EVERY STEP OF THE WAY: DSI'S EXPERTISE

Our team of expert consultants bring decades of experience to every stage of the regulatory and product development process, from initial selection of development and manufacturing sources, design and evaluation of the investigational manufacturing process thru the scale-up for commercialization. This includes expertise in each of the following elements of the product development process: quality management, manufacturing, product comparability, process design and evaluation, GMP, and the regulatory strategy and compliance concurrent with each step.

PHASE 3 PIVOTAL

Experts in product manufacturing and testing requirements – knowledge that we leverage to boost your chances of a successful Marketing application. Successful applications require that GMPs are strictly adhered to ensuring every lot is substantially equivalent, safe and effective. Established product development plans that encompass all aspects of testing, manufacturing, stability, storage, packaging and labelling and preparation for validation of manufacturing so you can rest assured that your operations are fully compliant. Gap-risk assessments of programs, filings and contractors to give that added confidence that your product will be successful.

PRE-MARKETING

Well positioned to assist your organization in preparing and submitting your marketing application (NDA/BLA/MAA). During the Authoring process, we provide hands-on support, leadership at agency meetings and guidance in interpreting Agency interactions. Our team can help translate development data and reports into a compelling story that will resonate with FDA reviewers, evaluate supply chain choices and justify any gaps in development and reasons why guidance was not followed to ensure accuracy, compliance and the best possible outcome. Hands on support and troubleshooting of issues during validation.

END OF PHASE 2

Integrated project management, supports your trial efforts with quality/compliance and regulatory customized to your product. From selecting the vendor for commercial material to the oversight of development studies and manufacturing, establishing stability indicating testing methodology, to a "phase appropriate" recommendation or review of data generated by Phase 3 studies, our regulatory CMC team brings strategic insights, compliance knowledge and industry experience necessary to ensure your studies are successful and part of an efficient overall regulatory strategy.

POST APPROVAL

Once your product has been approved and is ready to go to market, the DSI team is able to provide assistance in overseeing manufacturing and quality control, drafting required updates and post approval change control for the FDA and assisting your team through additional development and commercialization processes, including re-positioning the FDA application for international regulatory approvals, life cycle products and physician materials.

PHASE 1

Unique "industry" perspective to help generate the "right" data and interpret Agency requests and communications as well as to provide guidance on the latest thinking, positioning your new product for a successful outcome. Our team prides itself on quickly and accurately interpreting requests and comments, giving the not the most conservative advice but the advice we would stand behind and support, eliminating the guesswork and costly delays that plague many interactions.

PRE-IND

Collaborate to assess your product development plan, identify the appropriate pathway for approval, define all applicable technical and regulatory requirements, support preparation of critical toxicology materials, develop test methods and craft a customized product development strategy that minimizes cost and time to clinical trials. Hands-on leadership at meetings with the Agency as well as support for your regulatory interaction and IND submission. Advice every step of the way during the IND review process.

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