



The **Extractables and Leachables Safety Information Exchange (ELSIE)** Consortium is the leading industry voice and scientific resource on extractables and leachables. ELSIE'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 ELSIE's strategy
- Leverage data in the ELSIE 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 ELSIE 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
ELSIE Chair

“To me, ELSIE 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, ELSIE 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
ELSIE 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



Access to 10 Safety Reports

\$10k Annually

Trial Membership**

2 non-voting



Access to 3 Safety Reports

\$3k One-time

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

Current Members

AbbVie
Alcon
American Regent
Amgen
Ascendis Pharma
AstraZeneca
Baxter
Bayer
BBraun

Boehringer Ingelheim
Bracco
Bristol Myers Squibb
Elanco
Eli Lilly
EMD Serono
EVER Pharma
Fresenius Kabi
GE Healthcare

Genentech/Roche
Gilead Sciences
GSK
Hikma
Johnson & Johnson
LEO Pharma
LFB
Merck
Novartis

Novo Nordisk
Octapharma
Organon
Pfizer
Regeneron
Sandoz
Sanofi
Takeda
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UCB
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Connect With Us

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