

Scientific & Regulatory Consultants, Inc.

W. Robert MacDonald

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PROFESSIONAL SUMMARY

Customer driven, diligently striving for creative solutions for problem solving situations. Extensive background in numerous functions of product testing, registration, and marketing. Qualified by over thirty years of experience and professional growth in the various aspects required to bring products to market.

Areas of Expertise:

- ◆ Topical Antimicrobials
- ◆ Regulatory Affairs/Compliance
- ◆ Labeling Issues
- ◆ Problem Solving
- ◆ State Registration Negotiations
- ◆ Market Research/Appraisal
- ◆ Technical Marketing
- ◆ Testing Methodology
- ◆ Gold Seal Letters

PROFESSIONAL EXPERIENCE

SCIENTIFIC & REGULATORY CONSULTANTS, INC., Columbia City, IN

1998-present

Senior Consultant

Senior Consultant specializing in providing scientific and regulatory consulting services for antimicrobial products from inception to commercialization. Instrumental in complementing and expanding the services provided by SRC with particular focus on topical antimicrobials and the regulations affecting them through FDA and EPA.

- Monitoring of regulatory changes and inspection trends
- Customer research and compilation of available information
- Technical writing
- Antimicrobial market trends and direction

RSP Private Label Packaging Manager (1989-1998)

Managed the business, sales, and marketing of private label topical antimicrobial products, responsible for over 5 million dollars in sales to the consumer, hospital, and veterinary markets.

- Developed prototype literature and labels for RSP (topical antimicrobials) line, including CHG, PCMX, Iodophor, Alcohol, and Triclosan products
- Customized formulas for clients
- Established territories and sales call procedures
- Provided technical support for customer questions regarding manufacturer, raw materials, contract testing, shipping, and quality, etc.
- Established plans for meeting sales numbers on quarterly sales and projections along with determining business pursuits

Regulatory Affairs Manager (1981-1989)

Responsible to General Managers and President in ensuring compliance with State, Federal, and Canadian regulations. Provided leadership in regulated matters impacting the corporation and its product lines.

- Registration and re-registration of EPA antimicrobial products
- Assured compliance of FDA products with regulations
- Maintained current knowledge of regulations and activities in the market to advise management of potential effect on corporate products and customer base
- Assisted in development and presentation of instructional seminars to sales representatives and internal staff for training on regulatory policies and procedures
- Provided technical support to sales staff
- Responsible for regulatory compliance of labels, literature, and other collaterals
- Direct involvement with regulatory agencies in negotiations for obtaining and sustaining product registration

Microbiology Manager (1980-1981)

Responsible for EPA and FDA products with registered claims. Development of supportive testing for new registration of antimicrobial products

- Performed EPA Use-Dilution and AOAC Germicidal Spray Test
- Responsible for bacterial culture preparation and maintenance
- Performed Healthcare Personnel Hand wash (HCPHW) studies and glove juice testing
- Performed Sterility and Preservative Testing on topical formulations
- Performed daily microbial water analysis
- Development of efficacy test data for submission to various regulatory agencies
- Collaborated with EPA Laboratory (Beltsville, Maryland) on AOAC Use-Dilution Test

Quality Assurance Chemist (1979-1980)

Responsible for quality testing of each batch of product from a physical chemistry aspect. Tested raw materials for compliance with specifications. Performed problem solving for correcting deviations from specifications.

EDUCATION

Bachelor of Science in Biology, Manchester College, North Manchester, IN 1978

PROFESSIONAL AFFILIATIONS & CERTIFICATIONS

Optimist International
Regulatory Affairs Professional Society (RAPS)

CORPORATE PROFESSIONAL AFFILIATIONS

American Chemistry Council (ACC)
British Association for Chemical Specialties (BACS)
Consumer Specialty Products Association (CSPA)
International Association for Food Protection (IAFP)
International Sanitary Supply Association (ISSA)
National Spa & Pool Institute (NSPI)
Personal Care Products Council (PCPC; formerly CTFA)

PROFESSIONAL DEVELOPMENT

REGULATORY CONFERENCES, SEMINARS AND TRAINING

CSPA

To amend or not to amend? Will someone please explain PRN 98-10 to me!; Webinar; 10/09
Mid-Year and Annual Meetings
CSPA Consumer Product Labeling Workshop; 10/08
CSPA Workshop on Importing Pesticide Products; 06/08
Eighth Antimicrobial Workshop; 05/07
Seventh Antimicrobial Workshop; 11/05
CSPA Antimicrobial Regulatory Committee Stakeholder Meeting with EPA; 07/04
Nominated Candidate for Board of Directors
Steering Committee for Product Ingredient Review (PIR)
Response to EPA on 1986 re-registration standards
Antimicrobial Registrations Workshop "Application To Registration....And Beyond"
5th Annual Anti. Workshop – Anti. Registration, US EPA Antimicrobial Regulations, European Union
Biocidal Products Directive (BPD, US State Registration Activities)

