ELSIE Newsletter

ANNIVERSARY EDITION

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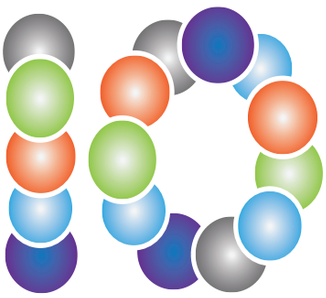
The Extractables and Leachables Safety Information Exchange (ELSIE) Celebrating a Decade of Collaboration and Engagement

The ELSIE Consortium was established in 2007, when Doug Ball (Pfizer) and Jon Cammack (then at Baxter) brought together leading scientists to advance the concept of sharing pre-competitive safety information on extractables and leachables, among industry. The vision was that such a collaborative effort would reduce duplicative safety studies across companies, streamline development projects, and allow industry and other stakeholders to share experiences and information to help advance the practice and science of extractables, leachables and materials evaluation. A driving ethos for ELSIE's formation, as articulated by founding Board member Lewis Kinter, was that "companies should not compete on safety". ELSIE's mission is to facilitate its member companies' ability to efficiently and effectively develop safe, efficacious products that sustain and save lives.

> "With the guiding principle '**we do not compete on safety**,' the ELSIE Consortium has fostered exemplary collaboration across the pharmaceutical industry."
>
> Steve Beck, Founding Chair, ELSIE Safety Information Working Group



Ten years later, ELSIE is a thriving consortium of 21 diverse companies, spanning biotech, pharma, and medical devices. In its formative years, ELSIE's founding member companies initiated creation and population of the Safety Information Database, starting with 30 high priority compounds identified by the members. In parallel, ELSIE members developed a comprehensive extractables protocol and tested it with the objective of creating a streamlined protocol focusing on key solvents and techniques that could serve as a generally applicable protocol for a wide range of plastic materials and components, and as a platform for generating extraction data that could be shared among the members. These early efforts led to a significantly expanded Safety Database, now containing reports on over 400 compounds; and a series of publications on the protocol testing pilot. ELSIE has expanded its activities to include active outreach to global regulators and standard-setting bodies, including commenting on guidelines and standards, and working with FDA, to develop and present a regulatory training course on E&L assessment. ELSIE has also held four impactful workshops, and a webinar addressing safety risk assessment and development of PDEs, materials quality and supply chain engagement, and single-use systems. Notably, ELSIE recently published a paper addressing the risk assessment and qualification process for extractables and leachables, and its members have presented on ELSIE work at leading conferences worldwide.

> "The ELSIE Consortium has the ability to properly and effectively shape the future of E&L thanks to its Safety Information Database, numerous contributions to the scientific literature, and active participation in scientific debates."
>
> Dennis Jenke, ELSIE Chair 2013-2015

ELSIE continues to innovate. A current priority is establishing the next phase Database - the ELSIE Knowledge Base, which will include both safety and materials information, integrating the legacy safety data, with data on materials. The ELSIE Knowledge Base should serve as a powerful resource for overall materials qualification. Coming out of a recent Workshop with the supplier community, ELSIE is working to launch a supplier forum with ELSIE to enhance interaction and knowledge sharing among key stakeholders.

