

Claire L. Kruger, Ph.D., D.A.B.T.
President

Dr. Claire Kruger is President of Spherix Consulting, Inc. With more than 25 years of consulting experience, her primary area of expertise is in foods, consumer products and pharmaceuticals, where she provides scientific, regulatory, and strategic support to clients in both the US and international regulatory arenas. She has designed, placed, monitored, evaluated and published results from toxicology studies ranging from acute to carcinogenicity in rodent, non-rodent and non-human primates for use in product approvals. Dr. Kruger has conducted toxicity evaluations of food, food contaminants, and dietary supplements, as well as health risk assessments and exposure assessments of drugs, cosmetics, and pesticides. Her clients include food, drug, and dietary supplement manufacturers, agricultural producers, biotechnology companies, trade associations, and law firms.

In her role as a consultant, Dr. Kruger has been involved in the safety evaluation of a variety of consumer products, including ingredients used in dietary supplements, infant formulas, medical foods, novel foods, and functional foods, and also provides oversight of product compliance with current and emerging scientific and regulatory guidance. Dr. Kruger provides evaluations of the potential health risks related to employee and/or consumer exposure to consumer products. She has worked with clients to develop Product Stewardship programs to ensure appropriate guidance for sourcing of ingredients and for manufacturing, distributing and using products. Dr. Kruger is responsible for critical evaluation of scientific literature, design and interpretation of preclinical and clinical studies for food ingredients, dietary supplements and pharmaceuticals, and the preparation of health risk assessments and regulatory compliance dossiers for Generally Recognized As Safe (GRAS) dossiers, New Dietary Ingredient Notifications (NDIN), Novel Foods Submissions, Investigational New Drug Applications (IND), and New Drug Applications (NDA).

Dr. Kruger has dealt with issues relating to all aspects of food production, from manufacturing process and ingredient specifications, to pre-clinical safety evaluation and human clinical testing. She has prepared numerous GRAS determinations and Notifications and has served as an expert for many GRAS determinations. Dr. Kruger has also assessed the safety of and prepared Premarket Notifications for a number of dietary supplements. In addition, she has developed novel approaches for evaluating the safety of bioactive components and has employed these approaches in completing GRAS determinations for several novel bioactive products and functional foods. Dr. Kruger has also assisted clients with the identification, screening and documentation of data for candidate ingredients to assist companies in evaluating these products for potential label claims.

Prior to joining Spherix Consulting, Dr. Kruger was CEO of Spherix Incorporated for five (5) years, where she successfully led and completed five public financings; developed the infrastructure to support pharmaceutical development including: successful execution of multi-center phase II and III drug trials for Type II diabetes drug, in-Licensing of pipeline drug candidates for new indications, initiation and execution of pre-clinical and toxicology studies, and IND submission for new dyslipidemia combination drug therapy; and established a successful consulting subsidiary to provide a source of revenue generation.



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Expertise

Foods & Food Safety

Claims Substantiation

Medical Devices

Drug Safety & Efficacy

Consumer Product Safety

Pesticides

Credentials

*Diplomate, American Board
of Toxicology*

*Certified Food Scientist,
Institute of Food
Technologists*

*Ph.D., Toxicology, Albany
Medical College*

*B.S., Biology, Clarkson
University*