

LUANN POWELL SHOEMAKER
Principal Consultant
Compliance Services International

SUMMARY OF EXPERIENCE

PROFESSIONAL EXPERIENCE

Over 15 years of experience in product registration, environmental toxicology and risk assessment within agrochemicals, specialty chemicals, biotechnology products and the food industry. Developed registration and data development strategies for EPA-regulated products, as well as for the USDA, FDA, and various states, Health and Environment Canada and the European Union.

CREDENTIALS

B.S. 1989 Biology, Old Dominion University, Norfolk, VA, Psychology minor

PROFESSIONAL AFFILIATIONS/APPOINTMENTS

Society of Environmental Toxicology and Chemistry (SETAC) 1992 to 2003, 2006-Present
Entomological Society of America, 1998 to 2003
American Association for the Advancement of Science (AAAS) 1998 to 2001
Institute of Food Technologist (IFT) 2005-Present

PROJECT EXPERIENCE

- As an environmental toxicologist, placed and monitored GLP studies at contract facilities and prepared test protocols and reports for regulatory (EPA) approval.
- Managed over 200 FIFRA testing programs for agrochemicals and specialty chemicals.
- As regulatory affairs manager, gained USDA non-regulated status and FDA clearances for LibertyLink® Cotton as well as obtained field permits for other regulated events in various crops.
- As regulatory scientist, worked closely with scientist to develop new products derived from biotechnology as well as testing regimes applicable to the plant incorporated pesticide and herbicide.
- Reviewed and approved over 3,000 Canadian beverage labels to meet Canadian Mandatory Nutrition Labeling deadline of December 12, 2005.

PROFESSIONAL EMPLOYMENT

Principal Consultant (2006-Present)

Compliance Services International (CSI) – Lakewood, WA (DC Office)

Organize and monitor projects and to act as a liaison between CSI's clients, the US Environmental Protection Agency, State Regulatory Agencies and/or foreign regulatory agencies. Provide advice and counsel to clients and staff to ensure that regulatory tasks are accomplished properly and efficiently.

Regulatory Affairs Analyst (2004 2006)

Cott Beverages, Inc. - Columbus, GA

Maintained in-depth knowledge of US and Canadian regulations as they related to finished beverages. Provided regulatory approval for new and revised labels for consumer packages. Prepared, updated and distributed nutrition information and beverage ingredient statements. Maintained knowledge of allergen and food sensitivity issues.

Registration Manager, Regulatory Affairs—Biotechnology (2000-2003)

Bayer CropScience (formerly Aventis CropScience, Inc.), - Research Triangle Park, NC

Maintained in-depth knowledge of US biotechnology regulations. Prepared data and reports into USDA, FDA, and EPA, as well as Health Canada and CFIA, petition documents in order to achieve US and Canadian regulatory clearances of transgenic plants. Collaborated with global expert functions, including Global Regulatory Managers, to define US and Canada data needs, maximize commercial success, promote international harmonization and reduce regulatory oversight of products derived from biotechnology. Managed FIFRA compliance issues and represented BioScience on 6(a)2 committee. Represented Bayer (Aventis) on regional project teams as well as industry groups to ensure the development of policies compatible with business strategy.

Regulatory Scientist IV, Regulatory and Government Affairs (1997-2000)

Novartis Seeds, Inc., - Research Triangle Park, NC

Supported Novartis Seeds regulatory science function worldwide. Designed and monitored contracted environmental and mammalian toxicology studies in support of US and international regulatory approvals of transgenic plants. Conducted safety evaluations of beneficial insects, birds, and aquatic organisms with respect to new transgenic products. Supported regulatory coordination pertaining to international movement and field testing of genetically engineered plants as well as individual state registrations. Managed FIFRA compliance issues and acts as 6(a)2 coordinator for all of Novartis Seeds.

