

## Navigating the Premanufacture Notice (PMN) Process Under Amended TSCA

Monday, March 18, 2019 Las Vegas, Nevada

### **Course Description**

Stakeholders are invited to engage in an interactive workshop focused on the U.S. Environmental Protection Agency's (EPA) implementation of requirements for new chemical review under the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act, also known as the amended Toxic Substances Control Act (TSCA).

#### **Course Objective**

The workshop will include an overview of the new chemical review process, a detailed discussion on current challenges the U.S. Environmental Protection Agency (EPA) and new chemical innovators face under TSCA and their associated commercial and market impacts, tips premanufacture notice (PMN) submitters should consider to ensure an efficient and surprise-free new chemical review, and a lively discussion on ideas to minimize review time.

#### **Intended Audience**

Regulatory and Hazard Communication professionals looking to obtain a deeper understanding and practical know-how in TSCA and the PMN preparation process.

Course Fee: \$450 / members

\$540 / non-members

### **Course Director / Instructor**



## Lynn L. Bergeson, Esq.

**Lynn L. Bergeson** is the Owner and Managing Partner of Bergeson & Campbell, P.C. (B&C<sup>®</sup>). Ms. Bergeson has earned an international reputation for her deep and expansive understanding of the Toxic Substances Control Act (TSCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the European Union's (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation, and especially how these regulatory programs pertain to nanotechnology, industrial biotechnology, synthetic biology, and other emerging transformative technologies. Her knowledge of and involvement in the policy process allows her to develop client-focused strategies whether advocating before Congress, the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), or other governance and standard-setting bodies.

Ms. Bergeson counsels corporations, trade associations, and business consortia on a wide range of issues pertaining to chemical hazard, exposure and risk assessment, risk communication, minimizing legal liability, and evolving regulatory and policy matters pertinent to conventional, biobased, and nanoscale chemicals, particularly with respect to TSCA, FIFRA, Food Quality Protection Act (FQPA), REACH and REACH-like programs, and U.S. Occupational Safety and Health Administration (OSHA) matters.



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#### **Course Instructor**



# Richard E. Engler, Ph.D.

**Richard E. Engler** is the Director of Chemistry at Bergeson & Campbell P.C. (B&C<sup>®</sup>). Dr. Engler is a 17-year veteran of the U.S. Environmental Protection Agency (EPA) and is one of the most widely recognized experts in the field of green chemistry, having served as senior staff scientist in EPA's Office of Pollution Prevention and Toxics (OPPT) and leader of EPA's Green Chemistry Program. He has participated in thousands of Toxic Substances Control Act (TSCA) substance reviews at EPA, as well as pre-notice and post-review meetings with submitters to resolve complex or difficult cases, and he draws upon this invaluable experience to assist B&C clients as they develop and commercialize novel chemistries.

Dr. Engler's expansive understanding of the specific challenges and opportunities TSCA presents for green and sustainable chemistry is a powerful asset for clients during regulatory review. He assists clients in performing toxicological reviews, performing environmental fate modeling using Sustainable Futures tools, and preparing scientific and test data for regulatory submission. He is particularly skilled in preparing Pollution Prevention (P2) statements to highlight the concrete environmental benefits of biobased or renewable chemicals, as well as other sustainable chemistry products and processes.

### **Course Instructor**



## Kathleen M. Roberts

**Kathleen M. Roberts** is Vice President of B&C<sup>®</sup> Consortia Management, L.L.C. (BCCM), an affiliate of Bergeson & Campbell, P.C. (B&C<sup>®</sup>). In her leadership role at BCCM, Ms. Roberts is an essential resource for industry groups, providing cost effective management support and administrative services for multiple industry consortia engaged in advocacy, research, public outreach, and communication activities. In addition, Ms. Roberts serves as a non-attorney professional with B&C, addressing domestic and international chemical control regulations and related chemical management issues. She is a recognized expert on the Toxic Substances Control Act (TSCA), with over 25 years' experience in engaged advocacy, compliance, and communication activities with industry and U.S. Environmental Protection Agency (EPA) staff. In June 2013, Ms. Roberts was invited to provide expert testimony on understanding the history and impact of TSCA before the U.S. House Energy and Commerce Subcommittee on Environment and the Economy.

Ms. Roberts writes and speaks frequently about the opportunities for industry to use TSCA to its competitive advantage and the challenges newer chemicals and technologies sometimes present under TSCA regulations. Her articles have appeared in *The Environmental Forum*, *Industrial Biotechnology*, *Law 360*, and *Biofuels Digest*, among others. She has presented numerous TSCA workshops and seminars, including at the National Association for Chemical Distributors' (NACD) annual meeting, the BIO World Congress, the Chemical Watch U.S. Regulatory Summit, and the inaugural Product Stewardship Society conference.



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Course Topics and Sched (Subject to Change)	ule
Monday, March 18, 2019	
7:30-8:00	Registration / Continental Breakfast
8:00-8:15	Welcome and Program Overview
8:15-9:45	Setting the Stage
	Overview of New TSCA Section 5
9:45-10:15	Understanding the PMN Process Old Versus New
10:15-10:30	Break
10:30-11:45	Reality Check, Part 1 – Case Study Reviews; New PMN Pitfalls
11:45-1:00	Lunch (buffet lunch provided)
1:00-1:15	Realty Check, Part 2 – Attendees' Experiences
1:15-2:00	Deeper Dive on PMN Process
2:00-2:20	Pre-submission Strategies
2:20-2:40	Post-submission Strategies
2:40-3:00	Break
3:00-4:00	Applying Lessons Learned
4:00-4:30	Questions and Closing Thoughts



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### Registration

Admission to the course will be on a first come basis. Payment must be received by February 9, 2019, to secure your space. Space is limited.

Fill out the registration form located on SCHC's website: http://www.schc.org

SCHC accepts checks, Visa, MasterCard and American Express.

### **Cancellation Policy**

No refunds will be given after February 9, 2019. No one will be admitted to the course unless all fees have been paid in advance. Substitutions are permitted. Every effort has been made to ensure the information in this brochure is accurate. SCHC reserves the right to modify this course without prior notice or to cancel the course 30 days prior to the course date. In the event this course is canceled, SCHC's obligation is limited to a full refund of the course fee.

#### **Hotel Accommodations**

Arrangements have been made for a block of rooms at the Tropicana Las Vegas Hotel – 3801 S. Las Vegas Blvd., Las Vegas, Nevada 89109 – 888-381-8767. The rate is \$119/night single or double occupancy through March 30, 2019. Use the <u>online reservation link</u>; or identify yourself with SCHC (group code SCH19 or Society for Chemical Hazard Communication).