

Exponent®
Engineering & Scientific Consulting

Marisa Rihner

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Professional Profile

Ms. Marisa Rihner has over 20 years of experience providing scientific and regulatory consulting services to a broad range of clients in the food and beverage, personal care product, and cosmetics industries. She is skilled at navigating global regulatory requirements and developing the appropriate strategies to accomplish her clients' objectives related to pre-market authorization, consumer safety, and product stewardship. Throughout her career Ms. Rihner has built lasting relationships with her clients, helping to maintain the continuity and historical knowledge needed to make informed safety and regulatory decisions.

Ms. Rihner provides the full range of services needed for a successful FDA Generally Recognized as Safe (GRAS) Notification program, including ingredient data gap assessment, literature reviews, consumer intake assessments, technical dossier preparation, manuscript co-authorship, and GRAS Panel coordination. In addition to GRAS Notifications, Ms. Rihner assists in the preparation of technical dossiers for GRAS Self-Affirmations, Food Contact Notifications, New Dietary Ingredient Notifications, and Novel Food Applications. Ms. Rihner also interfaces with regulatory authorities on her clients' behalf, presents technical material at Agency consultation meetings, and prepares responses to Agency questions or requests for data.

As a Registered Quality Assurance Professional in Good Laboratory Practices (RQAP-GLP), Ms. Rihner has spent many years providing GLP quality assurance oversight of toxicology testing programs that support safety assessment and regulatory approvals for a variety of consumer product ingredient types. In this role, Ms. Rihner evaluates study protocols for testing guideline adherence, performs scientific and technical reviews of draft study reports, and audits raw data for compliance with GLP requirements.

Academic Credentials & Professional Honors

M.P.A., Public Administration and Public Affairs, Virginia Polytechnic Institute and State Univ, 2014

B.A., Biology, University of Virginia, 2002

Prior Experience

Senior Managing Consultant, SafeBridge Regulatory & Life Sciences Group (Trinity Consultants, Inc.), 2018-2023

Senior Scientific Program Manager / QA Auditor, Toxicology Regulatory Services, Inc., 2013□2018

Scientific Program Manager / QA Auditor, Toxicology Regulatory Services, Inc., 2007□2013

Associate Scientist / QA Auditor, Toxicology Regulatory Services, Inc., 2004□2007

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Associate Scientist / QA Auditor, Toxicology Regulatory Services, Inc., 2004–2007

Professional Affiliations

Toxicology Forum (member, 2022–present)

Society of Toxicology (member, 2021–present)

Society of Quality Assurance (member, 2003–present)

National Capital Area Regional Chapter of the Society of Quality Assurance (member, 2003–present)

Publications

Llewellyn, G.C., Rihner, M.O., Hanlon, P.R. An evolution of risk assessment for potential carcinogens in food: Scientific session proceedings. Regul Toxicol Pharmacol. 2021; 126:105047.

Spears, J.L., Kramer, R., Nikiforov, A.I., Rihner, M.O., Lambert, E.A. Safety Assessment of Bacillus subtilis MB40 for Use in Foods and Dietary Supplements. Nutrients 2021; 13(3):733.

Stubbs B.J., Blade, T., Mills, S., Thomas, J., Yufei, X., Nelson, F.R., Higley, N., Nikiforov, A.I., Rihner, M.O., Verdin, E., Newman, J.C. In vitro stability and in vivo pharmacokinetics of the novel ketogenic ester, Bis Hexanoyl (R)-1,3-Butanediol. Food Chem Toxicol. 2021;147:111859.

Stubbs, B.J., Nikiforov, A.I., Rihner, M.O., Weston, S., Higley, N., Roy, S., Dakoulas, E., Verdin, E., Newman, J.C. Genetic toxicity studies of the ketogenic ester, Bis Hexanoyl (R)-1,3-Butanediol. Int J Toxicol. 2021; 40(3): 242-249.

Stubbs, B.J. Nikiforov, A.I., Rihner, M.O., Weston, S.L., Higley, N., Stump, D.G., Krane, G.A., Gadupudi, G., Verdin, E., Newman, J.C. Toxicological evaluation of the ketogenic ester Bis Hexanoyl (R)-1,3-Butanediol: subchronic toxicity in Sprague Dawley rats. Food Chem. Toxicol. 2021; 150:112084.

Brusick, D., Aardema, M.J., Allaben, W.T., Kirkland, D.J., Williams, G., Llewellyn, G.C., Parker, J.M., Rihner, M.O. A weight of evidence assessment of the genotoxic potential of 4-methylimidazole as a possible mode of action for the formation of lung tumors in exposed mice. Food Chem Toxicol. 2020; 145:111652.

Bitzer, J., Henkel, T., Nikiforov, A.I., Rihner, M.O., Verspeek-Rip, C.M., Usta, B., van den Wijngaard, M. Genetic toxicity studies of glycolipids from Dacryopinax spathularia. Food Chem. Toxicol. 2019; 123:162-168.

Bitzer, J., Henkel, T., Nikiforov, A.I., Rihner, M.O., Herberth, M.T. Developmental and reproduction toxicity studies of glycolipids from Dacryopinax spathularia. Food Chem. Toxicol. 2018; 120:430-438.

Bitzer, J, Henkel, T., Nikiforov, A.I., Rihner, M.O., Henderson, K.A. A 90-day oral toxicity study of glycolipids from Dacryopinax spathularia in Beagle dogs. Food Chem. Toxicol. 2017; 109:544-551.

