REGULATORY AFFAIRS SERVICES

DSI INPHARMATICS
A ProductLifeGroup Company

The DSI regulatory consulting team offers the experience and knowledge to guide the regulatory aspect of drug development from initial investigational submissions (IND, IMPD) through the final marketing application (NDA, MAA) process. DSI's experts are adept at the strategic aspects of the regulatory process as well as being "hands-on" resources for drafting and publication of the submissions.

SUBMISSION PROJECT MANAGEMENT

An organized and efficient project manager can be the difference maker in the execution of a successful NDA Submission project.

- DSI Project Managers have a strong working knowledge of Agency submission requirements current guidance (ICH, US FDA), and expectations based on years of direct experience and training.
- Our Project Managers can develop, and maintain, all resources that support your regulatory efforts.
  - Using organizational tools such as Microsoft Project and Smart Sheets to track and coordinate critical path topics to make the best use of resources.
  - By identifying interdisciplinary dependencies and rate-limiting tasks to ensure adherence to schedule.
- Interact with stakeholders and team members frequently and regularly as the primary point of contact for clients
- Host interdisciplinary stakeholder meetings with RA, client, and other technical experts both internal to the client and external (CMO's, test labs etc.)

SUBMISSION CONTENT DEVELOPMENT

DSI regulatory experts can author, review, and publish original IND, NDA, BLA, DMF, and ANDA applications, submission amendments, and supplements.

Regulatory experts can develop or assist with the client regulatory strategy throughout the product lifecycle.

- Author eCTD sections from available client documents (process development reports, analytical methods, batch records)
- Expert guidance for content, organization of information
- Provide SME support for Agency/Sponsor meetings and information requests.

TYPES OF SUBMISSION SUPPORT

DSI has within the organization a variety of resources with decades of collective experience in drug product, drug substance, and combination product development and commercialization. These resources can be leveraged to provide the client with expertise that would normally not be available without multiple contractors and consulting firms.

DSI can offer the following services and much more.

- Provide Subject Matter Experts to review content for technical accuracy
- Provide GAP assessments for submissions and provide solutions to issues found during development and agency review and offer remediation solutions.
- Provide data integrity reviews between submission and source documents.
- Pre-IND or NDA meeting preparation including strategic guidance, drafting and reviews of briefing packages, and implementation of agency responses.

REGULATORY AFFAIRS SERVICES

DSI's regulatory expertise is both broad and deep with global experience in multiple types of submissions including, but not limited to:

- US IND's and New Drug Applications, EMA IMPD and Marketing Authorization Applications, Abbreviated New Drug applications, Biological Licensing applications,
- Preparation of Drug Master Files (DMF), Active Substance Master Files (ASMF), Site master files
- Agency meeting preparation including briefing books and client support.
- Risk assessments for Nitrosamines and Elemental impurities

DSI offers experience and expertise in a variety of dosage forms and therapeutic areas including:

- Sterile Injectable preparations (solutions, suspensions and lyophilized products)
- Liquid and Solid oral dosage forms including capsules, compressed tablets and non-sterile liquids.
- Vaccine products, stem cell products and other biologics

IN-HOUSE PUBLISHING AND SUBMISSION SERVICES

Our experienced team provides end-to-end publishing services that will enable you to effortlessly meet current and future electronic submission requirements. This integrated approach is both time and cost-effective as it eliminates multiple contractors and reduces redundant activities.

- Complete and compliant eCTD submissions
- Full formatting support throughout the submission development, supplementing or replacing 3rd party publication and formatting software requirements.
- Integrated approach enables a condensed timeline for publishing.
- Convenient and flexible workflows and timing.

SUBMISSION LIFE CYCLE MANAGEMENT SERVICES

DSI offers an integrated approach to a partnership that offers technical, regulatory and quality support throughout the product lifecycle from Phase I through marketing authorization applications and on to commercialization.

- Provide post-submission review support and strategy
- DSI's deep team of technical experts can assist in developing responses to information requests from regulatory agencies during the review process.
- DSI can assist in post-approval change requests including assessment of change classification (PAS vs. CBE-30) and implementation of changes.DSI has successfully assisted in specification changes, manufacturing, and testing changes

Contact Us

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