

Drug Development Consultants, Inc.

Ron Filler, Ph.D.

Profile:

Regulatory Affairs/Scientist with 25 years of experience in the pharmaceutical and biopharmaceutical industries. Expertise in nonclinical pharmacology and toxicology, reproductive and developmental toxicology (specialty: male infertility), safety pharmacology, clinical writing, and in drug development. Extensive knowledge in the preparation of a wide variety of regulatory submissions to the U.S. FDA, and in the resolution of drug development issues with world-wide drug regulatory agencies.

Experience in the following therapeutic areas: traumatic brain injury, CNS therapies, antivirals, antibiotics, asthma, Respiratory Distress Syndrome, cardiovascular diseases, antihypertensives, anti-diabetic therapies, oncology, hormone replacement therapies, osteoporotic agents, and Crohn's disease.

Experience and Accomplishments:

Drug Development Consultants, Inc., Alexandria, Virginia.

President/CEO/Consultant 1999-Present. Owner/Senior consultant in a pharmaceutical consulting firm specializing in various aspects of drug development. Senior Associates in firm include experts in CMC/Formulations and Pharmacokinetics. Experience with the preparation of nonclinical and clinical sections of IND, NDA, 505(b)(2), ANDA, and CTD applications, Investigator Brochures according to ICH guidelines, and Package Inserts, qualification of drug substance's impurities and safety assessments of residual solvents, Act as an U.S. Agent to hold an IND for foreign pharmaceutical/biopharmaceutical companies. Also, experienced with scientific presentations and writing scientific papers for publication in peer-reviewed journals.

Regulatory Issues Confronted:

- Bridging Programs for formulation modifications
- NDA program development for a specific enantiomer of a previously approved racemate
- Program development for the pediatric application of previously approved drug for adults
- Orphan Drug Status
- Data gap fill-ins for IND and NDA filings
- Qualifying formulation impurities/degradants (CDER/OGD/EMEA)
- Qualifying new excipients and excipients present in formulations at greater than IIG levels
- Refuse-to-File: NDA Application
- Phase IV requirements
- Electronic submission of rodent carcinogenicity data to Carcinogenicity Approval Committee (CAC) of the FDA
- Cardiovascular arrhythmia in dogs
- Retinopathy in rats
- Histopathological finding of vacuolation in various organ tissues
- Pregnancy Classification

- Male Fertility-related Issues

Forest Laboratories, Inc., New York, New York.

Director, Nonclinical Pharmacology and Toxicology 1993-1999

Responsible for the nonclinical aspects of drug development.

- Develop nonclinical pharmacology, toxicology, and safety pharmacology programs to support IND and NDA submissions and Phase IV commitments.
- Monitor contract laboratory studies.
- Respond to FDA and international regulatory concerns for safety issues and support of international clinical programs.
- Liaison between extramural drug discovery and development and internal project planning.
- Participate in drug licensing reviews.
- Act as toxicology/pharmacology consultant to joint venture partners from U.S., Europe or Asia.

American Cyanamide Company, Lederle laboratories, Medical Research

Division Pearle River, New York

Manager, Reproductive and Genetic Toxicology 1990-1993

Acting Director, Toxicology Evaluation 1991-1992

- Supervise 5-30 technical and 8 Ph.D. staff in the conduction of GLP toxicology studies for filling IND and NDA applications with the FDA.

Argus Research Laboratories, Inc., Horsham, Pennsylvania

Associate Director of Reproductive Toxicology 1989-1990

- Manage and supervise technical staff conducting Segments I, II, and III reproduction studies.
- Established male fertility testing/evaluation laboratory.
- Performed duties as Study Director.

Microbiological Associates, Inc., Rockville, Maryland

Manger, Reproductive and Developmental Toxicology Department 1987-1989

- Manage and supervise technical staff conducting Segments I, II, and III reproduction studies.
- U.S. National Toxicology Program (NTP) approved Toxicologist to conduct acute, subacute, chronic, and carcinogenic bioassays.
- Supervise 1 Ph.D. scientist and one graduate student and 3 technicians in a collaborative research project with National Cancer Institute scientists to create transgenic mice.

Hazelton Laboratories America, Inc. , Rockville, Maryland

Head, Reproductive Toxicology/Teratology Group 1984-1987

- Supervise 8 scientific personnel involved in conducting reproductive toxicology/teratology studies.

National Center for Toxicological Research (FDA), Jefferson, Arkansas
Head, Teratology Section 1983-1984

- Supervise 1 Ph.D., 1 M.S., and 4 technicians in conducting teratologic studies
- Directed research activities of 3 Ph.D. staff fellows in the area of developmental toxicology using transgenic animals.
- Establish GLP protocols for conducting safety evaluations with FDA regulators.

Oak Ridge National Laboratory, Oak Ridge, Tennessee

Unit Leader, Mammalian Embryology and Teratogenesis Unit 1977-1982

- Conduct *in vitro* and *in vivo* assays to identify potential teratogens in energy related fuel sources.

Education:

Bachelors of Science Degree – Brooklyn College, City University of New York

Ph.D. Degree – Fels Research Institute, Biochemistry Department, Temple University
Medical School, Philadelphia, Pennsylvania.

Memberships in Professional Societies: Society of Toxicology, Teratology Society, American Association for Cancer Research, American Medical Writers Association, Regulatory Affairs Professionals Society, and Food and Drug Law Institute.

Publications: Over 40 publications in scientific journals, and two chapters in books/reviews.

Seminars and Conference Presentations: Numerous presentations on various topics involving reproduction, male fertility, developmental biology, transgenic mice, and drug metabolism.

Honors and Offices Held: Member of various societal committees, and listed in American Men and Women in Science. Member of Board of Directors of the Federation of America Societies for Experimental Biology (FASEB)