



Regulatory Services, Inc.

601 US Highway 206, # 26-443
Hillsborough, NJ 08844

Phone: (908) 281-6161
Fax: (908) 281-5297

dwood@pdregulatoryservices.com

P. Diane Wood, President of PD Regulatory Services Inc., is a seasoned Regulatory Affairs professional with significant experience in the pharmaceutical and biotechnology industries. She has a diverse background in industry including Product Development, Clinical Supplies Manufacture, Project Management, Medical/Scientific Writing, Clinical Trials Management, Quality Assurance, Compliance and Regulatory Affairs, as well as general staff supervision and management. Diane has both domestic and international experience having held positions of increasing responsibility at Beecham Laboratories, Hoechst-Roussel Pharmaceuticals, Ortho Pharmaceuticals, Novo Nordisk Pharmaceuticals, and Serono Laboratories where she was Executive Director of Regulatory Affairs. Associates with her company also have considerable experience in the pharmaceutical, medical device and biotechnology industries.

PD Regulatory Services Inc. provides consulting services for regulatory strategies, preparation of regulatory filings (domestic & international) with a particular emphasis in Chemistry, Manufacturing & Controls. Submission support includes project management, document review, advice and assistance to maintain regulatory compliance and regulatory document management.

Compliance is supported through cGMP audits as well as Quality System Development. Quality Systems are NOT done as "one model fits all" but are designed to meet the clients needs. We begin with an assessment of the current state of affairs (gap analysis) and can then recommend an overall plan, an action plan for implementation, provide/prepare SOPs, training, and continued support as needed. We conduct audits of drug / biotech / biological product and medical device manufacturers as well as API and excipient manufacturers/suppliers. We also participate on due diligence teams for acquisitions.

In our eleventh year of support to the pharmaceutical/biotech and medical device industries we are honored that all of our clients are a result of referrals.

Our team members are from a consortium of independent consultants, which allows us the greatest flexibility to provide expertise for the assignment. We have experience with US registrations of Pharmaceuticals, Generics/OTCs, Biologics, and Medical Devices. With our affiliate organizations in the US, Canada and Europe, we provide support for harmonized registrations of pharmaceuticals, biologicals and devices. All senior associates have 10 years or more of experience each in their disciplines. Our principal consultants each have 20+ years of experience. We work as part of your team, both at your site and from a distance.

The FDA's electronic submissions requirements create a new environment for submissions. We partner with experts in electronic submissions to provide our clients support/preparation of electronic formats for SPL, ANDAs, NDA/CTD, & INDs or partner with your in-house team or vendor of your choice. We also provide recommendations in this area for those who are beginning to bring technology in-house. I

We have a secure account on a private server for transmission of proprietary electronic files.

THERAPEUTIC and PRODUCT AREAS

Parenterals: Oncology Drugs, fertility drug products, antibiotics, hGH (rDNA origin), recombinant protein, factor VIII,
Ophthalmic Solutions drug and device
Solid Oral Dose Forms: respiratory & allergy indications, CNS, gastrointestinal indications, sleep aid, diabetes management, pain management, antibiotics, hormone replacement therapy
Combination Solid Oral Dose Form: pain management
Semi-solids and aerosols: vaginal contraceptives, vaginal & topical antifungals, and other dermatological/ skin care/personal products, osteoarthritis
Patch Delivery: hormone replacement therapy, nicotine
Rx to OTC Switch: vaginal antifungal, gastrointestinal indications

REGULATORY ACTIVITIES

Rx and OTC (monograph & NDA) experience
Regulatory Filing Strategies
INDs, Amendments & Annual Reports; CTA/IMPDs, amendments, responses to information requests
NDA/CTD, ANDAs, Amendments and Supplements, Annual Reports
510(k)s; PMAs, BLAs, Amendments and Supplements
Drug Master Files - API, Excipient, equipment
Labeling development, review and approval; advertising review and approval
International Project Teams
Interactions with Regulatory Authorities; Preparation of "pre-meeting packages" for FDA
Act as US Agent for DMFs and other submissions.

MANAGEMENT ACTIVITIES

Project Management / Project Team Leader
Clinical Study Project Management
Staff Supervision
Regulatory & GXP Training and Development
Electronic Document Management

COMPLIANCE ACTIVITIES

Regulatory Compliance – GMP; Quality System
Participate in Audits/ write audit reports
Regulatory Due Diligence
Develop/write SOPs
Document Review for Regulatory Submissions

RESEARCH & DEVELOPMENT ACTIVITIES (prior to PD Regulatory Services)

Clinical Study Project Management & Monitoring
Write/Edit Clinical Study Reports & Protocols
Review Case Report Forms
Project Management for Publication of Clinical Symposia
Author Manuscripts
Manufacture Clinical Supplies & Stability Test Batches
R&D Project Reports
Stability Testing

COMPUTER SKILLS

Proficiency with MS Office Suite: MS Word including use of styles and other templates, tables. MS Excel, MS Access, MS Project, MS Outlook
Documentum based EDMS; other EDMS systems

OTHER

Good interpersonal communication skills, excellent technical writing skills, detail and deadline oriented, good organization skills.

