2022 ELSIE YEAR IN REVIEW

Sharing progress, accomplishments and future goals

A Message from **ELSIE Chair**

Uma Bruen, PhD (Organon)

Dear ELSIE family,

My favorite time of the year is reflecting on all that we as a consortium have accomplished. This year seems to be closer to what normal (?!) work and life is supposed to be. Although at times we faced situations that were frustrating or that tested our patience, many of us returned to the office or began to travel to renew personal and professional connections to get back to business normal.

Needless to say, 2022 was another fabulous year for ELSIE. We followed the science through thoughtful collaboration among fellow scientists and companies. We continued in our vision to be the leading industry voice and scientific resource on extractables and leachables (E&L).

We pushed the science forward by:

- Addressing key knowledge gaps, including developing a position paper on specific challenges of leachables risk factors relevant to cell and gene therapies processing. We hope to better influence scientific and regulatory understanding by clearly outlining the issues in this area.
- Holding ELSIE webinars on leachable risk management reflecting ELSIE position papers on TTC for E&L compounds and a sensitization framework. These papers provide additional tools in the evaluation and risk management of E&L.
- Driving implementation and launch of the ELSIE Knowledge Base in 2023. We continued to socialize and promote data sharing from member companies to build a more integrated and robust database.
- Providing valuable guidance in a variety of areas, including supporting ICH Q3E efforts, USP and other regulatory/consensus groups.

These are just a few highlights from the past year. There are many more accomplishments that we achieved as outlined in this annual update. With all these accomplishments, together with my fellow E&L influencers, I look forward to the coming year in pursuing personal and professional connections. My sincere thanks to all the members and the Secretariat.

ELSIE **Founding Principle**

The ELSIE Consortium is comprised of pharmaceutical and medical device companies and was formed under the founding principle that companies should not compete on safety and that sharing data and collaborative, open dialogue are essential.

New in **2022**

1 Launched Strategic Plan for 2022-24

- Advance the state of the art for **E&L risk management**
- Enhance the **scientific and global regulatory** framework
- Improve the probability of **regulatory success**
- Provide a **dynamic forum** for networking and education
- Expand visibility as the pre-eminent resource for **information and thought leadership**

2 Advanced the Knowledge Base

ELSIE achieved excellent progress on the Knowledge Base project – a next generation database for organizing safety/toxicology and extractable data. Our Knowledge Base provider, ACD/Labs, released the first beta version of the Knowledge Base software to ELSIE for testing and feedback in Q2-2022 and enhanced the software through the year. The go-live date is expected in Q2-2023. The ELSIE Board of Directors has established a process for ELSIE members and suppliers to share extractables study and safety study data for storage in the Knowledge Base. ELSIE has also begun publicly promoting the Knowledge Base and calling for data with presentations at E&L Europe, E&L China and others planned for 2023.

3 Joined PQRI

The ELSIE Consortium joined the Product Quality Research Institute (PQRI) in July 2022. ELSIE members are actively participating in the PQRI Technical Committees and the Steering Committee. Membership in PQRI can serve as a valuable technical and consensus-building resource and allows ELSIE to collaborate with other PQRI members to develop and direct PQRI's activities.

Impact Across the **Scientific Community**

In 2022, ELSIE published two important papers:

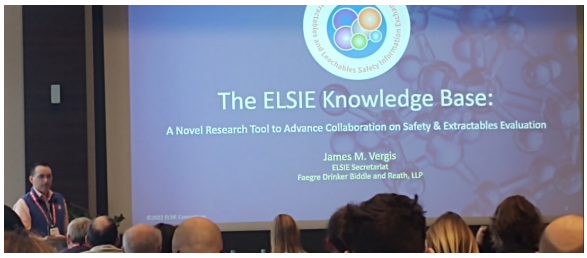
- Patricia Parris, Geraldine Whelan, Anders Burild, et al. (2022). "**Framework for sensitization assessment of extractables and leachables in pharmaceuticals**," *Critical Reviews in Toxicology*, 52:2, 125-138, DOI: 10.1080/10408444.2022.2065966
- Melisa J. Masuda-Herrera, Joel P. Bercu, et al. (2022). "**Development of Duration-Based Non-Mutagenic Thresholds of Toxicological Concern (TTCs) Relevant to Parenteral Extractables and Leachables (E&Ls)**," *PDA Journal of Pharmaceutical Science and Technology* Sep 2022, 76 (5) 369-383; DOI: 10.5731/pdajpst.2021.01269

ELSIE encouraged dialogue on these papers with two highly attended webinars. FDA, Anvisa and other regulatory agencies attended both webinars, with FDA participating in the TTC webinar panel.

