

Scientific & Regulatory Consultants, Inc.

DAVID SWAIN

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PROFESSIONAL SUMMARY

Hard-working, scientific oriented professional with over sixteen years of laboratory experience and EPA/FDA regulated manufacturing production and supervision. Expertise in various laboratory technologies and equipment including Agilent and Waters HPLC, gas chromatograph, FTIR and computer systems. Trained in document control of GMP, GLP and FDA regulated records.

Areas of Expertise:

- ◆ Laboratory Method Development
- ◆ Chemical Testing and Evaluation
- ◆ Good Manufacturing Practices
- ◆ Analytical Chemistry
- ◆ Creative Problem Solving
- ◆ Good Laboratory Practices
- ◆ Laboratory/Manufacturing Auditing
- ◆ Training/Mentoring

PROFESSIONAL EXPERIENCE

SCIENTIFIC & REGULATORY CONSULTANTS, INC., Columbia City, IN 2006-present

Consultant

Responsible for label auditing, state registrations, EPA submissions, testing strategy, GMP compliance/auditing and chemical consultation.

ECOLAB, INC. (Formerly Huntington Laboratories, Inc.), Huntington, IN 1990-2006

Manufacturing Supervisor (2005-2006)

Responsible for the training and supervision of 20-25 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 a new HPLC test method in conjunction with Huntington University to determine trace acids in lubricants.

- Conducted research to develop HPLC analytical method to quantify formic acid and acetic acid in developmental lubricants

Laboratory Technician (1997-2005)

Accountable for testing in-process batches and maintaining FDA/EPA regulated records

- Responsible for maintaining, writing, and auditing FDA formulary production records in accordance with Good Manufacturing Practices (GMP)
- Participated in various validations of laboratory equipment and methods including HPLC, GC and FTIR
- Responsible for troubleshooting, maintaining and interfacing with repair personnel for laboratory instruments including HPLC, GC and FTIR
- Responsible for method development for GC to quantify isopropyl alcohol in surgical scrubs
- Coordinated training and documented 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 samples provided by production and R&D laboratory for efficacy and sterility

- Conducted various research projects according to approved methods on a wide array of bacterial strains including:
 - ASTM E1174 Healthcare Personnel Hand Wash 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 hand wash testing
- Performed USP sterility testing of water, iodine products and surgical scrubs

Order Editing (1993)

- Worked with sales force in application of pricing and commissions
- Entered orders in mainframe computer system

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, Oklahoma

1985-1990

Administrative Assistant and Youth Worker

- Coordinated Church administration including cassette tape ministry, church bulletin and benevolence account
- Assisted with youth ministry including curriculum development, conducting youth meetings and teaching youth Sunday School class

US ARMY, Fort Sill, Oklahoma

1983-1985

Clerk/Typist and Artilleryman

- Received training in and operated various artillery systems including nuclear missiles
- Maintained various DOD documents and ammunition inventories

EDUCATION

Bachelor of Science in Chemistry, Huntington University, Huntington, IN 2006

CORPORATE PROFESSIONAL AFFILIATIONS

American Chemistry Council (ACC)
American Chemical Society (ACS)
British Association for Chemical Specialties (BACS)
Chemical Specialty Products Association (CSPA)
International Association for Food Protection (IAFP)
International Sanitary Supply Association (ISSA)
National Spa & Pool Institute (NSPI)
Personal Care Products Council (PCPC; formerly CTFA)

PROFESSIONAL DEVELOPMENT

REGULATORY CONFERENCES, SEMINARS AND TRAINING

CSPA

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; 05/09, 05/08, 05/10

EPA

PPDC PRIA Workgroup; 10/09

Personal Care Products Council (formerly CTFA)

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

“FDA Inspection of OTC Drug & Cosmetic Facilities: Your Rights & Obligations”; 05/07

Regulatory Affairs Professionals Society (RAPS)

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

Recall or Not to Recall; 02/09

British Association for Chemical Specialties (BACS)

Biocides Forum; 11/09

Pharmaceutical Technology

The Impact of Harmonizing Microbial Testing; 12/08

Executive Conferences

Validation and Performance Testing of Antimicrobial Technologies; 06/09

International Sanitary Supply Association (ISSA)

Green Cleaning Forum; 04/09

ISSA Legislative & Regulatory Forum; 04/09

West Coast Quality Training Institute

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

“Practical Approach” Seminar; Advanced GLP Issues; 07/09

Clinical Device Group

The Successful 510(k); 06/07

Wright Alliance, LLC.

Biocide Product Directive and REACH; 08/08

Executive Conferences

Validation and Performance Testing of Antimicrobial Technologies; 06/09

FDC Services LLC

CGMP/QSR Training Program; 06/08

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

National Sanitation Foundation (NSF) International

NSF Non-Food Compound Steering Committee Meeting; 10/07

Institute of Validation Technology (IVT)

GMP, Validation and Change Control: A Bird's Eye View of the Principles Involved; 08/06

SAFETY CONFERENCES, SEMINARS AND TRAINING

Ecolab Inc.

DOT Awareness Training; 2005
GMP Training; 2005, 2004

Dupont

DuPont Safety Training; 2006

Huntington Laboratories, Inc.

DOT General Awareness Training; 1995, 1994, and 1993
GLP Training; 1994

Hazards Training Institute

Hazardous Materials Training Seminar; 1995

OTHER PROFESSIONAL CONFERENCES, SEMINARS AND TRAINING

Gladieux Consulting

Powerful Presentation & Verbal Communication Skills; 05/09
What Your Words Say About You and Your Team: Business Writing; 04/09

Skill Path Inc.

Microsoft Word Seminar; 1999