



Case Study

Scientific Writing

REGULATORY AFFAIRS – US ANNUAL REPORTS

Client Situation

A large US pharmaceutical generic company had decided to transition their Annual report preparation to an external partner in order to achieve regulatory compliance to a defined quality standard, while performing the submissions on schedule. This company engaged Sciformix to write Annual reports for its approved ANDAs. This engagement is for its entire US product portfolio of 170+ products. The main challenge was to harmonize the submissions across different sites.

Sciformix Solution

Sciformix recruited a team that had a good depth of experience in regulatory submissions in general, and in annual reports in particular. The team was trained in client's SOPs and systems since the work had to be done using these. The activity was split into the following steps for execution:

- Review of changes relative to source documents provided by the client
- Call for missing data/supporting information if any
- Interpretation of the changes to be reported and preparation of draft annual report
- Quality review and style check
- Finalization of draft and prepare submission ready documents

Outcome

Sciformix team ensured smooth transition of the process in 3 months from start of engagement. As a result, the ramp-up to 100% volume was advanced by a few months. Sciformix now prepares ready to file Annual reports for over 160+ products annually and has helped the client consistently achieve 100% compliance on regulatory timelines. The manager of the Sciformix team suggested many quality and style improvements in data presentation that were accepted, and also standardized the templates followed for submission across all products. The overall quality of submission has improved due to exhaustive review and the productivity is also much higher now.

Sciformix is knowledge based global service provider for the Pharmaceutical and Biopharmaceutical industry.

We partner with our clients through the entire drug development cycle, to provide a full range of services from study design to post marketing services.

Our expertise lies in using scientific rigor to synthesize knowledge from the deluge of available information and using it, along with our understanding of the regulations, to help our clients make the right decision at the right time.

For more information on how Sciformix Biometrics service can benefit your enterprise contact us at

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