

DAVID SWAIN

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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 2006 - Present

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

Senior Consultant (2012 – 2014); promotion

- Specializing in scientific and regulatory consulting services for antimicrobial products from inception to commercialization
- Monitoring regulatory changes and inspection trends
- Client research and data compilation
- Technical writing
- Antimicrobial market trends and direction
- Managing GLP contract laboratory product chemistry and toxicity studies
- Utilize NPIRS and EPA databases for competitive surveillance
- EPA submission strategy
- Audit manufacturing sites for GMP and EPA Books and Records compliance

Consultant (2006 – 2012)

- Label auditing
- State registrations
- EPA submissions
- Testing strategy
- GMP compliance/auditing
- Chemical consultation
- Supervised state registration staff

Ecolab, Inc. (formerly Huntington Laboratories, Inc.), Huntington, IN 1990 - 2006

Manufacturing Supervisor (2005 – 2006)

- Supervised and trained manufacturing associates in the production of EPA/FDA regulated hand washes, disinfectants, and sanitizers
- Developed daily plan for production to meet deadlines and manufacturing goals
- Prepared daily production reports for management
- Audited each manufacturing area for adherence to GMP requirements

Independent Study Project (2005)

- Researched an HPLC test protocol in conjunction with Huntington University to determine trace acids in lubricants

Laboratory Technician (1997 – 2005)

- Accountable for testing in-process batches and maintaining FDA/EPA regulated records
- Maintain, write, and audit FDA formulary production records in accordance with Good Manufacturing Practices (GMP)
- Validate laboratory equipment and methods including HPLC and GC
- Troubleshoot, maintain and interface with repair personnel for laboratory instruments including HPLC, GC, and FTIR
- Conduct method development for GC to quantify isopropyl alcohol in surgical scrubs
- Train and document proficiency of new laboratory technicians
- Performed quality control testing of products being manufactured. Tests included active ingredient, specific gravity, pH, viscosity, appearance and workmanship
- Maintained and tested Reverse Osmosis (RO) water system, including USP microbiological testing
- Responsible for maintenance of laboratory supplies inventory and for ordering needed laboratory supplies

Microbiology Technician (1994 - 1997)

- Responsible for testing, production, and R&D laboratory samples for efficacy and sterility
- Conducted research projects according to approved methods on numerous bacterial strains including:
 - ASTM E1174 Healthcare Personnel Handwash Testing (HCPHW)
 - ASTM E1115 Surgical Scrub Testing
 - AOAC Use-Dilution Testing
 - Kill Time
 - USP/CTFA Preservative Testing
- Developed new microbiology methods, including an in-vitro method, to replicate in-vivo handwash testing
- USP sterility testing of water, iodine products, and surgical scrubs

Order Editing (1993)

- Worked with sales force in application of pricing and commissions

Batch Mixer (1990 - 1992)

- Responsible for production of hand washes, soaps, floor cleaners and strippers in accordance with Good Manufacturing Practices in an EPA/FDA regulated environment

Grace Fellowship, Lawton, OK

1985 - 1990

Administrative Assistant and Youth Worker

- Coordinated church administration; Youth Ministry assistant

Clerk/Typist and Artilleryman

- Operated various artillery systems; including nuclear missiles
- Maintained Department of Defense documents and ammunition inventories

EDUCATION

B.S. in Chemistry, Huntington University, Huntington, IN; 2006

PROFESSIONAL AFFILIATIONS & CERTIFICATIONS

American Chemical Society (ACS)

CORPORATE PROFESSIONAL AFFILIATIONS

American Chemistry Council (ACC) Biocide Panel
British Association of Chemical Specialties (BACS)
Household & Commercial Products Association (HCPA) (Formerly CSPA)
International Sanitary Supply Association (ISSA)
Personal Care Products Council (PCPC)

PROFESSIONAL DEVELOPMENT

U.S. Environmental Protection Agency (EPA)

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
eDisclosure: EPA's Plan to Modernize the Implementation of the Audit Policy and the Small Business Compliance Policy; 06/15
Pesticide Inert Ingredient Workshop; 12/14
Practical 21st Century Toxicity Methods; 07/13
PPDC PRIA Workgroup; 10/09

California Department of Pesticide Regulation (CDPR)

CSPA: California Pesticide Regulatory Course 2013 for Consumer Products; 03/13

U.S. Food and Drug Administration (FDA)

How to Conduct Effective Quality Audits; 04/17
Regulatory Education for Industry (REdI); Focus on cGMPs & FDA Inspections; 07/15
Food, Drug & Device Facility Inspections: Lessons from FDA, the Minnesota Department of Agriculture, and Industry Teleconference; 11/12

Health Canada Pest Management Regulatory Agency (PMRA)

New Versions of PMRA's On-Line Forms; 07/13

RPC PMRA Notification Non-Notification; 10/12

American Association of Pesticide Controller Office (AAPCO)

