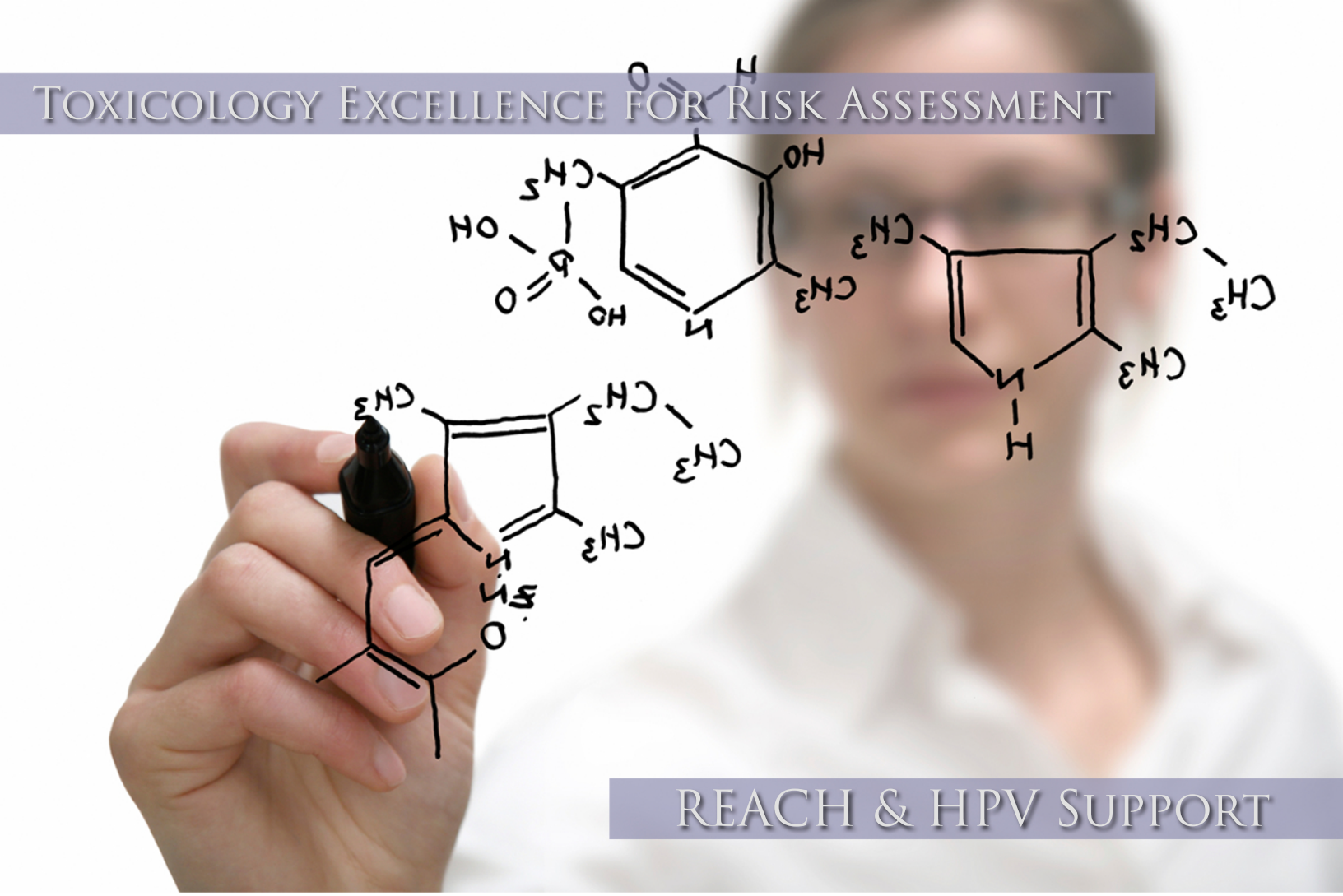
Toxicology Excellence for Risk Assessment



REACH & HPV Support

REACH (Registration, Authorization, Evaluation of CHemicals)

With the European Union's broad-reaching chemicals policy, companies face the significant and daunting task of registering their chemicals under REACH. TERA provides a team of leaders in the fields of toxicology, risk assessment, and exposure assessment who will provide the needed knowledge to help your company or consortium comply with these complex requirements.

Coalition Building and Problem Resolution

Data sharing and coordination are important aspects of the REACH process. TERA is internationally-recognized for our ability to bring diverse groups to consensus on complex issues. As an independent nonprofit organization, we can act as a trusted third party to assist SIEF (Substance Information Exchange Forum) members in coordination and meeting REACH requirements.

High Production Volume Chemicals

Under the High Production Volume Chemical Challenge (HPV) program, companies provided the USEPA with a test plan and robust study summaries for posting and comment by stakeholders. The need for developing such documentation sets continues under the Extended HPV (EHPV) effort, and grows as TP and RSS documentation will now be required for Moderate Production Volume Chemicals (MPVs).

TERA staff have authored and reviewed hundreds of toxicity assessments. We are experienced in all aspects of the work required for developing the documentation required for the HPV program and for REACH, including:

- Literature searching and management
- Critical review of toxicology studies and data gap identification
- IUCLID 5 data entry and robust summary preparation
- Preparation of test plans and risk documentation

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Data Gap Identification and Read Across

A key aim of HPV and REACH is identification of data gaps and maximizing use of existing data to address those gaps. Effective use of the available toxicity information, including for appropriate surrogate chemicals, can maximize the use of data to protect public health while also recognizing animal welfare considerations. TERA has expertise in key issues needed to address data gaps:

- A key approach for addressing data gaps is (Quantitative) Structure-Activity Relationship (Q)SAR analysis. TERA scientists have worked with the USEPA and private sponsors on issues related to read-across and improved QSAR methods. TERA served as the lead toxicology group working with the USEPA in applying SAR approaches in evaluating human health endpoints for premanufacturing notices (PMN) under EPA's Sustainable Futures program.

- Under a pilot program with industry and EPA, TERA organized an expert review process for high production volume (HPV) chemical hazard robust study summaries and test plans prepared by industry sponsors under the HPV and Extended HPV (EHPV) Programs. Consideration of structural groupings ("read-across") plays a key role in these test plans.

- Under a cooperative agreement with the U.S. EPA, TERA organized peer consultation meetings for risk assessments prepared for the Voluntary Children's Chemical Evaluation Program (VCCEP). The expert panels evaluated and identified data gaps (missing information), as well as data and testing needs (data gaps that should be filled to characterize risk). Panels included experts from government, industry, and NGO organizations, including from the animal welfare community.

For more information about how TERA can assist with HPV issues, contact Dr. Andrew Maier (513) 542-7475 x16 or maier@tera.org; for support of REACH issues contact Dr. Lynne Haber at (513) 542-7475 x17 or haber@tera.org.

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