Scientific & Regulatory Consultants, Inc.

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W. ROBERT MACDONALD

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Scientific & Regulatory Consultants, Inc. provides a full range of regulatory services for the antimicrobial industry. Our consultants' insight provides scientifically-sound, cost-effective, and timely solutions to routine and complex issues facing our clients. Our collective knowledge base includes experience in industry, laboratories and with government entities. For more information about Scientific & Regulatory Consultants, Inc. visit our website at www.srcconsultants.com

PROFESSIONAL EXPERIENCE

Scientific & Regulatory Consultants, Inc., Columbia City, IN 1998 - Present

Vice-President, Regulatory Affairs (2014 – Present); promotion
Senior Consultant (1998 – 2014)

- Specializing in scientific and regulatory consulting services for antimicrobial products from inception to commercialization
- FDA/EPA topical antimicrobials and regulations affecting them
- Industry regulatory changes and inspection trends
- Research and data compilation
- Technical Writing; Product positioning options based on claims, competitive offering and market assessment
- Antimicrobial market trends
- Client work plan formulation
- Author materials for SRC blogs and website, as needed

Ecolab, Inc. (formerly Huntington Laboratories, Inc.), Huntington, IN 1979 - 1998

RSP Private Label Packaging Manager (1989 – 1998)

- Manage sales, and marketing of private label topical antimicrobial products, responsible for $5MM in sales
- Developed prototype literature and labels for RSP (topical antimicrobials) line, including CHG, PCMX, Iodophor, Alcohol, and Triclosan products
- Formula customization
- Established territories and sales call procedures
- Provided broad-based client technical support
- Established quarterly sales quotas
- Identified new business pursuits

Regulatory Affairs Manager (1981 – 1989)

- Antimicrobial product EPA Registration
- FDA product compliance
- Maintained current knowledge of regulations and activities in the market to advise management of potential effect on corporate client products

- Development and presentation of regulatory policy and procedures, instructional seminars to sales and internal staff; assured regulatory compliance of labels, literature and collateral materials
- Negotiate with regulatory agencies to obtain product registration
- Ensure compliance with State, Federal, and Canadian regulations

Microbiology Manager (1980 – 1981)

- Responsible for EPA and FDA products with registered claims
- Development of supportive testing for new antimicrobial product registration
- EPA Use-Dilution and AOAC Germicidal Spray Test
- Bacterial culture preparation and maintenance
- Healthcare Personnel Handwash (HCPHW) studies and glove juice testing
- Sterility and Preservative Testing on topical formulations
- Daily microbial water analysis
- Development of efficacy test data for submission to regulatory agencies
- Collaborated with EPA Laboratory (Beltsville, MD) on AOAC Use-Dilution Test

Quality Assurance Chemist (1979 – 1980)

- Responsible for quality testing of product batch from physical chemistry aspect
- Tested raw materials for specification compliance
- Performed problem solving for correcting deviations from specifications

EDUCATION

B.S. in Biology, Manchester College (now Manchester University), North Manchester, IN; 1978

PROFESSIONAL AFFILIATIONS & CERTIFICATIONS

Canadian Consumer Specialty Products Association (CCSPA)

CORPORATE PROFESSIONAL AFFILIATIONS

British Chemicals Association (BCA) (Formerly BACS)
Center for Biocide Chemistries (CBC)
Household & Commercial Products Association (HCPA)
International Sanitary Supply Association (ISSA)
Personal Care Products Council (PCPC)

PROFESSIONAL DEVELOPMENT

U.S. Environmental Protection Agency (EPA)

Research and Regulation of Pesticidal Air Treatment Devices; 09/23
Antimicrobial Data Requirements 40 CFR Part 158, Subpart W:
Introduction and Overview; 07/16
Mammalian Toxicology Data Requirements for Antimicrobial Pesticides; 07/16

Environmental Fate & Transport; 08/16
Antimicrobials Used in Cooling Water Systems; 08/16
Smart Label Webinar; 12/15
Greening Operation Series: Regulatory Update-Antimicrobial Labeling Update from the EPA; 07/09

California Department of Pesticide Regulation (CDPR)
California Prop 65 Update; 11/12

