



Customer Profile

A leading global biopharmaceutical company, headquartered in the USA, with a portfolio including medicines, vaccines, and consumer healthcare products. With global submission volumes estimated to be somewhere between 13,000 and 20,000, including PPLS transactions, and expected to increase to a portfolio volume of somewhere between 45,000 and 55,000 per annum for national generic submissions, our client's mandate was to accommodate this growth without increasing cost. Ideally, the hope was to decrease it, but it was recognized that there could be no disruption to the business and no slip in quality or timeliness. TAKE Solutions were engaged to compile, format, publish, and distribute Regulatory compliant submissions to support new applications and, also, maintain current licenses.

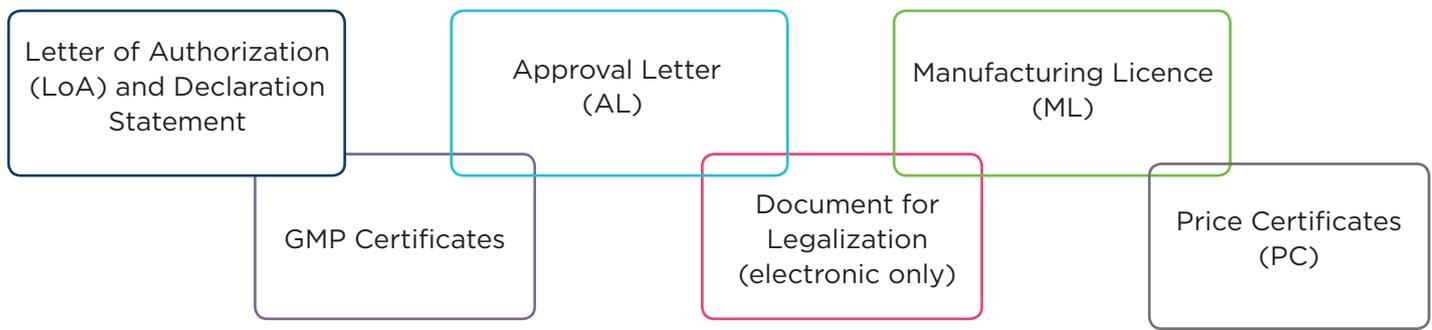
The Program Overview

We worked closely with our client to develop a first of its kind solution for both companies; jointly establishing metrics and measurements that ensure mutual success and enable an industry unique unit based price approach.

Key to the success of the project was ensuring that the right team was deployed from the outset. Our client actively participated in the selection of TAKE Solutions' Publishing Associates that would support them in their work. These Associates went on to receive a rigorous three-week training course in the client tools, as well as helping to establish a train-the-trainer program. The TAKE Solutions team quickly became an extension of the client Publishing group and developed comprehensive analytics that facilitate performance review, as well as identified areas where processes could be improved. Working together with our client, we established an effective joint Governance model.

The Solution and Results

TAKE Solutions now provides our client with 45+ Lead Publishers and Publishers from our offshore site in Chennai, India who manage the publishing of submissions. With direct connection to our client's submission management tool and Global Document Management System (GDMS), our Publishers participate in workflows to determine if submissions are ready to be published, or tasks have been assigned directly to them. TAKE Solutions is responsible for utilizing the publishing tool to build submission content that complies with the table of contents, performing QC, as well as tracking receipt of submissions in each country. In addition, our team also performs eCTD activities in hyperlinking, validation of eCTD XML backbone, and managing the lifecycle of eCTD metadata, all of which are submitted via the client's Gateway. The team also provides ancillary documents, certificates, and samples in support of product registrations, transfer, variations, and renewals in global emerging markets on behalf of the client. Such support includes work on the following documentation:



The analytics developed as part of the program have enabled recommendations for process improvements and technology enhancement, some of which have been implemented, resulting in SLAs being exceeded.

Together with our client we established a second hub in Bogotá, Colombia to provide Product License and Publishing support.

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

Americas **+1 609 720 1002** Europe **+49 69 668 0300** APAC **+91 44 4590 9000**

[✉ contact@takesolutions.com](mailto:contact@takesolutions.com) [🌐 www.takesolutions.com](http://www.takesolutions.com) [in /company/take-solutions](https://www.linkedin.com/company/take-solutions)