Personal Care Products Council (formerly CTFA)

Cleaning and Sanitization for the Manufacture of Personal Care Products; 11/08
Web Training “FDA Inspections of OTC Drug & Cosmetic Facilities: Your Rights & Obligations”; 05/07
“The Consumer Commitment Code: How to Comply” seminar; 05/06
FDA Compliance Seminar; 12/02

Regulatory Affairs Professionals Society (RAPS)

Natural Health Product (NHP) Licensing in Canada: Moving Forward-Updates, Initiatives and Challenges; 10/09
Pre-IND Meeting Success: Know and Remove Roadblocks to Trial Approval; 10/09
RAPS Preparing Compliant eCTD Submission Workshop; 05/09
Recall or Not to Recall Webcast; 02/09

SHEA

The Fifth Decennial International Conference on Healthcare Associated Infection; 03/10

APIC

Antimicrobial Associated Risk and Clostridium Difficile; 12/08
The Latest from the Centers for Disease Control and Prevention on Clostridium Difficile; 12/08
Clostridium Difficile Prevalence research Highlights; 12/08
Attendance to keep abreast of current improvements in the quality of healthcare and competitive offerings in the marketplace

American Chemistry Council (ACC)

Antimicrobial Exposure Assessment Task Force/EPA Meeting; 06/04

Canadian Consumer Specialty Products Association (CCSPA)

Annual CCSPA/Federal Government Interface; 04/10, 04/09, 03/07, and 03/05
CCSPA/PMRA: Registrant Training on Transparency requirements of the New Pest Control Products Act; 06/06

Canadian Pesticide Regulation Course (CPRC)

Training on policies, submissions, and required data; 02/08

Clinical Device Group

The Successful 510(k); 06/07

Consumer Healthcare Products Association (CHPA)

2008 cGMPs FDA/Industry Workshop; 08/08

Environmental Protection Agency (EPA)

Greening Operation Series: Regulatory Update-Antimicrobial Labeling Update from the EPA; 07/09
Pesticide Registration Improvement Act (PRIA) Workshop; 10/04
Pesticide Registration Improvement Act: Workshop for Stakeholders; 03/04

Federal Drug Administration (FDA)

Drug Establishment Registrations, Drug Listings and the FDA Electronic Submissions Gateway; 10/09
Preparing Electronic Drug Est. Registration and Drug Listing Submissions; 06/09, 05/09, 04/09
510(k) – Essentials of Gaining FDA Marketing Clearance; Bannick Consulting, LLC.; 03/09

California EPA

California Pesticide Product Registration Workshop; 05/06

FIFRA Instructural Conferences

Executive Enterprise

International Association for Food Protection

Annual Meeting (Atlanta); 2000

International Business Communication (IBC)

Attended regulatory and marketing strategies for advanced overview of cosmetic skin care product claims from an FDA and FTC perspective

Institute of Validation Technology (IVT)

GMP, Validation and Change Control: A Bird's Eye View of the Principles Involved; 08/06

National Sanitation Foundation (NSF International)

NSF Non-Food Compound Steering Committee Meeting; 10/07, 10/03, 09/02, 07/01
Nonfood Compounds and Proprietary Substances Registration Program; 10/08

Perspective Consulting

Four-day training course - OECD GLP Principles & Critical Aspects of Conducting GLP Studies

Quality Is Learned

Current Good Manufacturing Practice Regulations; 21 CFR Parts 210 & 211; 02/06

Thompson Publishing Group

Online Advertising: Ensuring Compliance as DDMAC Steps Up Enforcement; 08/09

OTHER PROFESSIONAL CONFERENCES, SEMINARS AND TRAINING

Dan Tholen Statistical Consulting

Training in Introductory Statistics; 09/03

Gladieux Consulting

Powerful Presentation & Verbal Communication Skills; 05/09
What Your Words Say About You and Your Team: Business Writing; 04/09
Better Business Writing/Documentation; 05/06

Powerful Presentations Skills; 08/02
Better Business Writing; 08/02
Time Management; 08/02

West Coast Quality Training Institute

“Practical Approach” Seminar; Introduction to Good Laboratory Practice Regulations; 07/09
“Practical Approach” Seminar; Advanced GLP Issues; 07/09
Good Laboratory Practices for Technical Staff; 03/06
Quality Assurance in GLPs; 09/02
Introduction to EPA/FDA/OECD Good Laboratory Practices; 09/02