U.S. Food and Drug Administration (FDA)
CDER Small Business and Industry Assistance (CDER SBIA) – Environmental Monitoring in Compounding; 07/24
CDER Small Business and Industry Assistance (CDER SBIA) – Electronic Drug Registration and Listing (eDRLS) Using CDER Direct; 09/23
OTC Monograph Reform: OMOR Format and Content & Electronic Submissions Webinar; 08/23
CDER Small Business and Industry Assistance (SBIA) - Reporting Drug Amount Under Section 510(j)(3) of the FD&C Act; 09/22
OTC Monograph Reform: Overview of Draft Guidance for Formal Meetings; 03/22
OTC Monograph Reform: Deemed Final Orders; 12/21
OTC Monograph Reform in the CARES Act: Safety Orders; 01/21
Electronic Drug Registration and Listing Using CDER Direct Workshop; 10/20
CDER (Center for Drug Evaluation and Research) – CDER Direct (Electronic Drug Listing); 10/19, 10/18
FDA Study Data Technical Conformance Guide; 11/18
Dietary Supplements: How to Deal with New Criminal, Civil Enforcements; 05/17
How to Conduct Effective Quality Audits; 04/17
Premarket Notification Requirements Concerning Gowns Intended for Use in a Health Care Setting; 01/16
Regulatory Education for Industry (REdI); Focus on cGMPs & FDA Inspections; 07/15
Overview of Medical Device Data Systems, General Wellness Devices, and Medical Device Accessories; 02/15
Regulatory Education for Industry (REdI) Conference; 09/17, 05/15, 09/14, 09/12
Food, Drug & Device Facility Inspections: Lessons from FDA, the Minnesota Department of Agriculture, and Industry Teleconference; 11/12
Clinical Trials and Electronic Submissions; 09/11
SPL R4 Training Session 58 – Bulk Ingredient/Bulk Product SPL; 03/11
SPL R4 Training Session 57 – OTC Drug Product SPL; 03/11
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

Health Canada Pest Management Regulatory Agency (PMRA)
New Versions of PMRA's On-Line Forms; 07/13
RPC PMRA Notification Non-Notification; 10/12

Natural and Non-Prescription Health Products Directorate (NNHPD)
The Consumer Health Products Framework; 01/15

American Chemistry Council (ACC)

Biocides Panel Meeting with PMRA; 07/10

American Society of Agronomy

Definitions and Regulatory Requirements; 07/15

American Management Association (AMA)

Real Influence: Persuade Without Pushing and Gain without Giving In; 01/13
iPad at Work; Tools for Business Productivity and Time Management; 10/12

Association for Professionals in Infection Control and Epidemiology (APIC)

Infection Prevention: Improving Outcomes, Saving Lives; 04/12
Role of Surfaces in the Transmission of Emerging Healthcare-Associated Pathogens: Norovirus, Clostridium Difficile and Acinetobacter Spp.; 02/12
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

American Society for Testing & Materials (ASTM)

Committee Week; 04/14

Beckman Lawson, LLP

Employment Law & Best Practices; 11/23, 10/23

Bergeson & Campbell, P.C.

Emerging Ingredient Disclosure Requirements and Confidential Business Information; 10/18
Border Security: EPA's Increased FIFRA Import Enforcement Initiative; 03/15

Canadian Consumer Specialty Products Association (CCSPA)

CCSPA/Health Canada Member Workshop; 03/21
Annual CCSPA/Federal Government Interface; 05/22; 05/19, 09/18; 04/18, 05/17, 09/16, 04/16, 04/15, 09/13, 04/13, 04/10, 04/09, 03/07, 03/05
Regulated Products Committee (RPC) Bilateral Meeting with Therapeutic Products Directorate (TPD); 11/13, 05/10
Regulated Products Committee (RPC) Meeting; 05/23, 05/22; 09/21
CCSPA/PMRA: Treated Articles; 06/11

Canadian Pesticide Regulation Course (CPRC)

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

CDRH, Division of Industry and Consumer Educations (DICE)

