

## 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](http://www.srcconsultants.com)

### PROFESSIONAL EXPERIENCE

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**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

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**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

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**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**

British Association of Chemical Specialties (BACS)  
Center for Biocide Chemistries (CBC)  
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 21<sup>st</sup> 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**

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

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

**ECG, Inc.**

Convince Me: Persuasion and Negotiation Training; 08/18

**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 21<sup>st</sup> Century Toxicology/New Integrated Testing Strategies; Where Vision Meets Action: Practical Application of 21<sup>st</sup> 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)**

Raising the Regulatory voice – Persuasive Framing; 01/18

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

Recall or Not to Recall; 02/09

**Scientific & Regulatory Consultants, Inc.**

Exempt vs. Non-Exempt Treated Articles; 01/18

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)**

4<sup>th</sup> 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

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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