

SALLY HAYES
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PROFESSIONAL SUMMARY

Results oriented, creative, persevering and persistent. Able to manage many projects at the same time in a fast-paced, dynamic environment. Able to communicate concise, accurate, timely, and understandable interpretations of regulatory issues affecting corporate or customer business activities and offer solutions to regulatory hurdles. Over 30 years of increasing responsibility and achievements in the chemical industry.

Areas of Expertise:

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| ◆ Regulatory Affairs/Compliance | ◆ Technical Presentations |
| ◆ Good Laboratory Practices (GLP) | ◆ Negotiating with Government Agencies |
| ◆ Good Manufacturing Practices (GMP) | ◆ Creative Problem Solving |
| ◆ Analyzing Regulatory Impact on Business | ◆ Auditing |
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PROFESSIONAL EXPERIENCE

SCIENTIFIC & REGULATORY CONSULTANTS, INC., Columbia City, IN 1996-Present

Consultant, (Vice-President/Co-Owner)

Responsible for developing regulatory strategies to obtain regulatory approvals with EPA (Federal and State), FDA, and other Domestic and International Agencies, negotiation with government agencies with respect to labeling and testing requirements, reviewing ads, promotional literature and websites for regulatory compliance, facility auditing for compliance with GLP and GMP.

- Consumer Specialty Products Association, Regulatory Committee Chair, 2004 to 2007
- Presented “Assembling the Package” at the Introduction to Regulatory Toxicology & Registration hosted by CSPA, November 2004.
- Presented “How to Submit an Application” at the 6th Annual EPA Antimicrobial Division Program, June 2003.
- Customized internal GLP Training Program for a multi-national firm.
- Represented Consumer Specialty Products Association (CSPA) at an EPA Scientific Advisory Panel Meeting.
- Prepared corporate position statement on FQPA and Streamlining issues.
- Advise clients on data compensation.
- Drafted scientific and regulatory portion of an Initial Public Offering (IPO).
- Designed and coordinated the CSPA Antimicrobial Registration Workshop.
 - “Application... to Registration...and Beyond”, 1999, in association with US EPA.
- Prepare responses to proposed regulations and governmental policies.

HUNTINGTON LABORATORIES, INC., Huntington, IN

1988-1996

Regulatory Affairs Manager

Responsible to President for the development, implementation, and analysis of regulatory programs, and procedures to ensure compliance with State, Federal, and International regulations. To provide regulatory strategy and leadership to management, scientific, and technical staff.

- Developed regulatory strategies to obtain regulatory approvals with EPA, FFDA, and other Domestic and International agencies of over 100 EPA registrations, one new drug and six medical devices.
- Negotiated with the various government agencies with respect to labeling and testing requirements to obtain and maintain registrations.
- Reviewed, analyzed and advised management on proposed and final regulations for impact on corporate and customer business.
- Prepared and conducted seminars for sales representative and customers on current regulatory and legislative issues.
- Presented at ISSA Pesticide Labeling Workshop.
- Implemented internal GLP program as a member of Good Laboratory Practices (GLP) team. Resulted in Council for Antimicrobial Quality Certification in 1995.
- Chair of the CSMA EPA/FDA Jurisdictional Task Force. Presented industry position at FDA Panel Meeting.
- Audited contract laboratories, contract manufacturers, and corporate branches to ensure compliance with regulatory requirements.
- Directed staff in areas such as State Registrations, USDA, SARA Title III, OSHA Right-To-Know, Domestic and International Shipping, and VOC Regulations.
- Promoted in 1989.

THE FULLER BRUSH COMPANY, Great Bend, KS

1977-1988

Supervisor Quality Control Lab

Responsible for day-to-date quality of \$20MM Chemical line. Interfaced and resolved problems involving contract suppliers, vendors, manufacturing, marketing groups, purchasing, and production control. Wrote training program for OSHA Hazard Communication Standard, trained over 500 employees and monitored on-going program.

- Research and Development Chemist – aerosols, personal care, and cleaning supplies. Developed product and package stability, established specifications and followed through manufacturing start-up.
- Quality Control Chemist – inspected all incoming raw materials for compliance to standards. Checked batches and determined adjustments needed.
- Promoted 1979 and 1983.

