

BOB 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 twenty-four years of experience and professional growth in the various aspects required to bring products to market.

Areas of Expertise:

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|---------------------------------|-----------------------------------|
| ◆ Topical Antimicrobials | ◆ Market Research/Appraisal |
| ◆ Regulatory Affairs/Compliance | ◆ Technical Marketing |
| ◆ Labeling Issues | ◆ Testing Methodology |
| ◆ Problem Solving | ◆ Impact of Pending Regulations |
| ◆ Gold Seal Letters | ◆ State Registration Negotiations |
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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.
- Presenter/Facilitator of EPA and FDA issues including companies with GLP's and GMP's.

ECOLAB/HUNTINGTON LABORATORIES, INC., Huntington, IN 1979-1998

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

PROFESSIONAL AFFILIATIONS

- British Association for Chemical Specialties (BACS)
- Consumer Specialty Products Association (CSPA)
- Cosmetic Toiletries Fragrance Association (CTFA)
- International Association for Food Protection (IAFP)
- International Sanitary Supply Association (ISSA)
- National Spa & Pool Institute (NSPI)
- Optimist International

PROFESSIONAL DEVELOPMENT

American Chemistry Council (ACC)	Antimicrobial Exposure Assessment Task Force/EPA Meeting, June 2004.
Association for Professionals in Infection Control (APIC)	Attendance to keep abreast of current improvements in the quality of healthcare and competitive offerings in the marketplace.
Consumer Specialty Products Association	<p>Attended Mid-Year and Annual Meetings.</p> <p>CSPA Workshop on Importing Pesticide Products, June 2008.</p> <p>Eighth Antimicrobial Workshop, May 2007.</p> <p>Seventh Antimicrobial Workshop, November 2005.</p> <p>CSPA Antimicrobial Regulatory Committee Stakeholder Meeting with EPA, July 2004.</p> <p>Nominated Candidate for Board of Directors.</p> <p>Steering Committee for Product Ingredient Review (PIR).</p> <p>Response to EPA on 1986 re-registration standards.</p> <p>Antimicrobial Registrations Workshop “Application To Registration....And Beyond”.</p> <p>5th Annual Antimicrobial Workshop – Antimicrobial Registration, US EPA Antimicrobial Regulations, European Union Biocidal Products Directive (BPD, US State Registration Activities).</p> <p>“The CPSC From A to Z”, September 2003; October 2000.</p>
Canadian Consumer Specialty Products Association (CCSPA)	<p>Annual CCSPA/Federal Government Interface 2007, March 2007.</p> <p>CCSPA/PMRA: Registrant Training on Transparency requirements of the New Pest Control Products Act, June 2006</p> <p>Annual CCSPA/Federal Government Interface 2005, March 2005.</p>

Canadian Pesticide Regulation Course (CPRC)	Training on policies, submissions, and required data, February 2008
Pest Management Regulatory Agency	
Clinical Device Group	The Successful 510(k), June 2007.
Cosmetic, Toiletries & Fragrance Association (CTFA)	CTFA Web Training “FDA Inspections of OTC Drug & Cosmetic Facilities: Your Rights & Obligations”, May 2007. “The Consumer Commitment Code: How to Comply” seminar, May 2006 FDA Compliance Seminar, December 2002.
Environmental Protection Agency (EPA)	Pesticide Registration Improvement Act (PRIA) Workshop, October 2004. Pesticide Registration Improvement Act: Workshop for Stakeholders, March 2004.
California EPA	California Pesticide Product Registration Workshop, May 2006
FDC Services LLC.	CGMP/QSR Training Program, June 2008
FIFRA Instructional Conferences	Executive Enterprise.
Gladieux Consulting	Better Business Writing/Documentation, May 2006. Powerful Presentations Skills, August 2002. Better Business Writing, August 2002. Time Management, August 2002.
International Association for Food Protection	Attended Annual Meeting in 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)	Good Manufacturing Practice, Validation and Change Control: A Bird's Eye View of the Principles Involved, August 2006
National Sanitation Foundation (NSF International)	NSF Non-Food Compound Steering Committee Meeting, October 2007, October 2003; September 2002; July 2001.
Perspective Consulting	Attended four-day training course OECD Good Laboratory Practice Principles & Critical Aspects of Conducting GLP Studies.
Quality Is Learned	Current Good Manufacturing Practice Regulations; 21 CFR Parts 210 & 211, February 2006
West Coast Quality Training Institute (Pacific Rim Consulting)	Good Laboratory Practices for Technical Staff, March 2006. Quality Assurance in GLPs, September 2002. Introduction to EPA/FDA/OECD Good Laboratory Practices, September 2002.
Dan Tholen Statistical Consulting	Training in Introductory Statistics, September 2003.