

# Regulatory Affairs

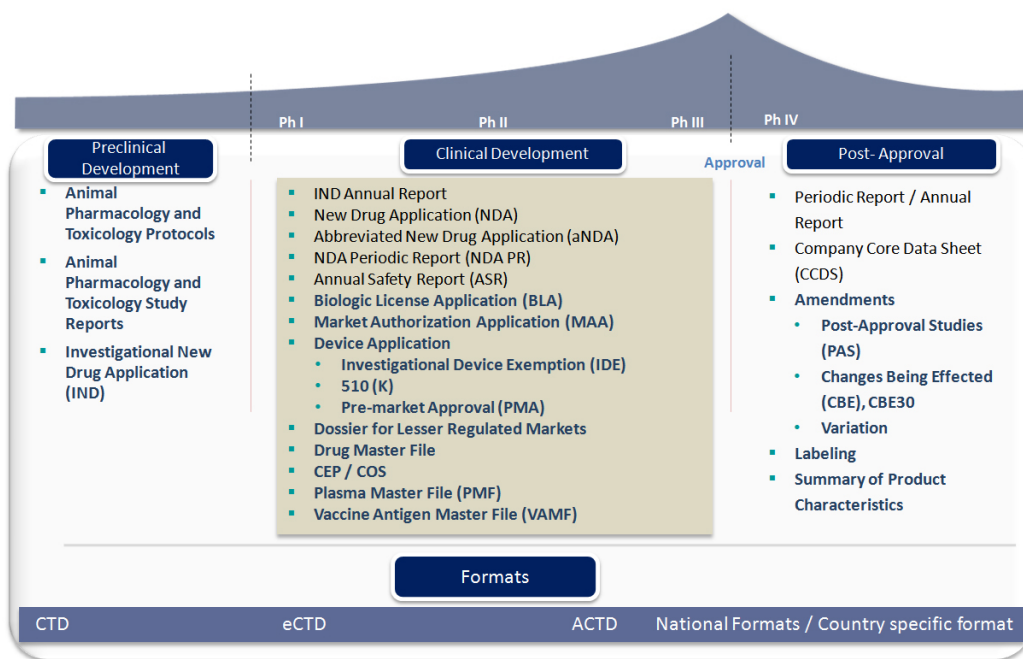
Accelerating Approval, Sustaining  
Compliance



The regulatory affairs team at Sciformix assists you in navigating through the regulatory submissions & management process, developing your registration strategy and helping you in submissions management. Our regulatory affairs team works alongside our clinical and safety experts to author and compile dossiers, in part or in whole, and also to publish and maintain the dossiers.

### Advisory Services

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



Sciformix’ regulatory experts have years of cumulative experience in the development of regulatory strategy and submissions. We can advise and help you formulate regulatory and submission strategies across various markets, including regulated markets like US and Canada in which the requirements are stringent and emerging markets in which regulatory requirements are often nebulous and need to be interpreted based on prior experience.

### Submission Management

- 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

With expertise across pre and post marketing regulations and due diligence strategies, our team will help accelerate approval through custom reporting that reduces the chance of deficiencies. We also provide all the support you need to meet internal and regulatory agency timelines and the credibility to face regulatory scrutiny, thus increasing the chance of approval for your product.

Our specialists can help you with new submissions, whether it is an IND, NDA, aNDA, MAA, BLA, IDE, 510(k), PMA, DMF, VMF, PMF or CEP/COS. We provide submission management support by way of authoring, compiling and publishing. We also help you in addressing deficiencies and handling pre approval regulatory audit responses.

We help you maintain compliance after your product secures approval, through its entire lifecycle, by authoring amendments, variations, annual reports and post approval regulatory audit responses. Our regulatory affairs team authors specific CMC reports across all the modules of the dossier, such as Product Development Report, Annual Product Quality review, Summary of Product Characteristics (SmPC), stability reports and Quality Overall Summary (QOS). We also author clinical and non-clinical overviews.

### Report Authoring

- Quality Overall Summary (QOS)
- 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]

Talk to us and identify how we can help you in approval and compliance.

## Sciformix Corporation

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