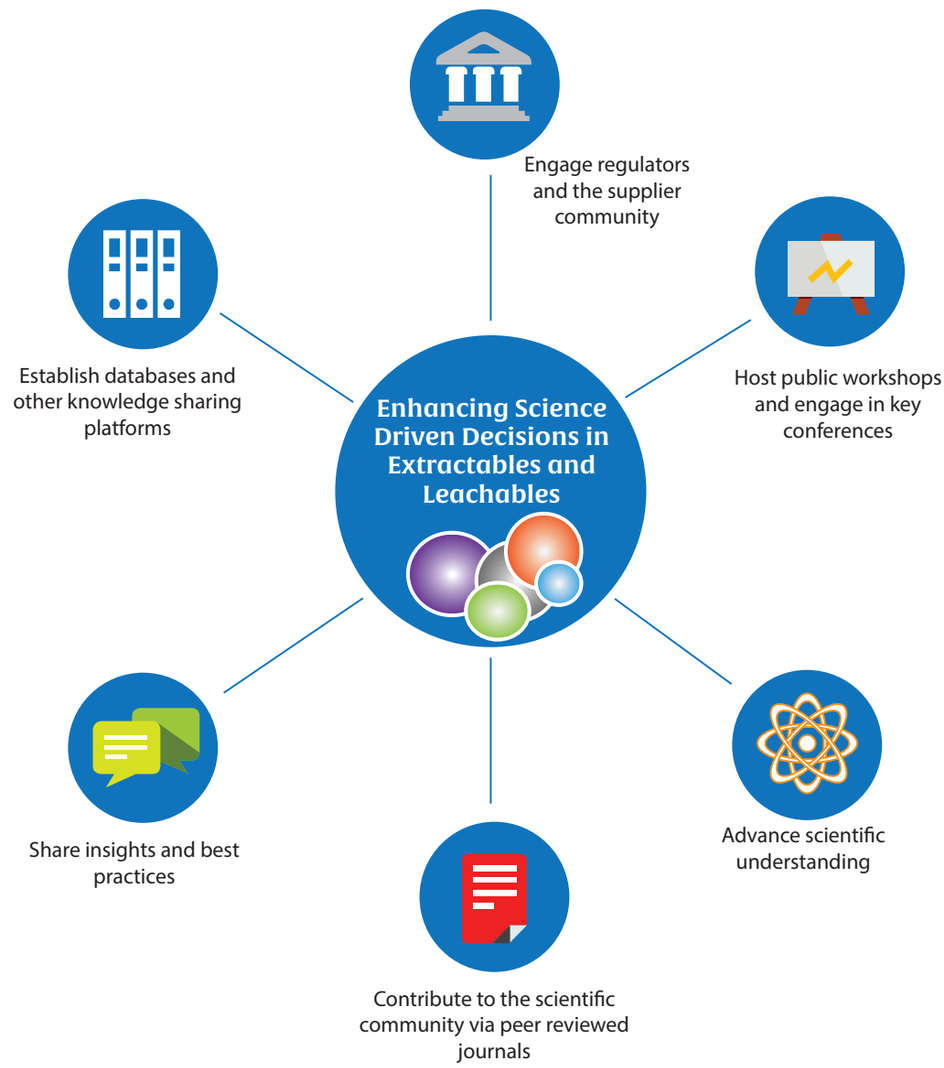
As ELSIE enters its next decade, we reflect on our successes and look forward to continuing to advance extractables/leachables and materials quality science and regulation.

A Note from the ELSIE Chair

Greg Erexson, AbbVie Inc.

It has been a wonderful journey over the past 10 years watching the evolution of ELSIE into an internationally-recognized consortium of experts in the E&L field. ELSIE has had and continues to have a dynamic impact to the medical device, combination product, primary packaging and manufacturing industries, just to name a few. ELSIE has generated safety reports for close to 500 compounds and is now entering into a new horizon in interfacing knowledge management capabilities. It is also absolutely amazing that the ELSIE membership has grown to over 20 member companies and continues to grow year-after-year.

10 YEARS is only the beginning. ELSIE continues to...



ELSIE Speaking Engagements in 2017

5th Annual Extractables and Leachables (Part of the 14th Annual PepTalk)
(9-13 January 2017 - San Diego, CA)
Kim Li, Amgen and Doug Kiehl, Eli Lilly

Society of Toxicology (SOT) 56th Annual Meeting and ToxExpo
(12-16 March 2017 - Baltimore, MD)
Greg Erexson, AbbVie, Uma Bruen, Merck & Co. and Brad Stanard, MedImmune/AZ

Annual Extractables and Leachables Summit
(19-20 October 2017 - Berlin, Germany)
Ken Wong, Sanofi

2017 Occupational Toxicology Roundtable
(23-25 October 2017 - Austin, Texas)
Greg Erexson, AbbVie, Uma Bruen, Merck & Co., and Brad Stanard, MedImmune/AZ

Smithers RAPRA Extractables & Leachables Europe
(7-9 November 2017 - Lyon, France)
Greg Erexson, AbbVie

ELSIE Members

AbbVie • Amgen • Aguettant • AstraZeneca • Baxter • Biogen Idec • Boehringer Ingelheim • Bracco
Eli Lilly • Gilead • Roche/Genentech • GlaxoSmithKline • Johnson & Johnson • LFB • Merck
EMD Serono • Novartis • Pfizer • Sanofi • Teva • Ultragenyx