FOUNDED IN 1999 BY DR. CHERYL BLUME

PDG® is a leading and extensively experienced full service pharmaceutical consultancy headquartered in Tampa, Florida. PDG® is prepared to fully address assignments associated with branded, generic, prescription, non-prescription, and biologic products. Directed to FDA registration and compliance purposes, our services include all necessary efforts to secure U.S. drug and biologic regulatory approvals for companies around the world.

I'M CHARLES JAAP

MBA, RAC, V.P. Operations & Business Development at PDG®. I invite you to learn more about the various ways we can help you and your company. Please feel free to contact me directly on my cell at (813) 419-PDG1 (7341). From Pre-IND through Phase IV, PDG believes you should reach the experts you need, when you need them, for any task, from any time zone.

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Scan this QR code to add PDG®'s contact info directly into your cellphone.

PDG® leadership and/or staff are members of the following organizations:

The Academy of Pharmaceutical Sciences
American Association of Pharmaceutical Scientists
American Pharmacists Association
BioFlorida
Drug Information Association
International Society of Pharmacoepidemiology
Regulatory Affairs Professional Society

PDG leadership and staff also hold multiple U.S. and worldwide patents, have served as reviewers for professional societies, as voluntary faculty at the University of South Florida College of Medicine and on committees in various of the organizations listed above.

PDG®

PHARMACEUTICAL DEVELOPMENT GROUP

GROWTH PROPELLED BY A HIGH PROPORTION OF REPEAT BUSINESS IS OUR MOST TREASURED MARK OF SUCCESS

EXPERIENCED ACCESSIBLE PHARMA PROFESSIONALS

PDG® has an experienced and accessible full time professional staff and expert consultants including a multidisciplinary team of pharmacologists, toxicologists, clinicians, epidemiologists, statisticians, analytical scientists, regulatory professionals and other product development specialists. PDG® believes you should have access to the experts you need, when you need them.

GLOBAL REGULATORY SERVICES

From Pre-IND through Phase IV, PDG® designs, executes and oversees all phases of strategic product development and regulatory programs including standard & fast track reviews, orphan drugs, new molecular entities, combination products, Rx to OTC switches, grandfather/DESI products, and OTC medications:

- Pre-IND/Pre-NDA Briefing Packages
- Coordination/Facilitation of FDA Meetings
- Investigational New Drug Applications (IND)
- New Drug Applications (NDA) both 505(b) & 505(b)(2)
- NDA Safety Updates
- Abbreviated New Drug Applications (505(j); ANDA)
- Biologic License Applications (BLA)
- Citizen Petitions

FOR PREPAREDNESS

The professionals at PDG® are positioned to address both pre- and post-approval preparedness concerns related to your drug product, manufacturing facilities, analytical laboratories and suppliers including:

- Pre-approval Inspection Readiness
- Biennial/Routine Inspection Readiness
- Product Safety Reviews
- On-site GMP audits & Mock FDA Inspections
- Supplier Audits/Qualification
- Compliance Assessment across Disciplines
- SOPs Across Functional Areas

BRIDGING ALL LIFECYCLE STAGES

PDG's services are applicable throughout your products' lifecycles and include efforts directed to all or part of your drug and biologic applications. This includes critical product maintenance services such as pharmacovigilance responsibilities, safety surveillance, periodic reporting, and labeling updates. Utilize our experienced pharma professionals for any task from any time zone:

- Clinical/Non-Clinical/Bioequivalence Trial Protocols
- Clinical Study Reports
- Literature Reviews
- Integrated Summaries
- Investigator Brochures
- Professional Labeling Design and Reviews (currency, correctness, completeness & consistency)
- Consumer Labeling including Drug Facts, Patient Labeling & Medication Guides
- Promotional Labeling Reviews/OPDP Submissions
- Drug Master Files (DMF)
- Establishment Registration
- Product Listings/Labeler codes/NDCs
- Post-Marketing Requirements (Phase IV)
- Pharmacovigilance/Safety Surveillance
- Annual Reports/PADERs

AND RESPONSE

Delays caused by unplanned audits or unanticipated inspection results can be costly. Whether planned or unexpected, proactive or reactive, PDG® is known for nimble responses to our clients' regulatory needs, including but not limited to:

- FDA Inspections
- Form 483s
- Warning Letters
- Untitled Letters
- Field Corrections and Recalls
- Customs Issues
- Dispute Resolution