Annual Conference; 03/13

American Chemistry Council

Biocides USA Conference; 04/16

Biocides Panel Meeting; 09/17, 02/17, 09/16, 01/16, 07/15, 01/15, 09/14, 05/14, 01/14, 09/12, 03/11

American Management Association (AMA)

Mastering Excel PivotTables: How to Crunch the Numbers like an Expert; 01/13

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 of Textile, Apparel & Materials Professionals (AATCC)

Antibacterial & Odor Control: Marketing and Technology Advancements; 09/15

Association for Professionals in Infection Control and Epidemiology (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

British Association for Chemical Specialties (BACS)

Biocides Forum; 11/09

Compliance4All

Excel Spreadsheets – Step by Step Instructions for Compliance; 05/17

21 CFR Part 11 – Compliance for Electronic Records and Signatures; 04/17

ChemWatch

Preparing a Biocide Authorization Dossier; 03/15

Executive Conferences

Validation and Performance Testing of Antimicrobial Technologies; 06/09

FDA News

Preparing for an FDA Preapproval Inspection: 11/16

Spreadsheet Validation 2016; Tools and techniques to Meet FDA Requirements

FDA Strategies, LLC.

FDA's Current Priorities; 08/13

FDC Services LLC

CGMP/QSR Training Program; 06/08

Gladieux Consulting

Powerful Presentation & Verbal Communication Skills; 05/09

What Your Words Say About You and Your Team: Business Writing; 04/09

Global Compliance Panel

Bullet Proof 510(k) - Latest FDA Proposed Changes to the Process; 02/13

Household & Commercial Products Association (HCPA) (Formerly CSPA)

Prop 65: California's Right to Know Law: Complying With New Warning and Labeling Requirements: Are you Ready?; 10/16

Learn How to Satisfy Walmart Ingredient Communication Requirements; 09/14

NYDEC Workshop; 03/14

Pesticide Program Dialogue Committee 21st Century Toxicology/New Integrated Testing Strategies; Where Vision Meets Action: Practical Application of 21st Century Methods; Stakeholder Workshop; 07/13

CA Pesticide Registration Course; 03/13

CSPA Consumer Product Labeling Seminar; 09/11

CSPA-California DPR Label Meeting; 03/11

What Is a Misbranded Product? Webinar; 10/10

What Every Active Ingredient Supplier and Formulator Need to Know About Supplemental Distributor Agreements; 08/10

Understanding Pesticide Data Requirements and Compensation; 03/10

CSPA Air Quality Conference; 11/09

CSPA/ISSA Ninth Antimicrobial Workshop; 10/09

To amend or not to amend? Will someone please explain PRN 98-10 to me!; Webinar; 10/09

Mid-Year Meeting; 05/14, 05/13, 05/12, 05/11, 05/10, 05/09, 05/08,

Year-End Meeting; 12/10

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

The International Center

Understanding Japanese Business Culture; 02/13

International Sanitary Supply Association (ISSA)

Green Cleaning Forum; 04/09

ISSA Legislative & Regulatory Forum; 04/09

Keller & Heckman

Seminar: "What U.S. Companies Need to Know: How to Manage the Regulatory Hurdles of TSCA, FIFRA & FDA"; 05/11

The Microbiology Network

Topics in Pharmaceutical Microbiology; 08/10

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

NC State University

Good Laboratory Practices; 02/16

Personal Care Products Council (PCPC)

Disruption and Personal Care Products – Science and Regulatory Developments; 07/10

Purified Water System Monitoring; 06/09

Dermal Sensitization Risk Assessment-The QRA; 02/09

Cleaning and Sanitization for the Manufacture of Personal Care Products; 11/08

Pharmaceutical Technology

The Impact of Harmonizing Microbial Testing; 12/08

Regulatory Affairs Professionals Society (RAPS)

NHP Licensing in Canada: Moving Forward-Updates, Initiatives and Challenges; 10/09

Recall or Not to Recall; 02/09

Scientific & Regulatory Consultants, Inc.

NSF Overview; 02/16

Telephone Etiquette; 02/16

NOA (Notice of Arrival); 06/15

Training - OECD bactericidal method and results of 2011-12 BEAD Collaborative; 10/12

6(a)(2) reporting guidelines; 09/12

Society of Quality Assurance (SQA)

OECD 17 – Application of FLP Principles to Computerized Systems; 01/17

Assessing Compliance in a Cloud Computing Environment; 07/15

State FIFRA Issues Research & Evaluation Group (SFIREG)

Pesticides Operations and Management Meeting (POM); 05/12

Symposium on Biocidal Product Authorization (SBPA)

4th Symposium on Biocidal Product Authorization; Vienna, Austria; 05/13

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

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**

Swain, D. 2016 US Registration/Review Program and Data Call-Ins, Biocides USA 2016 Conference, 2016

Swain, D. 2015. EPA and Global Regulatory Guidelines, Antibacterial & Odor Control: Marketing and Technology Advancements Conference, 2015

Swain, D. 2014. "CRP (Child Resistant Packaging)", Scientific & Regulatory Consultants, 2014