ELSIE Membership

The Extractables and Leachables Safety Information Exchange (ELSIE) Consortium

The ELSIE Consortium:

- Is comprised of pharmaceutical, biotechnology, and medical device companies.
- Collects, reviews, and compiles toxicological data on extractables and leachables in an information-rich database, enabling rigorous assessments.
- Advances understanding of the impact of extractables and leachables on patient safety, product quality and process performance.
- Provides opportunities to share and leverage experiences, insights, and practices with respect to the potential safety impact of drug product packaging, delivery and manufacturing systems.
- Advances the state of the art in chemical/tox assessment of extractables and leachables by supporting and publishing research and participating in the global scientific and regulatory communities.

ACCOMPLISHMENTS AND KEY DELIVERABLES

- ELSIE is engaging regulators around the world, recently working with FDA and PQRI to develop an FDA training course on extractables and leachables.
- ELSIE members curated a robust Safety Information Database with over 400 toxicological reports written by dedicated toxicologists. The membership is currently designing a second generation database to incorporate material information and further increase efficiency.
- Published a paper on "Assessing Safety of Extractables from Materials and Leachables in Pharmaceuticals and Biologics – Current Challenges and Approaches" in Regulatory Toxicology and Pharmacology.
- Conducted a Materials Information Pilot Program to test a broad protocol that could help companies select materials relevant for a number of product types. The results were published in AAPS PharmSciTech.

ELSIE Members

AbbVie - ACS Dobfar - Amgen - Aguettant - AstraZeneca - Baxter - Biogen - Boehringer Ingelheim - Bracco - Bristol Myers Squibb Elanco - Eli Lilly - Genentech/Roche - Gilead - GlaxoSmithKline - Johnson & Johnson - LFB - Merck - EMD Serono Moderna - Novartis - Novo Nordisk - Organon - Pfizer - Regeneron - Sanofi - Teva- Ultragenyx - Xellia

ELSIE MEMBERSHIP

Please Contact the ELSIE Secretariat for a Demonstration of the Safety Database

Public Website: www.elsiedata.org
Phone: + 1 202 230 5299
E-mail: info@elsiedata.org

ELSIE is managed by a Board of Directors that regularly meets to discuss ongoing activities and identify issues and opportunities of mutual importance to member companies. The Working Groups and Committees meet regularly by teleconference.

Full Membership

Research-based pharmaceutical, biotechnology, and medical device companies are eligible to join ELSIE. Membership entitles each company to two seats on the Board of Directors, representation on all Working Groups, and full access to the private and secure Safety Information Database and member share site.

Current fees: $39,000 per company per year.

Associate Membership

Research-based pharmaceutical, biotechnology, and medical device companies with a worldwide gross revenue less than $2 billion annually are eligible for associate membership.

Associate members can send two representatives (non-voting) to Board of Directors meetings and can participate in all ELSIE Working Groups and Committees.

Associate members can access ten safety reports of their choice and request one emergency report.

Current fees: $10,000 per company per year.

Trial Membership

Research-based pharmaceutical, biotechnology, and medical device companies are eligible for a six month limited trial membership.

Trial members can access two safety reports of their choice.

Cost: $3,000 per company (one time only)