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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.srconsultants.com

PROFESSIONAL EXPERIENCE

Scientific & Regulatory Consultants, Inc., Columbia City, IN

2008 - Present

Consultant (2018 – Present); promotion

Consulting Associate (2015 - 2017)

- EPA & California pesticide registration strategy and submissions
- GLP efficacy, chemistry, and toxicity report and raw data reviews; write DERs
- Label review for federal and state submission
- 6(a)(2) and adverse event reports to EPA and states
- 25(b) pesticide regulations and requirements
- State fertilizer and soil/plant amendment registrations
- OMRI and state organic certifications
- Scientific research and competitive surveillance
- Company and product transfers
- Due diligence for EPA company acquisitions
- FDA Drug Listings

State Registration Manager (2011 - 2015); promotion

- Oversee initial state product registrations, state registration renewals and label review submissions
- Implement and maintain database programs
- Client liaison for State Registration Department
- Propose and negotiate new client services
- Conduct quarterly financial data review and forecasting
- Compile client 6(a)(2) and adverse event reports according to Federal and State requirements

Consulting Assistant (2008 - 2011)

- Research database and Internet (NPIRS, PPLS, etc.) for client or competitor surveillance
- Assist in filing FDA Drug Listings
- Support NSF submission filings
- Prepare and review state product registration applications
- Advise on agricultural related study design, field trials, and compliance

Maize Development Research Associate

- Regulated Field Trial Contact: Managed experiments, data collection, regulatory records and reports as required by EPA and USDA
- ISO 9000 Management Representative: Implemented and maintained a quality management system for ISO 9000:2000 standards
- Field research and management of maize development and breeding
 - Managed spring seed filling of hybrid yield tests to prepare for planting
 - Coordinated pollinating season of over 100,000 pollinations across several nursery blocks
 - Collected phenotypic field data in inbred nurseries, hybrid yield tests and observation plots planting through harvest
 - Directed spring filling and pollinating crews, assisted interns with projects

Graduate Research Assistant (2001 - 2003)

- Conducted field trials and accompanying laboratory analysis for thesis research on maize responses to deep placement of phosphorus and potassium
- Guided plot tours for international scientists and industry leaders
- Partnered with fellow graduate students in research projects involving tillage, cropping systems, polymer coated seeding systems, and phenological plant variation studies

Crops Resource Center Teaching Assistant (1999 - 2000)

- Assisted students in Agronomy/Crops courses
- Set up laboratory sessions for instruction

Lab Technician – Quarantine Parasitic Weed Lab (1998 - 1999)

- Investigated germination properties of *Orobanche* and *Striga*, parasitic weeds with devastating effects on crops in Africa and the Middle East

Science Intern – Field Research

- Assisted with establishment and evaluation of herbicide, fungicide and insecticide trials
- Initiated and maintained vineyard and orchard pesticide testing
- Conducted fungicide trial involving *Cercospora beticola*, a sugar beet disease
- Vegetable and soybean crop GLP studies

EDUCATION

M.S. in Agronomy, Purdue University, West Lafayette, IN; 2005
B.S. in Agronomy, Purdue University, West Lafayette, IN; 2000
Huntington College (now Huntington University), Huntington, IN; 1998

PROFESSIONAL AFFILIATIONS & CERTIFICATIONS

Certified Crop Advisor (2003 – present)
National Alliance of Independent Crop Consultants (2016 – present)
Organic Materials Review Institute (OMRI) (2017 – present)

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)

Introduction to Down-the-Drain Assessment for Antimicrobial Pesticides; 10/16
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
SmartLabel Webinar; 12/15
Registering with CDX and user roles; 08/15
eDisclosure: EPA's Plan to Modernize the Implementation of the Audit Policy and the Small Business Compliance Policy; 06/15

U.S. Food and Drug Administration (FDA)

Electronic Drug Registration & Listing Using CDER Direct Extended Webinar; 10/17
How to Conduct Effective Quality Audits; 04/17
Promotion of Drugs, Devices and Biologics Using Social Media; 02/17
Developmental Approval Process/Small Business Assistance; 09/15
CDER Direct Electronic Submissions Portal: Drug Facility Registration; 09/15
Regulatory Education for Industry (REdI): Focus on cGMPs & FDA Inspections; 07/15
SPL R4 Training Session 58 – Bulk Ingredient/Bulk Product SPL; 03/11
SPL R4 Training Session 57 – OTC Drug Product SPL; 03/11
SPL R4 Training 101: Preparing Electronic Drug Est. Registration and Drug Listing Submissions; 03/10

A&L Great Lakes Laboratories Soil Fertility Workshop

Nutrient Management, Crop Management & Soil and Water Management Topics; 03/10

American Management Association (AMA)

Mastering Excel PivotTables: How to Crunch the Numbers Like an Expert; 01/13
Reenergize Your Best Employees Before They Leave; 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

American Society of Agronomy

Cover Crops Series; 01/17, 02/17
Weed Resistance Management; 02/17
Neonic Seed Treatments; 02/17, 03/17
Bee Health & Stewardship; 02/16
Nutrient Management; 12/15
Science Behind a Soil Conservation Practice Standard for Soil Amendments; 12/15
Revisiting Organic Agriculture Webinar
Seeds and Sources; 11/15
Yields: More or Less; 10/15
Pest Control; 09/15
Nutrient Sources; 08/15
Definitions and Regulatory Requirements; 07/15

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

Certified Crop Advisor (CCA)

NRCS Tools to Meet the Water Quality Challenge; 12/15
Zinc Fertility; 12/15
Crop Advisor Day; 08/17, 08/15
Indiana CCA Annual Meeting; 12/13, 12/10, 12/09, 12/08, 12/07