EDUCATION

- Bachelor of Science in Secondary Education, Kansas State University, Manhattan, KS
- Undergraduate Business Courses (30 hours), Fort Hays State University, Hays, KS

PROFESSIONAL AFFILIATIONS

- British Association for Chemical Specialties (BACS)
- Chemical Specialty Products Association (CSPA)
- Cosmetic Toiletries Fragrance Association (CTFA)
- International Association for Food Protection (IAFP)
- International Sanitary Supply Association (ISSA)
- National Spa & Pool Institute (NSPI)
- Regulatory Affairs Professional Society (RAPS)

PROFESSIONAL DEVELOPMENT

Regulatory Affairs Professional Society (RAPS)	Conducting Successful Negotiations in Regulatory Affairs, 1994.
Association of Official Analytical Chemists (AOAC)	How to Testify as an Expert Witness, 1992.
Environmental Protection Agency (EPA)	Pesticide Program Dialogue Committee Fall Meeting, October 2007. The Globally Harmonized System of Classification and Labeling of Chemicals, October 2006. Seventh Antimicrobial Workshop, November 2005. Pesticide Registration Improvement Act: Workshop for Stakeholders, March 2004. EPA Workshop, June 2003. National Meeting on the Regulation of Antimicrobial Pesticide Workshops, 1997, 1998, 1999, 2000, 2003.
Consumer Specialty Products Association	Mid-Year and Annual Meetings, 1988-2008 CSPA Workshop on Importing Pesticide Products, June 2008. Globally Harmonized System of Classification and Labeling of Chemicals (GHS) Potential Modifications to HazCom Standard, October 2006. International Affairs Conference/CSPA, October 2006. Introduction to Regulatory Toxicology & Registration hosted by CSPA (Speaker and attendee), November 2004. CSPA Meeting with California DPR – Streamlining, August 2003. CSPA Regulatory Meeting, February 2003. CSPA Meeting with California DPR – Mill Assessment, December 2002. Toxicology 101, 2002.

	Antimicrobial Registrations Workshop “Application To Registration....And Beyond”, 1999.
	Good Laboratory Practices Seminar, 1992.
Canadian Consumer Specialty Products Association (CCSPA)	Annual CCSPA/Federal Government Interface, May 2008; April 2006
California EPA	VOC Workshop, August 2006
FDC Services LLC	CGMP/QSR Training Program, June 2008
Quality Is Learned	Current Good Manufacturing Practice Regulations; 21 CFR Parts 210 & 211, February 2006
Chemical Producers & Distributors Association/International Sanitary Supply Association (CPDA/ISSA)	Confidential Statement of Formula and Other Emerging Issues, June 2003. Reporting of Adverse Effects-FIFRA 6(a)(2), June 2002.
California Department of Registration	Antimicrobial Registration Workshop, October 2002.
Clinical Device Group, Inc.	The Successful 510(k), June 2007. The Successful 510(k), June 2005.
Western Crop Protection Association (WCPA)	California Pesticide Regulations Course, August 1995.
Health Canada	Canadian Pesticide Regulation Course, 1998.
New York State Department of Environmental Conservation	Pesticide Producers Regulatory Workshop, June 2002.
American Management Association (AMA)	Quality Control: Meeting the New Competition, 1987.
Hazardous Materials Advisory Committee/Dangerous Government Services Institute (HMAC/GSI)	Transportation of Hazardous Materials and Goods Advanced Course, 1995.
Northeast Indiana Quality Network	Benchmarking Your Competitor, 1996.
Target Research Associates	The Mechanics of Preparing INDS & NDAs and

(Dr. Robert McCormack)	FDA regulations, 1998.
Center for Environmental & Regulatory Information System – Purdue University	National Pesticide Information Retrieval System Training, 1998.
Gladioux Consulting	Better Business Writing/Documentation, May 2006. Powerful Presentation Skills, August 2002. Better Business Writing, August 2002. Time Management, August 2002.
West Coast Quality Training Institute (Pacific Rim Consulting)	Good Laboratory Practices for Technical Staff, March 2006. Quality Assurance in GLPs, September 2002. Introduction to EPA/FDA/OECD Good Laboratory Practices, September 2002.
The University of Toledo	In-Plant Industrial Chemical Spill Response Course, April 1989.
Center for Professional Advancement	Aerosol Technology Course, June 1982.
Varian Associates	Maintenance and Troubleshooting of the 3700 Gas Chromatograph, October 1983.
American Bar Association – Committee on Pesticides, Chemical Regulations, and Right-To-Know	Antimicrobial Pesticides – Regulation of Innovative and Unique Products, May 2004.

PRESENTATIONS

Presented “How to Submit an Application” at the 6th Annual EPA Antimicrobial Division Program, June 2003.

PUBLICATIONS

Cozad A, Hayes S. Regulatory Strategy and EPA Requirements for the Corrosion Control Using Regenerative Biofilms (CCURB) Product. EPRI, Palo Alto, CA: 2004. 1009465.