CDRH Industry Basics Workshop; 11/14

Compliance4All

Analytical Method Validation Under Good Laboratory Practices – GLP's; 02/18

21 CFR Part 11 – Compliance for Electronic Records and Signatures; 04/17
GMP Perspectives on Working with Contracting Laboratories; 11/14

Consumer Healthcare Products Association (CHPA)
2008 cGMPs FDA/Industry Workshop; 08/08

Consumer Product Safety Council (CPSC)
A to Z & Beyond; 06/14

ECG, Inc.
Convince Me: Persuasion and Negotiation Training; 08/18

FDA News
Communicating Directly with Consumers on Social Media: What You Must Know About FDA and FTC Ad and Promo Rules; 04/22
FDA's New Food Safety Regulations, Part 1; 08/17
Writing Effective SOPs; 04/17
Promotion of Drugs, Devices, and Biologics Using Social Media; 02/17
Spreadsheet Validation 2016; Tools and techniques to Meet FDA Requirements Form 483 and Warning Letter Responses; 12/16
Preparing for an FDA Preapproval Inspection; 11/16

FDA Strategies, LLC.
FDA's Current Priorities; 08/13

The Food and Drug Law Institute (FDLI)
Sunscreen Innovation Act; 01/15

Gladieux Consulting
Better Business Writing; Add Power to Your Words at Work; 05/18
Powerful Presentation & Verbal Communication Skills; 05/09
What Your Words Say About You and Your Team: Business Writing; 04/09

Global Compliance Panel
Meeting FDA requirements for OTC Drug Labeling; 12/13

Global Leadership Network
Global Leadership Summit; 08/22; 08/20, 08/19, 08/18

Global Strategies
An Overview of Brazil's Cosmetic Regulations; 07/13

Household & Commercial Products Association (HCPA)
Changes to the Notice of Decision to Register Pesticide Products; 01/19
Discover the New Consumer Product Ingredients Dictionary; 11/17

Eleventh Antimicrobial Workshop; 03/15
Consumer Product VOC Compliance; 10/14
What Is a Misbranded Product? Webinar; 10/10
The CPSC from A to Z….and Beyond; 09/10
What Every Active Ingredient Supplier and Formulator Need to Know About Supplemental Distributor Agreements; 08/10
To amend or not to amend? Will someone please explain PRN 98-10 to me!; Webinar; 10/09
Annual and Mid-Year Meetings; 05/21, 12/20, 05/15, 12/14, 05/13
CSPA Consumer Product Labeling Workshop; 10/08
CSPA Workshop on Importing Pesticide Products; 06/08

Indiana University – Purdue University – Fort Wayne (IPFW)
Professionalism and Etiquette for Business; 10/17
The Building Blocks of Effective Messages; 08/17

Institute for In Vitro Sciences (IIVS)
An In Vitro Ocular Hazard Testing Strategy for EPA Registered Antimicrobial Cleaning Products; 11/12

International Association for Food Protection
Overview of the Safe Food for Canadians Act: CFIA Food Safety Regulatory Modernization; 11/13

International Sanitary Supply Association, Inc (ISSA)
Antimicrobial Workshop; 03/21, 04/21

The International Center
Understanding Japanese Business Culture; 02/13

The Jackson Laboratory
Understanding the Landscape of the Skim Microbiome and Potential Applications for Personal Care Products; 06/17

Lewis Way Leadership Development
Communication and Public Speaking; 09/21
Diversity Training; 07/23, 07/20

M4 Global Consulting LLC
Mexican Chemical Regulation; 08/20

The Microbiology Network
Microbiological Laboratory Investigations; 08/12
Review of Microbiological Involvement in Product Recalls; 02/12
Topics in Pharmaceutical Microbiology, 08/10

NSF International
Annual Steering Committee Meeting; 10/16, 10/14, 10/13, 11/10, 10/07, 10/03, 09/02, 07/01
Nonfood Compounds and Proprietary Substances Registration Program; 10/08