Bitzer, J., Henkel, T., Nikiforov, A.I., Rihner, M.O., Thomas, J.A. Pharmacokinetics, excretion balance, and tissue distribution of [14C]-labeled glycolipids and long chain fatty acids ([14C]-LCFA) from Dacryopinax spathularia in rats. Food Chem. Toxicol. 2017; 109:552-568.

Bitzer, J., Henkel, T., Nikiforov, A.I., Rihner, M.O., Leuschner, J. A 90-day oral toxicity study of glycolipids from Dacryopinax spathularia in CD® rats. Food Chem. Toxicol. 2017; 109:569-584.

Crincoli, C.M., Nikiforov, A.I., Rihner, M.O., Lambert, E.A., Greeley, M.A., Godsey, J., Eapen, A.K., van de Ligt, J.L.G. A 90□day oral (dietary) toxicity and mass balance study of corn starch fiber in Sprague Dawley rats. Food Chem. Toxicol. 2016; 97:57□69.

Crincoli, C.M., Garcia□Campayo, V., Rihner, M.O., Nikiforov, A.I., Liska, D., van de Ligt, J.L.G. Evaluation of the gastrointestinal tolerability of corn starch fiber, a novel dietary fiber, in two independent randomized, double□blind, crossover studies in healthy men and women. International Journal of Food Sciences and Nutrition. 2016; 67(7):844□856.

Crincoli, C.M., Brathwaite, W.A., Casterton, P.L., Rihner, M.O., Nikiforov, A.I., Sloter, E.D., Harris, S.B. A dietary two□generation reproductive toxicity study of (2R,4R)□monatin salt in Crl:CD(SD) rats. Food Chem. Toxicol. 2016; 91:167□180.

Crincoli, C.M., Brathwaite, W.A., Rihner, M.O., Nikiforov, A.I., Harris, S.B., Greeley, M.A., Eapen, A.K. A 90□day dietary study of a (2R,4R)□monatin salt in Beagle dogs. Food Chem. Toxicol. 2016; 91:181□190.

Brathwaite, W.A., Crincoli, C.M., Eapen, A.K., Rihner, M.O., Nikiforov, A.I., Picut, C.A. A two□year dietary carcinogenicity study of (2R,4R)□monatin salt in mice. Food Chem. Toxicol. 2016; 91:191□201.

Brathwaite, W.A., Crincoli, C.M., Eapen, A.K., Rihner, M.O., Nikiforov, A.I., Remick, A.K. A combined dietary chronic toxicity and two□year carcinogenicity study of (2R,4R)□monatin salt in Sprague□Dawley rats. Food Chem. Toxicol. 2016; 91:202□216.

Darpo, B., Bjornsson, T.D., Brathwaite, W.A., Crincoli, C.M., Eapen, A.K., Fisher, G.L., Kowey, P.R., Miller, M.P., Nikiforov, A.I., Rihner, M.O., Zhou, M. Detection of ECG effects of (2R,4R)□monatin, a sweet flavored isomer of a component first identified in the root bark of the Sclerochitin ilicifolius plant. Food Chem. Toxicol. 2016; 91:217□224.

Casterton, P.L., Crincoli, C.M., Brathwaite, W.A., Rihner, M.O., Nikiforov, A.I., Thomas, J.A. Plasma pharmacokinetics and routes of excretion of [14C]□labeled arruva, a high□potency sweetener, following oral administration to Beagle dogs. Int J Toxicol. 2014; 33(3):238□245.

Brathwaite, W.A., Casterton, P.L., Nikiforov, A.I., Rihner, M.O., Sloter, E.D., Hlywka, J.J. A dietary embryo/fetal developmental toxicity study of arruva, an R,R□monatin salt isomer, in Crl:CD(SD) rats. Food Chem. Toxicol. 2013; 62:68□75.

Nikiforov, A.I., Rihner, M.O., Eapen, A.K., Thomas, J.A. Metabolism and toxicity studies supporting the safety of rebaudioside D. Int J Toxicol., 32(4):261□273. Hlywka, J., Brathwaite, W.A., Rihner, M.O., Nikiforov, A.I., and Eapen, A.K. (2013). A 90□day oral (dietary) toxicity study of arruva, an R,R□monatin salt isomer in Crl:CD□1(ICR) mice. Food Chem. Toxicol. 2013; 55:676□683.

Hlywka, J., Brathwaite, W.A., Rihner, M.O., Nikiforov, A.I., Eapen, A.K. A 90□day oral (dietary) toxicity study of the 2R,4R□isomer of monatin salt in Sprague□Dawley rats. Food Chem. Toxicol. 2011; 49(12):3249□3257.

Project Experience

Coordinated, monitored, and quality assured a multi-year toxicology testing program supporting safety determination and US FDA GRAS status of a new food ingredient. Published pivotal study results in peer-reviewed literature.

Prepared a Novel Food Application submitted to and accepted by EFSA (European Food Safety Authority). Engaged with EFSA throughout the multi-year review period to facilitate resolution of all requests for information.

Managed a systematic literature review and weight-of-evidence assessment evaluating the genotoxic hazard of a food processing impurity. Co-authored a publication presenting the outcome of the assessment and final Expert Panel Opinion.

Delivered customized training materials to clients covering the topics of GLP Study Audits, US Food Ingredient Regulations, US Food Ingredient Safety Evaluation, and Totality of the Evidence Assessments. Prepared case studies and workshop activities to accomplish learning objectives.