WHEN TRAVERSING REGULATORY LANDSCAPE, Rx, OTC & MEDICAL DEVICE FIRMS CONFIDENTLY CHOOSE

PDG
PHARMACEUTICAL DEVELOPMENT GROUP

GUIDING OUR CLIENTS ACROSS THE EXPANSE OF REGULATORY AND SCIENTIFIC TERRAIN

INCLUDING PRODUCT DEVELOPMENT, LIFECYCLE MANAGEMENT AND POST MARKETING CHALLENGES

PRESCRIPTION, OTC & MEDICAL AND STEADY GUIDANCE OF PDG TO EXPERIENCE DEFICITS, AND

YOUR VOICE AT FDA

PDG is a drug & medical device consultant continuously engaged in meetings and interactions with FDA. In addition to all types of pre-submission and milestone meetings, we can help orchestrate the full range of communications such as orphan designation requests, requests for designation (drug, device or biologic), 513(g) submissions, etc.

REGULATORY STRATEGISTS

As industry-experienced regulatory strategists, scientists, and business-professionals, we are true project managers. PDG can help you request fast-track or breakthrough designations, manage priority or rolling reviews, and design study protocols to fit accelerated approvals – all while planning the next line extension.

EXCLUSIVITY AND LOW-COMPETITION NICHES

Experienced in acquiring both regulatory and patent exclusivities, PDG is also well versed in repurposing drugs and medical devices to address low-competition niche markets. We revitalize discontinued, DESI and grandfather drug products; combine OTC, prescription, and medical device products, and help with Rx-to-OTC switches. Our senior scientific team holds multiple patents, knows how to write or vet your patent, as well as how to formulate complex dosage forms that are novel, unique and difficult for competitors to duplicate.

DRUG AND MEDICAL DEVICE CONSULTANTS

Whether you plan to submit an ANDA, NDA, BLA, PMA, or 510(k), PDG will guide you through the process. Our clients range from those who wish to market their first Class I medical device or nonprescription drug product through complex generics facing patent exclusivities, combination products, Rx-to-OTC switches and biologics. Our diversity and range of experience crosses a multitude of populations, indications and dosage forms for small and large molecules with source materials as diverse as botanicals, minerals, animals, and human tissue.

RETAIL (OTC) AND PROFESSIONAL (Rx) MARKETS

The opportunities for sponsors of prescription drugs to enter the OTC market, or for retail/OTC marketers to enter the prescription space is vast. PDG has the resources to place prescription drug makers in the retail/OTC marketplace or nonprescription manufacturers into the professional healthcare/prescription marketplace. We can also help you formulate a new drug or design a new medical device (including new drug delivery devices).

DEVICE FIRMS TRUST THE SURE NAVIGATE SCIENTIFIC CHALLENGES, FDA REGULATORY PATHWAYS

CLINICAL, PHARMACOKINETIC, TOXICOLOGY, CONSUMER USE AND USABILITY STUDIES

PDG is an expert in the negotiation and optimization of study requirements with FDA. For example, it is not uncommon for us to justify a waiver of pediatric study requirements. PDG can help you plan laboratory testing, non-clinical and clinical studies, and consumer use studies such as label comprehension (understanding the key label message), self-selection (choosing the right product), actual use (using according to labeled directions), or human factors (interacting with the product). When PDG writes or edits a protocol, it is integrated with FDA regulatory strategy and meets relevant and current data standards.

VENDOR SOURCING AND QUALITY BY DESIGN

PDG has logged countless miles for our clients sourcing, qualifying & validating API and component suppliers, CROs, CDMOs and CMOs around the world.
As such, we integrate sound quality by design and project management principles into our efforts. Because we design and implement quality systems for our clients, we know how to prepare you for pre-approval inspections, help define requirements for analytical methods, process development, specifications, and stability studies. Our medical device unit can help the start-up implement quality systems or perform QSR compliance assessments and define the manufacturing requirements for 510(k) and PMA submissions. Our science and risk-based approach coupled with complete product and process understanding facilitates consistent and compliant manufacture of quality products.

LIFE CYCLE

PDG serves as our clients' lifecycle management guide including line extensions e.g. new indications, supplemental NDAs or additional 510(k)s; Annual Reports, Periodic Adverse Drug Experience Reports (PADERs), Periodic Safety Update Reports (PSURs), MedWatch reports, recalls, etc.

SAFETY AND LABELING

Companies rely on PDG to provide dependable, accurate and compliant safety surveillance programs, pharmacovigilance/ device vigilance services and unbiased assessments of labeling and DFU accuracy and completeness. PDG's experts deliver evidence-based benefit/risk assessments of your drug products, biologics and medical devices.

GLOBAL REACH; DIVERSITY AND DEPTH OF EXPERIENCE

PDG was founded in 1999. Our team includes overseas affiliates, former FDA inspectors, pharmacologists, toxicologists, clinicians, epidemiologists, formulators, CMC specialists and multiple RAC certified personnel. We place high value on remaining current in the science and global regulatory affairs, data standards and electronic filing requirements.

PDG combines clinical and commercial insights to shepherd the strategic development of drug products, biologics, medical devices, and combination products. Our team possesses extensive experience in the comprehensive integration of products, indications, dosage forms and FDA regulatory pathways. We offer turnkey development assistance to include formulation, medical device design, toxicology, pharmacokinetics, pharmacodynamics, clinical, statistical, epidemiology, CMC/QSR, labeling and safety surveillance consulting. We source and interact with support organizations worldwide. These include contract laboratories, testing facilities, CROs, CMOs as well as API and component suppliers. Contact PDG to show you the way, or to simply help you along the way.

PDG®
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