National Pesticide Information Retrieval System (NPIRS)/Purdue University

ALSTAR Training; 09/10

National Training Seminars

8 Steps for Highly Effective Negotiation; Letting the Other Person Have Your Way; 04/15
How to Facilitate Meetings Effectively; 02/15
Business Writing Essentials: Make Your Point Clearly & Concisely; 02/15
Mastering Microsoft Excel Macros; 06/14
How to Manage Priorities & Time; 08/13

Personal Care Products Council (PCPC)

Getting Started with FDA's Cosmetics Direct for Facility Registrations and Product Listings; 03/24
2016 Science Symposium; 10/16
Member Briefing; 04/17, 01/16
GMP Workshop; 06/17, 04/15
Australian Regulatory Requirements for Cosmetic Products; 08/14
Personal Care Products Council – 2011 Legal & Regulatory Meeting; 05/11
Disruption and Personal Care Products – Science and Regulatory Developments; 07/10
Cleaning and Sanitization for the Manufacture of Personal Care Products; 11/08

Reglaw Regulation Week Broadcasts

OSHA- Hazard Communication Standard; 10/13

Regulatory Affairs Professionals Society (RAPS)

Raising the Regulatory voice – Persuasive Framing; 01/18
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

Scientific & Regulatory Consultants, Inc.

Anti-Bribery; 09/20
EPA 101 Part 2; 02/19
Child Resistant Packaging; 01/19
Exempt vs. Non-Exempt Treated Articles; 01/18
6(a)(2) Training; 07/16
EPA 101: Submission Review, Training, and Overview; 06/16
NSF Overview; 02/16
Telephone Etiquette; 02/16
NOA (Notice of Arrival); 06/15
CRP (Child Resistant Packaging); 05/14
Training - OECD bactericidal method and results of 2011-12 BEAD Collaborative; 10/12

SHEA

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

Smith & Co. Consulting, Inc.

GMP: FDA Regulatory Action and Enforcement Trends; 12/22
GMP Beyond the Basics; 12/22
Advanced GLP Training; 10/22, 09/20
GLP Refresher Training; 09/22, 09/20
GLP Data Integrity; 09/22
cGMP Training; 11/22, 10/19

Society of Quality Assurance (SQA)

EPA Regulatory Update; 11/18
Good Clinical Laboratory Practices; Coloring Outside the Lines; 11/14
The US EPA Agricultural Field Trials – An Overview; 06/14
Good Clinical Laboratory Practices (GCLP) Auditing; 10/12

Steptoe & Johnson LLP

What's on the Food Contact Horizon?; 11/18
Advertising Class Actions: The Latest Litigation Fad; 11/13

Thompson Publishing Group

An In-Depth Panel Discussion: Dealing with Potential FDA Enforcement; 03/12
Online Advertising: Ensuring Compliance as DDMAC Steps Up Enforcement; 08/09

VCTrainings

Root Cause Analysis – Starting at the Beginning; 06/22

Washington Legal Foundation

FDA Goes Astray on Device Oversight: Proposed Guidance on 510(k) Review, Adverse Events Reporting, and Results; 10/13

Waters Corporation

Why is Electronic CDS Data a Major Data Integrity Concern for Regulators?; 04/17

Webber Training

Chlorhexidine Use and Bacterial Resistance; 09/18
Contamination of the Ward Environment: The Importance of Hand Hygiene When Leaving the Patient; 12/12
Surface Disinfection and Microbial Resistance; 12/12
The Hand is Quicker than a Sneeze in the Spread of Disease; 09/12

West Coast Quality Training Institute

"Practical Approach" Seminar; Introduction to Good Laboratory Practice Regulations; 07/09

"Practical Approach" Seminar; Advanced GLP Issues; 07/09

Wright Alliance

Introduction to Toxicology; 10/20

Advanced Toxicology; 10/20

Toxicology 101: General Principles and Applications for Assessing Human Health Effects of Chemical Substances; 02/13

Biocide Product Directive and REACH; 08/08

PUBLICATIONS & PRESENTATIONS

PRESENTATIONS

MacDonald, B., 2014. "Distributor Considerations", Regulators/Labeling and "What's in a Claim", Scientific & Regulatory Consultants, 2014

MacDonald, B., 2012. "6(a)(2) Reporting Guidelines", Scientific & Regulatory Consultants, 2012