- **Duration-Based Non-Mutagenic Thresholds of Toxicological Concern (TTC) for Parenteral Extractables and Leachables.** Listen to the Recording | View the Presentation
  Panelists: Melisa Masuda-Herrera (Gilead), Joel Bercu (Gilead), Thomas Broschard (EMD Serono), Ron Brown (Risk Science Consortium), and Timothy Robison (FDA)
- **Framework for Sensitization Assessment of E&Ls and Practical Application.** Listen to the Recording | View the Presentation
  Panelists: Patricia Parris (Pfizer), Geraldine Whelan (GSK), Jessica Whritenour (Pfizer), Martyn Chilton (Lhasa Limited), and Glenn Myatt (Instem), Bruce Naumann (Merck, retired)

ELSIE members attended and presented ELSIE work at the E&L Europe conference in Frankfurt, Germany, in November.

Jamie Vergis (ELSIE Secretariat) presented an overview of the new ELSIE Knowledge Base, and Trish Parris (Pfizer, ELSIE Vice-Chair) presented an "Update on ELSIE Framework for Sensitization Assessment of E&Ls and Practical Application." Several other sessions were influenced by ELSIE initiated and/or driven topics. There was very positive feedback regarding the Knowledge Base concept and value. Another key outcome was opportunities for supporting and advancing regulatory alignment and education.



ELSIE at 2022 Conferences

Looking **Ahead**

ELSIE is developing a manuscript addressing considerations for managing leachables risk related to **cell and gene therapies**. The manuscript discusses and references publicly available information and will provide current thinking on challenges as well as considerations related to safety assessments. Information related to E&L for these modalities is not common in the public domain, and ELSIE seeks to contribute to and proactively advance the scientific and regulatory discourse regarding E&L considerations for cell and gene therapies.

As members continue to address questions from regulators and from within their companies regarding E&L information and studies on **"ancillary" components** (e.g., administration sets, syringe and vial adaptors, wearables), ELSIE conducted a membership benchmarking survey in order to gather perspectives and information on these issues. Survey results provide information on, for example, the types of questions members are hearing from regulators, whether companies conduct E&L studies on such components, and if not, how is leachables related risk mitigated. The results will form the basis for further discussion and activity in 2023.

ELSIE is developing additional manuscripts to follow up on the already published TTC and sensitization papers. Future papers will **analyze sensitization data** within the ELSIE safety database and describe approaches and strategies for **toxicological read-across**.

Highlights from
ELSIE Board Meetings

ELSIE Board Meeting in Washington, DC: May 2022

The Board endorsed the ELSIE Strategic Plan for 2022-24 and heard an update on the USP Packaging and Distribution Committee efforts from guest speaker, Desmond Hunt, Senior Scientific Liaison, USP. The Board approved the formation of a new subteam to improve alignment in E&L study methodology among labs that conduct such studies for sponsors.

ELSIE Board Meeting in Ingelheim, Germany: Nov 2022

The ELSIE Board of Directors met in November to progress a number of important activities, to share highlights of ongoing efforts and outreach to regulators, confirm priority initiatives for 2023, and discuss current and emerging regulatory matters. Many Board members joined the meeting in person in Germany, where we were kindly hosted by Boehringer Ingelheim and Thomas Egert.

Congratulations

to Melisa Masuda-Herrera (Gilead Sciences) and Petra Booij (GSK) for receiving the **2022 ELSIE Chair Award** for their outstanding leadership and many contributions to ELSIE.

Melisa Masuda-Herrera

Petra Booij

ELSIE **Members**

AbbVie
Aguettant*
American Regent
Amgen
AstraZeneca
Baxter
Bayer
BBraun
Biogen
Boehringer Ingelheim
Bracco*
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Elanco
Eli Lilly and Company
EMD Serono
EVER Pharma*
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Organon
Pfizer
Regeneron
Sanofi
Takeda
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Verona Pharma*
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Xellia

*Associate Members

ELSIE **Secretariat**


Maureen Hardwick


Lee Nagao, PhD


Maureen Cruz, PhD


Jamie Vergis, PhD


Mary Kate Bielinski

For more information about ELSIE:

+1 202 230 5133

secretariat@elsiedata.org

www.elsiedata.org