



Case Study

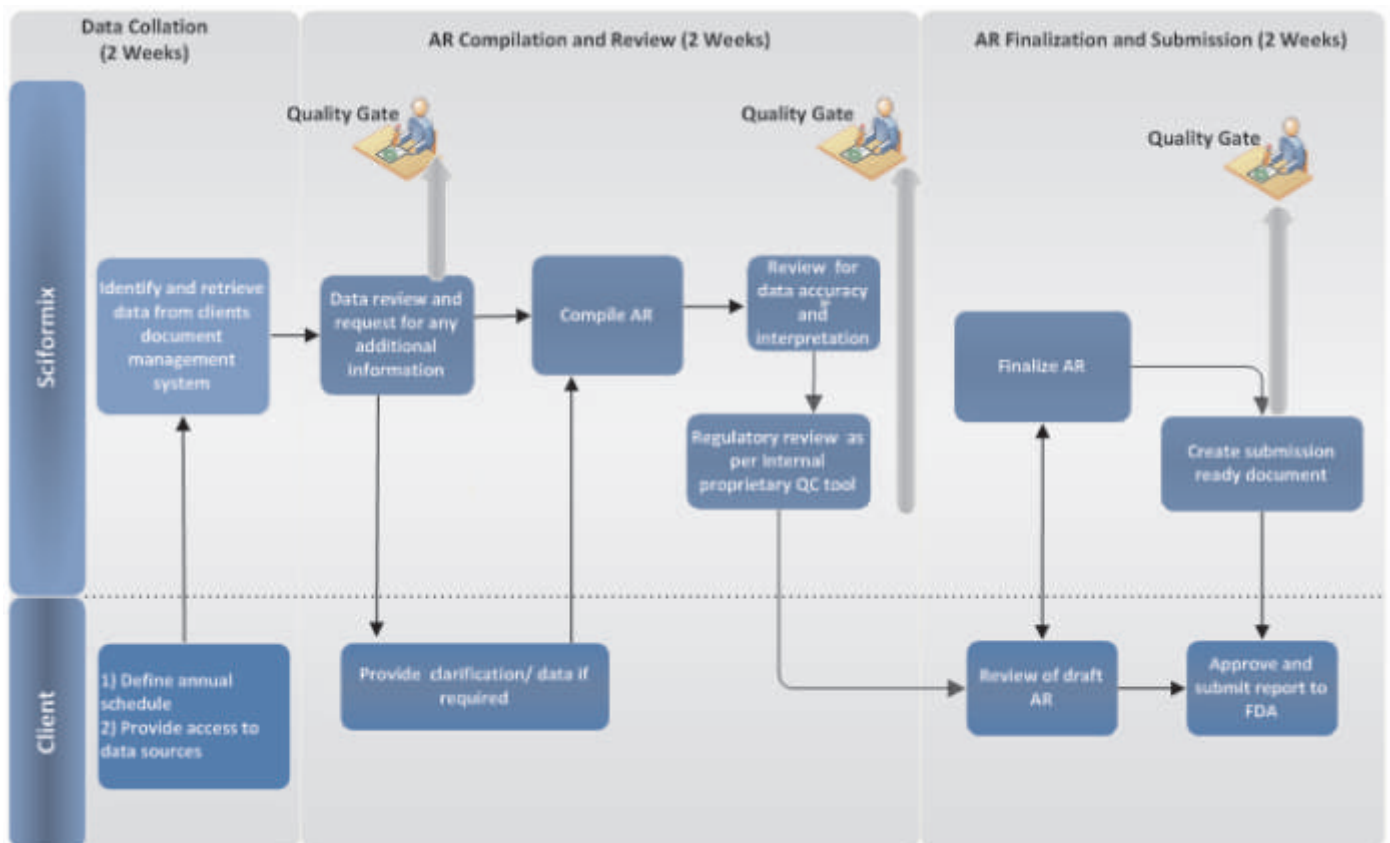
Post Approval Submission Support

Post approval submission support in US

Client Situation: A large global pharmaceutical engaged Sciformix to write Annual reports for its approved 170+ ANDAs and NDAs. The company was facing significant challenges in meeting FDA reporting timelines and in harmonizing processes across various manufacturing sites.

Sciformix Solution: Sciformix used client SOPs and systems. Based on the initial training, the team developed internal work instructions and QC checklists for annual reports. Authoring of AR was split into the following steps for execution:

1. Identify and extract changes from Clients quality management system
2. Request for missing data/supporting information if any
3. Interpretation of the changes to be reported and preparation of draft annual report
4. Quality review and style check
5. Finalization of draft and prepare submission ready documents





Case Study

Post Approval Submission Support

FDA timeline compliance increased significantly from less than 40% per annum to 100%. Sciformix now prepares ready to file Annual reports for over 170+ products annually and has helped the client consistently achieve 100% compliance on regulatory timeline of 60 days from the anniversary date. 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 and this helped free up internal resources of the client for other activities. Other significant achievement was harmonization of AR template across different manufacturing sites. Not only this, quality and style improvement suggestions given by the Sciformix team was appreciated and accepted by the client, thus improving the overall productivity and quality of submission.

Post approval submission support in Canada

Client Situation: A major Canadian pharmaceutical company engaged Sciformix to write Annual Notification for its portfolio of 300+ products. In Sept 2009 Health Canada had revised the post- approval guidance, according to which all minor CMC changes have to be reported in Annual Notification; this was not required to be reported under the earlier guidance.

Sciformix Solution: Sciformix created a new template to comply with the revised TPD guidance and used the following approach to complete annual notification process and CPIDs within 6 months.

- Identification and analysis of annual reportable changes within the period. ~20,000 changes were analyzed out of which ~ 6000 changes identified as being annual reportable.
- Interpretation of the changes to be reported and preparation of annual notification(L3 form) along with supporting documentation
- Creation and updation of CPIDs (Certified Product information Document). Over 200 CPIDs were created over a 4 month period.
- Quality review and style check- Review checklists were created for every step which helped ensure data accuracy
- Finalization of draft reports and preparation of submission ready documents

Regulatory timelines were met. Quality of the work and the effort of Sciformix team to accomplish the task were appreciated by the client.

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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