



Exponent[®]
Engineering & Scientific Consulting

Sarah Dahlberg, M.S., RAC-Drugs

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Professional Profile

Ms. Dahlberg is an interdisciplinary health scientist who specializes in regulatory affairs of pharmaceutical, medicinal, and biotechnology products, leveraging her breadth of experience in pharmacovigilance safety, human health risk assessment, toxicology, and regulatory science.

Ms. Dahlberg has extensive experience with leading and conducting systematic literature reviews and meta-analyses across a variety of disciplines, providing technical support for exposure science and pharmacoepidemiology litigation matters, and in evaluating and assessing biases in epidemiologic studies. Ms. Dahlberg has evaluated US FDA and EU EMA regulatory requirements for drug product lifecycles and has provided consulting services to life science clients on clinical strategies for early-stage drugs and regulatory submissions support.

Ms. Dahlberg's experience includes assessing feasibility of post-marketing studies, pharmacovigilance consulting, assessing human health risk from exposure to a variety of chemical agents, such as volatile and semi-volatile organic compounds (e.g., benzene, methacrylates, toluene), metals / metalloids (e.g., lead, arsenic, cadmium, nickel), perfluorinated compounds (e.g., perfluorooctanoic acid or PFOS), silicates (e.g., asbestos, crystalline silica), and BPA.

Prior to joining Exponent, Ms. Dahlberg received her M.S. in environmental health sciences with a concentration in toxicology from UC Berkeley School of Public Health. Additionally, she brings a strong foundation in the core sciences. She received her B.S. in biology and B.A. in chemistry from Pepperdine University, where she was heavily involved in laboratory research in the fields of microbiology and physical chemistry.

Academic Credentials & Professional Honors

M.S., Environmental Health Sciences, University of California, Berkeley, 2020

B.A., Chemistry, Pepperdine University, 2018

B.S., Biology, Pepperdine University, 2018

Licenses and Certifications

RAC-Drugs Certified Professional

Prior Experience

Graduate Student Researcher, Superfund Research Group, UC Berkeley, 2019-2020

Graduate Student Instructor, Department of Environment, Science, Policy and Management, UC Berkeley, 2019

Graduate Student Instructor, Department of Molecular and Cellular Biology UC Berkeley, 2019

Professional Affiliations

American Industrial Hygiene Association, 2020-2023

- Toxicology Subcommittee
- Women in IH Subcommittee
- Stewardship and Sustainability Subcommittee

Genetic and Environmental Toxicology Association of Northern California, 2021-2023

- Business Representative

Society of Toxicology (Associate Member), 2021-present

Regulatory Affairs Professional Society, 2024-Present

International Society of Pharmacovigilance, 2024-Present

- Women's Medicines Special Interest Group
- Real-World Evidence and Big Data Special Interest Group
- PV in the Community Special Interest Group

Languages

Mandarin Chinese

Publications

Zhang L, Louie A, Rigutto G, Guo H, Zhao Y, Ahn S, Dahlberg S, Sholinbeck M, Smith MT. A systematic evidence map of chronic inflammation and immunosuppression related to per- and polyfluoroalkyl substance (PFAS) exposure. *Environ Res.* 2023 Mar 1;220:115188. doi: 10.1016/j.envres.2022.115188. Epub 2022 Dec 30. PMID: 36592815; PMCID: PMC10044447.

Dahlberg S, Chang ET, Weiss SR, Dopart P, Gould E, Ritchey ME. Use of Contrave, Naltrexone with Bupropion, Bupropion, or Naltrexone and Major Adverse Cardiovascular Events: A Systematic Literature Review. *Diabetes Metab Syndr Obes.* 2022 Sep 29;15:3049-3067. doi: 10.2147/DMSO.S381652. PMID: 36200062; PMCID: PMC9529009.

Rana I, Dahlberg S, Steinmaus C, Zhang L. Benzene exposure and non-Hodgkin lymphoma: a systematic review and meta-analysis of human studies. *Lancet Planet Health.* 2021 Sep;5(9):e633-e643. doi: 10.1016/S2542-5196(21)00149-2. Epub 2021 Aug 25. PMID: 34450064; PMCID: PMC9109598.

Castriota F, Rieswijk L, Dahlberg S, La Merrill MA, Steinmaus C, Smith MT, Wang JC. A State-of-the-Science Review of Arsenic's Effects on Glucose Homeostasis in Experimental Models. *Environmental Health Perspectives* 2020; 128 (1):16001.

