Scientific & Regulatory Consultants, Inc.

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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
- Author materials for SRC blogs and website, as needed

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

US Army, Fort Sill, OK 1983 - 1985

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 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)

Best Practices for Antimicrobial Product Registration; 03/24
EPA's Implementation of Data Evaluation Records (DERs); 11/23
PRIA 5 Workshop 04/23
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

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)

OMUFA: Understanding FY 2024 User Fees and Registration; 07/24

FDA Electronic Drug Registration and Listing (eDRLS) Using CDER Direct 2024; 09/24
CDER Small Business and Industry Assistance (CDER SBIA) – Electronic Drug Registration and Listing (eDRLS) Using CDER Direct; 09/23
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 Chemicals Association (BCA) (Formerly 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

Global Leadership Network

Global Leadership Summit; 08/20

GxP Training

GMP Course – Refresher; 05/25

Household & Commercial Products Association (HCPA)

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; 12/20, 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

Integrity of Data
GLP Refresher and Advanced Training; 06/25

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

Lewis Way Leadership Development
Communication and Public Speaking; 09/21
Diversity Training; 11/24, 07/23, 07/20

M4 Global Consulting LLC
Mexican Chemical Regulation; 08/20

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)

Science Symposium 10/24
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

Q Laboratories

FDA Microbiology Enforcement Trends: What Non-Sterile Pharma Must Know; 11/25

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.

GLP Electronic Signature; 10/25
Anti-Bribery; 09/25, 10/24, 08/23, 08/22
GLP Mock Laboratory Audit 05/24
GLP Electronic Signature & Study Management Training; 10/24, 07/23
EPA 101 Part 2; 02/19
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

Smith & Co. Consulting, Inc.

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

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

Steptoe & Johnson LLP

Best Practices in FIFRA Data Compensation; 03/21
Threshold of Toxicological Concern; 01/19

Symposium on Biocidal Product Authorization (SBPA)

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

Velocity 360 USA Training, LLC

Pharmaceutical - FDA 21 CFR 210 and 211 CGMP Requirements; 05/25

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

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