



Service Listing

# Regulatory Affairs

### Advisory Services

Our team of regulatory experts has many years of cumulative experience in regulatory strategy and submissions across various markets, including emerging markets where regulatory requirements are often nebulous and need to be interpreted based on experience.

We can provide consulting and advisory services in the following areas:

- Global registration strategy
- Interactions with regulatory agencies in emerging markets
- Identification of deficiencies in submissions
- Training and audit preparedness

### Submission Management

Our team of regulatory affairs specialists can help you with your new submissions; whether it be an IND, NDA, aNDA, IDE, 510(k), PMA, DMF, VMF, PMF or CEP/COS. We provide submission management support in terms of authoring, compiling and publishing.

Our Submission Management services include:

- Regulatory briefing packages and submissions
- Annual reports (labeling, stability, distribution and CMC changes)
- Dossiers (in CTD, eCTD and ACTD format or country-specific format)
- Supplements, amendments and variations
- Responses to deficiency queries
- Maintenance of labels and reference safety information

### Report Authoring


We also author individual reports and documents and maintain documentation as listed below.

- Clinical and non-clinical overviews
- Product Quality reports
- Analytical method validation and process development reports
- Stability reports
- Labeling - pack shots and pack inserts
- Site Master File [SMF]

Sciformix is a 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 Regulatory Affairs services can benefit your enterprise contact us at

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