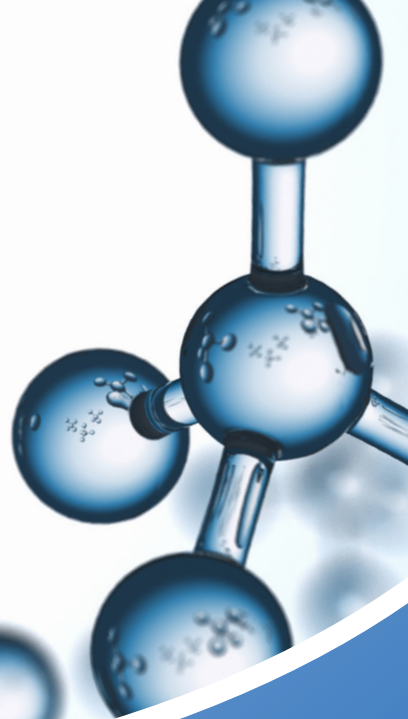




The **Extractables and Leachables Safety Information Exchange (ELSI)** Consortium is the leading industry voice and scientific resource on extractables and leachables. ELSI's objectives are to **reduce duplicative safety studies** across companies, **streamline development projects**, and to help **advance the practice and science** of extractables, leachables and materials evaluation.



Membership Benefits

- Participate in collaborative Working Groups and Subteams to address key knowledge gaps, support members' daily work, and advance the state of E&L risk management
- Meet with industry peers and stakeholders to discuss current and emerging E&L issues
- Network with colleagues
- Help create, drive, and implement ELSI's strategy
- Leverage data in the ELSI Knowledge Base
- Engage with regulatory agencies and standard setting bodies
- Conduct joint toxicology and extractables studies

“Members can greatly benefit from the shared resources, expertise, and research opportunities from the ELSI Consortium. This is exemplified by the working groups and subteams that drive innovation and foster continuous improvement of extractables and leachables risk management.”



Melisa Masuda-Herrera
Gilead Sciences
ELSI Chair

“To me, ELSI represents the foremost industry forum for knowledge sharing within E&L. I greatly value the collaborative exchange of expertise that has allowed my colleagues and me to reshape our company's risk-based E&L documentation processes. Additionally, ELSI has played a significant role in shaping regulatory E&L practices through participation in workshops and meetings with health authorities, as well as through peer reviewed papers, white papers, and scientific presentations.”



Carsten Worsøe
Novo Nordisk
ELSI Vice Chair

Key Activities



Addressing critical challenges in toxicological and materials evaluation



Collecting data and publishing on PDEs and sensitization



Advancing understanding of predictive modeling applied to E&L



Helping industry to align on lab practices



Sharing strategies on current challenges in medical devices



Populating the ELSIE Knowledge Base



The **ELSIE Knowledge Base** stores toxicological safety information and extractable study results on raw materials, single-use products, drug product packaging and delivery systems, and medical devices. The Knowledge Base serves as a research tool containing safety information and extractables data from the public domain, joint studies, and information shared from our members and the E&L community.

Membership

Open to research-based pharmaceutical, biotechnology, and medical device companies

Seats on the Board of Directors

Representation on Working Groups

Access to Knowledge Base

Membership Fee

Full Membership

2 voting



Full Access

\$39k Annually

Associate Membership*

2 non-voting



Limited Access

\$10k Annually

Trial Membership**

2 non-voting



Limited Access

\$3k One-time

* Worldwide gross revenue must be less than \$2 Billion annually ** Trial Membership runs for 6 months

Current Members

- | | | | | |
|----------------------|----------------------|-------------------|--------------|------------|
| AbbVie | Bracco | Gilead Sciences | Novo Nordisk | Teva |
| Alcon | Bristol Myers Squibb | GSK | Octapharma | UCB |
| American Regent | Elanco | Hikma | Organon | Ultragenyx |
| Amgen | Eli Lilly | Humacyte | Pfizer | Vantive |
| AstraZeneca | EMD Serono | Johnson & Johnson | ProKidney | Viatrix |
| Baxter | EVER Pharma | LEO Pharma | Regeneron | |
| Bayer | Fresenius Kabi | LFB | Sandoz | |
| BBraun | GE Healthcare | Merck | Sanofi | |
| Boehringer Ingelheim | Genentech/Roche | Novartis | Takeda | |

Connect With Us

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