Presentations

Dahlberg S, Orzechowski A, Cotter M, Horowicz-Mehler N. Optimizing Drug Market Exclusivity in the US and EU Markets. Presented at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Meeting in Atlanta, Georgia. May 2024.

Orzechowski A, Dahlberg S, Cotter M, Horowicz-Mehler N. Prescription Nutraceutical Clinical Evidence Requirements in the Treatment of Depression: Comparing U.S. and EU Guidance for Phase II and III Clinical Trials. Presented at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Meeting in Atlanta, Georgia. May 2024.

Rigutto G, Louie A, Smith M, Guo H, Zhao Y, Dahlberg S, Sholinbeck M, and Zhang LP. Identifying Studies on the Key Characteristics of Carcinogens Related to Chronic Inflammation and Immunosuppression. Poster presentation, Superfund Research Program Annual Conference, 2020.

Dahlberg S, Louie A, Nguyen P, Ranjbar K. Risk Assessment of Glycidyl Methacrylate: A Cause for Concern. Poster presentation, Northern California Society of Toxicology Spring Symposium, South San Francisco, CA, 2019.

Louie A, Dahlberg S. An Analysis of Benzene Exposure and B-cell Lymphoma. Poster presentation, Northern California Society of Toxicology Spring Symposium, South San Francisco, CA, 2019.

Project Experience

Pharmacovigilance and Pharmacoepidemiology Consulting

Conducted systematic literature reviews and critically assessed the peer-reviewed literature of pharmaceutical contaminants and potential health effects, pharmaceutical drugs and MACE outcomes, and pharmaceutical drugs and potential adverse side effects.

Reconstructed acceptable intake limits for contaminants from animal studies.

Supported the regulatory submission of a prescription-to-OTC switch, involving the integration of historical safety data from various databases (e.g. FAERS, VigiBase).

Assisted pharmaceutical clients with the development and execution of a DELPHI study aimed at developing a new clinical tool for assessing clinical response to a new drug.

Assessed study protocols, peer-reviewed literature, and regulatory guidance documents to assess the feasibility of required post-marketing studies for a newly approved pharmaceutical product.

Evaluated study protocols against regulatory requirements in the US and EMA for new drug applications. Estimated the maximum market exclusivity period for a potential new drug in both the US and EMA markets.

Litigation Support

Served as project manager and primary technical reviewer of discovery documentation in large multi-district litigations, in the area of exposure science/industrial hygiene, and pharmacovigilance.

Evaluated pharmaceutical post-marketing safety reporting using the FAERS database, Periodic Safety Update Reports (PSUR), and IND annual safety reports to ensure compliance with safety reporting regulations.

Reviewed discovery documentation and generated narratives of plaintiff exposure histories in support of expert testimony in asbestos and talc product liability litigation. Described the nature of alleged exposures (e.g., frequency, duration) to the product of interest and other relevant exposure risk factors (e.g., tobacco smoke, therapeutic radiation).

Proposition 65

Conducted analysis on hundreds of content and leach samples from textiles to assess and determine potential consumer chemical exposure

Conducted Proposition 65 evaluations to assess potential exposure to metals (e.g., arsenic, cadmium, lead) and semi-volatile organic compounds (e.g. methylene diphenyl diisocyanate) during various consumer product use scenarios. Example products include appliances and tableware.

Evaluated reproductive toxicity and developmental neurotoxicity outcomes reported in published studies concerning a pesticide that is undergoing review by the Proposition 65 Developmental and Reproductive Toxicant Identification Committee (DARTIC).

Exposure Simulations

Simulated the use of a colored cosmetic product and quantified potential personal breathing zone exposures to respirable crystalline silica. Contextualized data in terms of lung cancer risk, using established regulatory guidance.

Dermal Sensitization

Conducted testing to understand the potential for known dermal sensitizers to leach from wearable products during use. Used leach data in a model to predict allergic contact dermatitis elicitation risk. Utilized common chemical databases (e.g. PubChem, ECHA, ATSDR) to identify potential dermal sensitizers and dermal irritants in consumer products.

Additional Education & Training

Managing the COVID-19 Pandemic, UC Berkeley, 2020

Contact Tracing for COVID-19, Johns Hopkins University, 2020

Peer Reviews

Archives of Toxicology

Environment International

Environmental Research

Toxicology and Industrial Health

International Archives of Occupational and Environmental Health

Journal of Toxicology and Environmental Health, Part B: Critical Reviews

Ecotoxicology and Environmental Safety