EXPERIENCE: 1998 - 2009 PD Regulatory Services, Inc., Hillsborough, NJ
President

Provide Regulatory consulting for the pharmaceutical/biotech/medical device industries with respect to project development activities, meetings/communications with FDA, and sections of regulatory applications and related documents from investigational through post marketing submissions. Emphasis is in Chemistry, Manufacturing, and Controls (CMC) including consultation and planning; development, preparation, and review of CMC sections of regulatory dossiers and related documents along with GMP inspections/services. Contribute highly to clinical/product development projects strategy and write and review protocols. Compliance activities (GXP) include audits, development/review of SOPs and QS review.

I have an aptitude for assimilation and utilization of detailed information in a cohesive and cognizant manner to provide succinct understandable documents.

Major Projects:

- 2009: Created and implemented a Quality System for a start-up clinical supply aseptic fill manufacturing facility
Wrote a DMF for an "active" excipient.
- 2008: Supported Quality Section of PMA; audited the facility and provided advice for PAI readiness (SKK, Japan)
- 2007-2008: Regulatory Consultant, CMC specialist (Boehringer-Ingelheim)
- 2007: Substituted for Assoc. VP Drug RA (L'Oreal USA) while on leave (4.5 months)
- 2006: Regulatory CMC support (Daiichi-Sankyo) 9 months
- 2003-2004: Regulatory Consultant - regulatory strategies, project management & IND writing (J&J CPPWW)
- 2000-2004: Acted as Dir RA & US Agent for Bigmar Pharmaceuticals (Switzerland); filed 3 ANDAs & major supplements
- 1998-2000: Substituted for Dir .RA (J&J PRI) while on leave; continued as RA consultant for IND & NDA filings
- 1998-2007: Regulatory Consultant all areas; became CMC specialist due lack of staff (Warner-Lambert/Pfizer Consumer)

PREVIOUS EXPERIENCE

- 1997 – 1998 Serono Laboratories, Norwell, MA
Executive Director Regulatory Affairs
- 1991- 1997 Novo Nordisk Pharmaceuticals, Inc., Princeton, NJ
Director Regulatory Affairs (therapeutic areas) & Regulatory Operations (submissions)
- 1987 – 1991 Advanced Care Products Division, Ortho Pharmaceutical Corp., Raritan, NJ
Sr. Manager Regulatory Affairs
- 1975 – 1987 Hoechst- Roussel Pharmaceuticals, Inc., Somerville, NJ
Systems Supervisor, Quality Assurance & Technical Regulatory Affairs
Sr. Clinical Research Associate
Sr. Medical Writer/Editor
- 1969 – 1975 Beecham Laboratories, Piscataway, NJ
Technical Associate to R&D Director
Supervisor, Pharmaceutical Pilot Plant
Sr. Chemist, Product Development
Chemist/Group Leader, Stability Testing

EDUCATION:

- Farleigh Dickenson University, Madison, NJ - MBA program
- Rutgers University Extension Division, Certificate in Supervision and Business Management
- Georgian Court College, Lakewood, NJ - BA Biology

PROFESSIONAL SOCIETIES

- Drug Information Association (DIA)
- International Society of Pharmaceutical Engineers (SPE)
- American Chemical Society (ACS)
- American Society for Quality (ASQ)
- International Pharmaceuticals Excipients Council-Americas (IPEA)
- Regulatory Affairs Professional Society (RAPS)

HONORS and RECOGNITIONS

2003, 2005	Excellence in Customer Service (Pfizer Consumer Healthcare)
2000 & 2001	Excellence in Customer Service (Warner-Lambert Company)
1998, 2003	International Who's Who of Professionals
2003, 2006, 2007	Manchester Who's Who, United Who's Who
1995	Sterling Who's Who
1993	Who's Who World Wide, Platinum Edition
1998 – 2002	President, Middlesex Chapter GCC Alumni Association
1988	Alumni Service Award, Georgian Court College
1982 – 1985	President, Georgian Court College Alumni Association
1980 – 1982	VP Funds, Georgian Court College Alumni Association
1978 – 1982	President, Middlesex Chapter GCC Alumni Association
1974 – 80, 1998-2002	Alumni Council Georgian Court College
1970 – 1978	Various Officer positions, Middlesex Chapter GCC Alumni Association