Compliance4All

Excel Spreadsheets – Step by Step Instructions for Compliance; 05/17
21 CFR Part 11 – Compliance for Electronic Records and Signatures; 04/17

Compliance Online

Clearing Up Roles and Responsibilities in the GLPs; 10/16

Executive Conferences

Validation and Performance Testing of Antimicrobial Technologies; 06/09

FDA News

Promotion of Drugs, Devices and Biologics Using Social Media; 02/17
Spreadsheet Validation 2016; Tools and techniques to Meet FDA Requirements

FDC Services LLC

CGMP/QSR Training Program; 06/08

Gladioux Consulting

Better Business Writing; 03/14

Powerful Presentation & Verbal Communication Skills; 05/09

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

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

Discover the New Consumer Product Ingredients Dictionary; 11/17

California Pesticide Registration Course & Boot Camp; 09/17

US Pesticide Regulation Workshop; 10/15

Consumer Product VOC Compliance; 10/14

New York DEC Workshop; 03/14

Fundamentals of Surfactant Types; 10/12

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

Annual Meeting; 12/17

Mid-Year Meeting; 05/15, 04/14, 05/13, 05/12, 05/09

Indiana University – Purdue University – Fort Wayne (IPFW)

Professionalism and Etiquette for Business; 10/17

The Building Blocks of Effective Messages; 08/17

The International Center

Understanding Japanese Business Culture; 02/13

The Microbiology Network

Topics in Pharmaceutical Microbiology, 08/10

National Alliance of Independent Crop Consultants (NAICC)

Annual Meeting; 01/17, 01/16

National Pesticide Information Retrieval System (NPIRS)/Purdue University

Conference; 10/12, 10/11, 09/09

ALSTAR Training; 10/12, 09/10

ALSTAR Annual Meeting; 09/14, 10/12, 10/11, 09/10

ALSTAR Mid-year Meeting; 04/12

National Training Seminars

The Essentials of Credibility, Confidence, and Composure; 06/15

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

FISH!; 08/14

Mastering Microsoft Excel Macros; 06/14

How to Manage Priorities & Time; 08/13

NSF International

Nonfood Compounds Registration Webinar; 04/10
NSF Conference; 11/11, 10/13

Personal Care Products Council (PCPC)

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

Purdue University

Crop Management Workshop; 01/17, 01/15
Implementing Cover Crops in Your Crop Rotation to Improve Soil Health; 08/16
Updates on Problem weeds/Pesticides Resistance Strategies; 08/16
Identification and Management of Corn and Soybean Diseases; 08/16
Indiana Certified Crop Advisor Days; 08/17, 08/11
Agronomy Field Day; 07/11
Seed Treatment Workshop; 06/11

Regulatory Education for Industry (REdI)

The Pharmaceutical Quality System (PQS); 12/15
Laboratory: Laboratory Controls; 12/15
Facilities & Equipment: cGMP Requirements; 12/15

Scientific & Regulatory Consultants, Inc.

NSF Overview; 02/16
Telephone Etiquette; 02/16
EPA Good Laboratory Practice Learning Series; 03/16
6(a)(2) reporting guidelines; 09/12

Society of Quality Assurance (SQA)

Common Misunderstandings Surrounding US and International GLPs; 11/17
Agricultural Biotechnology: Product Development & Auditing; 11/17
Tactical Questioning; 11/17
Honeybee Health: The latest buzz on colony decline; 10/17
Introduction to Lean 5S for Quality Systems; 07/17
Method Validation and ILV; 12/16
Conducting Field Audits; 12/15
Assessing Compliance in a Cloud Computing Environment; 07/15
US EPA Agricultural Field Trials- An Overview; 06/14
EPA Inspection Process and Discuss Points; 07/09
Auditing Skills Seminar; 05/13
Annual Meeting; 05/13

Waters Corporation

Why is Electronic CDS Data a Major Data Integrity Concern for Regulators?; 04/17

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, LLC.

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

Kline, A. “6(a)(2) Training”, Scientific & Regulatory Consultants, 2016

Kline, A. “NOA (Notice of Arrival)”, Scientific & Regulatory Consultants, 2015

Kline, A.; Pyle, A. 2014. “Label Review Overview”, ALSTAR Meeting, 2014

PUBLICATIONS

Kline, A.M. 2005. Corn Responses to Deep Placement of Phosphorus and Potassium in High Yield Production Systems. M.S. Thesis, Purdue University.

Kline, A.M., S.M. McCoy, T.J. Vyn, and E.P. Christmas. 2003. Management Considerations for Relay Intercropping I: Wheat. Purdue University Agronomy Extension Publication (AY-315).

S.M., McCoy, T.J. Vyn, A.M. Kline, and E.P. Christmas. 2003. Management Considerations for Relay Intercropping II: Soybean. Purdue University Agronomy Extension Publication (AY-316).

Kline, A.M., T.J. Vyn, and S.M. Brouder. Phosphorus and Potassium Placement Depth: Effects on Corn Growth. Presented at North Central American Society of Agronomy National Meetings, Madison, WI, March 2003.

Kline, A., T. Vyn, and S. Brouder. 2002. Effects of Fertility Placement in High Yield Corn Situations. Research Report to Foundation for Agronomic Research. Purdue University.

Kline, A.M., T.J. Vyn, and S.M. Brouder. Effects of Fertility Placement on Early Corn Growth. Presented at American Society of Agronomy National Meetings, Indianapolis, IN, November 2002 and at the North Central Industry-Extension Soil Fertility Conference, Ames, IA November 2002.

Kline, A., T. Vyn, and S. Brouder. 2001. Effects of Fertility Placement in High Yield Corn Situations. Cropping Systems Research Report. Purdue University.