audits and 5 inspections across the globe, our client had to address 540+ findings; some of which were the result of a failure to deliver on previous commitments made to the MHRA from a previous inspection. TAKE Solutions worked with the client to carry out a full overhaul of their PV processes, governance, and technology to make sure that the team had increased oversight of patient safety and to ensure compliance.

### The Challenge(s)



- With a changing regulatory context, and updated EMA GVP regulations coming into effect, many of our client's systems were non-compliant.
- Owing to years of inconsistent data entry practices, a significant data cleansing initiative was also required to allow for data migration to take place.
- In addition, the version of ARISg that they were using was being phased out so a major upgrade was required.

## The Solution and Results

TAKE Solutions designed and established a **Program Management Office** that coordinated activities over a 2-year period, across 3 major projects:

- Pharmacovigilance Process and Governance Improvement Project
- CAPA Project (to address audit and inspection findings)
- ARISg Upgrade Project

Executive management were engaged in the program right from the start, with broad awareness of activities across the department, other functions, and affiliates (achieved via town hall meetings and newsletters). Staff buy-in was an essential component to the success of the program.

The program of work successfully re-engaged affiliates and established strong links to the QPPV office, further strengthening global oversight. All audit and inspection findings were addressed.

The entire QMS hierarchy of PV documents; from policy to work instructions at the affiliate level, were all redesigned and simplified, with best practice PV processes and cross-functional safety governance being embedded across the PV organization to ensure oversight of patient safety.

TAKE Solutions supported the data cleansing exercise to enable successful data migration and aggregation. In addition, we established both coding and data entry standards to ensure the consistency of data going forward.

A graphic with a blue background featuring circuit-like patterns and arrows. The text "Benefits to Client" is written in large, white, bold letters.

Post program, the client has not had any subsequent major findings and has since received positive feedback from the Regulator. Our client's investment was maximized by implementing a scalable solution which has continued to support their organic growth and portfolio acquisition.



### 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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