Research Associate II (1996-1997)

Genetic Therapy, Inc. (a Novartis company) - Gaithersburg, MD

Conducted gene therapy research with retro and adeno viral vectors for malignant brain cancer (Glioblastoma multiforme). Responsible for animal facility SOPs and maintenance of records for adherence to GLP standards and FDA regulatory requirements. Assisted with protocol development and experimental implementation to treat subcutaneous and intracerebral tumors, established safe effective Ganciclovir (GCV) dose ranges and determined pharmacokinetics of GCV with both intravenous and

intraperitoneal routes of administration in three mouse strains. Established expression duration of thymidine kinase gene in transduced cells. Extensive experience in animal manipulations and survival surgeries. Trained other employees in various animal procedures and assured their proficiency for the Institutional Animal Care and Use Committee (IACUC).

Environmental Toxicologist (Independent Consultant) (1995-1997)
Consultants in Toxicology, Risk Assessment and Product Safety - Washington, DC

Provided technical assistance to clients in the area of wildlife and aquatic toxicology. Prepared/reviewed documents for submission to EPA. Wrote review papers relating to environmental endocrine effects for the web site of the Center for Environmental Endocrine Effects. Assisted members of IMCAP (Inner Mongolian Cooperative Arsenic Project) with data compilation and review.

Environmental Toxicologist (1991-1995)
Jellinek, Schwartz & Connolly, Inc. – Washington, DC/Arlington, VA

Assisted with scientific management of FIFRA pesticide testing programs, including transgenic plants. Managed aquatic, avian, nontarget insects, and nontarget plant toxicology studies. Prepared GLP compliant protocols and reports for submission to EPA. Provided scientific and technical assistance for the development of pesticide testing regimes. Conducted risk assessment evaluations on pesticides to determine potential hazards to wildlife. Conducted environmental modeling; Pesticide Root Zone Model (PRZM), Pesticide and Industrial Chemical Risk Analysis and Hazard Assessment (PIRANHA), and Simulator for Water Resources and Rural Basins (SWRRB) to determine the fate of chemicals in the environment for the purpose of predicting environmental concentrations, pesticide run-off and leaching concentrations, and potential hazards to wildlife. Prepared European Community dossiers according to Directive 91/414 for European agricultural chemical reregistration.

Research Associate II (1990-1991)
Cancer Research Center of Hawaii, University of Hawaii – Honolulu, HI

Conducted gastric carcinoma research.

PUBLICATIONS

D.M. Byrd, **M.L. Roegner (Powell)** J.C. Griffiths, S.H. Lamm, K.S. Grumski, R. Wilson, and S. Lai. (1996) Carcinogenic risks of inorganic arsenic in perspective. *Int Arch Occup Environ Health*. 68:484-494.

D.M. Byrd and **M.L. Roegner (Powell)**, (1998) Endocrine Modulation and the Federal Government, *International Journal of Toxicology*. 17:111-128.

Privalle LS, Meghji M, and **Powell L**. 1999. Safety assessment of a novel plant selectable marker: Phosphomannose isomerase. Abstract No. 395. Annual Meeting of the American Society of Plant Physiologists (July, 1999; Baltimore, MD).

ADDITIONAL TRAINING

- 1993 **Environmental Toxicology**, Graduate course, George Mason University
- 1993 **Freshwater Ecology**, Graduate course, George Mason University
- 1994 **Environmental Law**, Graduate course, George Mason University
- 2004 **Labeling Requirements for Foods Marketed in the United States**
- 2004 **Canadian Ingredient Labeling**, Guelph Food Technology Center
- 2004 **Canadian Nutrition Labeling**, Guelph Food Technology Center
- 2005 **Powerful Persuasion: Getting your point across without making enemies**, Rockhurst University, continuing education
- 2005 **Managing conflict with tact and finesse**, Rockhurst University, continuing education
- 2005 **Organic Evolution**, Graduate course University of Nebraska, Kearny
- 2005 **Six Sigma Green Belt Certification**
- 2006 **Behavioral Ecology** Graduate course University of Nebraska, Kearny